Institutional Review Board Handbook

Guidelines and Information Related to the Certification of Research Projects Connected to Westcliff University

2020

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SECTION ONE: INTRODUCTION

Overview of the IRB Handbook

The Institutional Review Board Handbook (herby referred to as the IRB Handbook or the Handbook) contains descriptions of regulations, procedures, and forms required by Westcliff University for any research project requiring human participation including data about those humans. The Handbook is intended for research conducted by employees or students of Westcliff University, and for the conduct of research by outside organizations or institutions seeking the involvement of any Westcliff University employee or student. If a faculty or staff member is conducting research that has no relationship to his or her duties or affiliation with Westcliff University, the research is not subject to review by Westcliff University's Institutional Review Board (IRB).

Research projects include those activities involving human participants as required for dissertation research, applied research, and clinical research projects (CRPs) as well as research conducted for poster and PowerPoint presentations or for potential publication. To ensure consistency, this Handbook uses the terms *principal investigator* to identify the person performing the research and *faculty research supervisor* to identify the principal investigator's doctoral research chairperson or any other person who is responsible for supervising the research described in the principal investigator's application.

This Handbook supersedes previous handbooks, and principal investigators and research supervisors are responsible for understanding and applying the rules in this edition. Section Two of this Handbook provides a list of substantive changes to the previous edition (2014) in compliance with the latest revisions of the Code of Federal Regulations (CFR) and revised Common Rule (Health and Human Services regulations) to include:

1. responsibilities and duties of IRBs,
2. conducting research with children,
3. definition of the *Exempt* application category, and
4. Electronic *Informed Consent* guidelines.

Contents of the principal investigator's *Application for IRB Review and Certification of Compliance* (hereby referred to as the IRB application) are not guaranteed to be treated confidentially. In a limited number of situations, applications are subject to public disclosure and researchers should be aware of this potential outcome.

Organization of the Handbook

The Handbook is organized into five sections and appendices described below. For easy access to principal investigators and their supervisors within the university community, this Handbook is available on the faculty common, campus common, and within the Course Resources page of doctoral research courses and dissertation courses.

Section One: Introduction provides an overview of the handbook and its use by principal investigators, faculty research supervisors, and IRB members; the mission and guiding principles of the IRB, key terms to be understood in accordance with the *Code of Federal Regulations (CFR Title 45, Part 46)* and *The Belmont Report*; and an overview of the compliance review process in brief.

Section Two: Administration and Governance describes the governance of IRBs including an explanation of its role as the certifier of compliance for the protection of research participants, and the guidelines for membership and operation of Westcliff University's National and Campus IRBs.

Section Three: IRB Reviews and Certification presents the purpose and benefits of the IRB certification process; types of studies requiring IRB certification; the categories of review (exempt, expedited, and full review levels); cooperative research activities between campuses; and research at the international, national, and campus levels.

Section Four: Consent for Participants describes the informed consent process; elements of informed consent and assent; special consent procedures; and conditions for waivers of informed consent or assent.

Section Five: IRB Application and Review Process provides guidelines for preparing the IRB application and required documents; steps of the review process; criteria for certification; and potential outcomes and follow-up requirements.

Appendices are provided with instructions, forms, and links to the applications and additional resources. An overview of the various forms and resources contained in the appendices appears below.

Description of Appendices

Applicants should expect to complete an exempt (Appendix A), expedited (Appendix B), or full application (Appendix C). The Principal Investigator must also include a completed Conflict of Interest Disclosure Statement (Appendix D) and CITI completion reports/certificates for the principal investigator, faculty research supervisor, and committee member(s). Readers are not required to complete the CITI training. The Letter of Informed Consent (Appendix E) must be included as part of the application. In some cases, oral consent and instructions (Appendix F) are appropriate.

The IRB will respond with a *Certification Statement* or a *Letter To Correct IRB Application Deficiencies* (Appendix G). For some research with cooperative institutions, the IRB will send a letter to any other institution that requests Westcliff University Certification (Appendix H). If full-review level research data gathering extends for a longitudinal study, the principal investigator will complete a *Continuing Certification of Compliance* form before the designated review date (Appendix I).

Research protocols may change after certification, requiring an *Amendment to Original IRB Certification* form (Appendix J). Researchers may not implement a change without IRB prior review and approval except in the event of an emergency (e.g., to prevent harm to participants). In those circumstances, an *Adverse Event Report* form (Appendix K) is also required and should inform the IRB of any changes to eliminate risk to participants. The IRB may require a change to the consent form as a result or may change the review level. IRB decisions for any modification to original certification will be communicated in the same manner as the initial certification decisions.

When research is completed, the principal investigator must file a *Project Completion* Report (Appendix L). The principal investigator will receive an acknowledgement of receipt from the IRB in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b). Appendix M and Appendix N provide forms used by the national and campus IRBs. IRB Board members must adhere to their profession's code of conduct; the Code of Federal Regulations, Title 45, Part 46; and the Belmont Report. Appendix O provides links to these and other helpful resources principal investigators, faculty research supervisors, and IRBs.

Mission of the IRB

The mission of the Institutional Review Board (IRB) of Westcliff University is to ensure the ethical treatment of human participants in the conduct of research by any individual affiliated with Westcliff University, in accordance with the guidelines set forth in the Code of Federal Regulations (CFR) and the Belmont Report.

Purpose of the IRB

The purpose of an IRB review is to determine whether participants in a research study will be placed at physical or mental risk and, if risk is involved, to certify that the following conditions have been met.

1. Risks to participants are minimized. This is an essential condition for certification. The determination of when a research participant is at risk is a matter of the application of common sense and sound professional judgment as it relates to the circumstances of the research activity in question. The IRB will carefully weigh the relative risks and benefits of the research procedures as they relate to the participants.

2. Participants in the study (and their guardians) are fully aware of the risks and that individuals may withdraw from the study at any time without any form of penalty.

3. Research activities, designed to yield fruitful results for the benefit of individual participants or society in general, may incur risks to the participants provided such risks are outweighed by the benefit to be derived from those activities.

4. Risks to the participants are so outweighed by the sum of the benefits to the participants and the importance of the knowledge to be gained as to warrant a decision to allow the participants to accept these risks voluntarily.

5. The degree of risk involved in any activity should never exceed the humanitarian importance of the problems to be solved by that activity. Likewise, compensation to volunteers should never be such as to constitute an undue inducement to the participants.

6. Rights and welfare of any such participants will be adequately protected. There is a wide range of medical, social, and behavioral research projects and activities of which the physical or mental risk to the participant is no greater than what participants experience in daily life (e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, which may constitute a risk.

7. Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this document.

8. Stored data or other information obtained for a different purpose is used within the scope of the original consent, consent is waived, or new consent is obtained. The IRB may ask to see the original consent to make this determination.

Conduct of the research activities may be reviewed at intervals determined by the IRB, but not less than annually.

Guiding Principles of the IRB

The IRB does not approve research designs but certifies that the protection of research participants has been adequately provided, per federal regulations, and as described in an *Application for IRB Review and Certification of Compliance*. The IRB application provides a framework for regulatory compliance and ethics standards for conducting research. The principal investigator and the faculty research supervisor are responsible for implementing the procedures for the protection of human participants as described in the IRB application for certification.

Code of Federal Regulations

Westcliff University IRBs adopt the *Code of Federal Regulations* as part of their guiding principles. These regulations are adopted in their most current version. If disagreements arise between the Westcliff University IRB policies and procedures and Title 45 of the *Code of Federal Regulations*, the latter has preeminence.

Ethical Principles

As part of their guiding principles, Westcliff University IRBs also adopt the Ethical Principles for the protection of human research participants as published in the *Belmont Report* and other documents. Westcliff University IRBs take a cautious stance; IRBs will choose to err on the side of caution to ensure the protection of research participants.

Code of Business Ethics and Conduct

Westcliff University's board of directors and employees must be free of conflicting interests that might influence, or be perceived to influence, their decisions when representing the university. Consequently, employees must not maintain any interest that conflicts with the interests of the University and should make every effort to avoid even the appearance of any such conflict.

A conflict of interest occurs when an employee's private interest interferes in any way, or even appears to interfere, with the University's interests as a whole. A conflict of interest can arise when employees take actions or have interests that may make it difficult to perform their work on behalf of Westcliff University, objectively and effectively; and/or an employee or family member receive any improper personal benefits because of the employee's position with Westcliff University.

Employees who believe that they may have a potential conflict of interest must report their concerns to the General Counsel immediately. Directors or executive officers who believe that they may have a potential conflict of interest must report their concerns to the Chairman of the Board, who will consult with the Nominating and Corporate Governance Committee to resolve the situation.

Employees of Westcliff University should adhere to the following guidelines to avoid potential conflicts of interest, keeping in mind that conflicts of interest are not limited to these guidelines.

1. Dealings with students, employers of our graduates, suppliers, contractors and others should be based solely on what is in the university's best interest, without favor or preference to any third party, including close relatives.

2. Employee who deal with, or influence decisions of, individuals or organizations seeking to do business with Westcliff University must not own interests in, or have other personal stakes in, those organizations, which may affect your decision-making process and/or objectivity.

3. Employees must not do business with close relatives on behalf of Westcliff University unless they have disclosed the relationship and received written authorization.

4. Personal loans, or any guarantee of such loans, by Westcliff University to employees or family members are strictly prohibited.

5. Unless supervisor approval is granted in writing, employees must not accept or attempt to accept costly entertainment or gifts from third parties with whom Westcliff University directly or indirectly does, has, or is seeking to do business. The following direct and indirect forms of compensation are strictly prohibited:
    a. separate individual payment or commission arrangements;
    b. personal loans or services;
    c. excessive entertainment and travel;
    d. gifts of more than nominal value.

If such a gift is unavoidable because of local custom, the employee must report the gift to the General Counsel, who may consult with the Nominating and Corporate Governance Committee, for a determination whether, or the extent to which, the gift may properly be considered the employee's personal property.

Collaborative Institutional Training Initiative (CITI)

The Collaborative Institutional Training Initiative (CITI) program is a subscription service that supports research ethics education. Westcliff University subscribes to CITI to promote the highest ethical standards for research reviewed by its Institutional Review Boards. Prior to applying for IRB certification, each principal investigator must complete the required CITI modules and document successful completion as part of his or her application. Westcliff University faculty are also required to complete the CITI modules necessary for their status as a chairperson or member for a dissertation, CRP, or for seeking IRB certification of the faculty member's research project. The training must be renewed at 3-year intervals (see link to CITI training in Appendix O).

Definition of Key Terms

To provide clarity and promote understanding of the information and guidelines presented in this handbook, Westcliff University uses the following definitions of terms as adapted from the *Code of Federal Regulations (CFR Title 45, Part 46)* and the Belmont Report.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Exempt (Level 1) reviews are reserved for public activities, unidentified data, identified data protected by HIPAA regulations, and activities with no more risk than normal daily activity.

Expedited (Level 2) reviews encompass all minimal risk research that do not meet the conditions for an exempt or full level review.

Faculty Research Supervisor refers to the doctoral research chairperson or other person responsible for supervising the research described in the principal investigator's application.

Full (Level 3) reviews are required for research carrying more than minimal risk or involving vulnerable populations.

Human participant is a living individual from whom an investigator conducting research obtains possible identifiable private information through intervention or interaction and uses, studies, analyzes, and/or generates data. (Following the position of the American Psychological Association, the term *participant* is used in place of the term *subject*.)

Human Research is any activity with the primary intent of securing information from or about human participants for advancing basic, clinical, or psychosocial understanding of humans.

Such activity may or may not differ significantly from psychological or other professional practice. (See examples of research activities categorized as human research and research activities not categorized as human research below.)

Anonymous Data is data free of personal information, including codes or links that can be traced to participants by the research investigator(s).

*Coded Data i*s data where names are replaced by codes by the investigator(s)

Intervention[1] *i*ncludes both physical procedures used to gather data and manipulations of the participant or the participant's environment that are performed for research purposes.

IRB Certification represents the determination of the IRB that the research (project or activity involving human participants) has been reviewed and may be conducted at an institution within the constraints (guidelines) set forth by the IRB and by other institutional (including employer) and federal regulations.

Legally authorized representative (LAR) is an individual or body authorized under applicable law to consent on behalf of a prospective subject for participation in the procedure(s) involved in the research. If no law exists, institutional policy is acceptable.

Minimal Risk[2] refers to the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Principal Investigator refers to the person performing the research.

Research (project, study, protocol, etc.) denotes a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

Activities Categorized as Human Research

Any activity with the primary intent of securing information from or about human participants for advancing basic, clinical, or psychosocial understanding of humans is considered human research. Such activity may or may not differ significantly from psychological or other professional practice. Human research includes, but is not limited to:

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[1] Institutions whose employees or agents perform commercial or other services for investigators are not engaged in human subjects research provided that all of the following conditions are also met: (a) the services performed do not merit professional recognition or publication privileges;(b) the services performed are typically performed by those institutions for non-research purposes; and (c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

[2] This definition sets the baseline used to define the three levels of risk used by Westcliff IRBs to establish review guidelines for the certification of compliance. (See definitions of Exempt, Expedited, and Full levels of review.)

- group design studies,
- classroom projects,
- single participant design studies,
- case reports and analyses, chart review,
- observational studies,
- paper and pencil-based studies,
- qualitative studies,
- research in preparation for a conference presentation or poster session,
- comparison of interventions, and
- pilot studies with small samples.

Activities Not Categorized as Human Research

Some professional, scholarly, and journalistic activities are not considered human research in the sense of the regulatory definition of the Common Rule or Code of Federal Regulations because information is collected about *specific individuals* vs. aiming to generalize findings to a larger population. Four categories of activities no longer included in the definition of human research include:

1. certain scholarly and journalistic activities (e.g., literary criticism);
2. public health surveillance activities;
3. criminal justice activities (e.g., legal research/case law); and
4. authorized operational activities in support of national security missions.

These activities occur in various fields of inquiry and methodological traditions that have their own codes of ethics, according to which, consent is obtained for oral histories (and should address the issue of oral histories of tribal members). Literary criticism was removed from the definition of research because it typically focuses on the specific author(s). Legal research was removed because it typically focuses on the circumstances of specific plaintiffs or parties involved in a case. Note that it is not the particular field that removes the activity from the definition but rather the particular activity's focus on specific individuals.

The Compliance Review Process in Brief

The IRB application elicits a review of the proposed research study for the purpose of certification of compliance with governmental and organizational rules and guidelines for the protection of human participants. A critical aspect of compliance is the principal investigator's described understanding of the present and potential risks to the proposed research participants and the principal investigator's plan to ameliorate any possible adverse reaction to participation. It is the principal investigator's responsibility to control, to a reasonable extent, any potential harm and to have a plan ready to correct any potential harm.

The Westcliff University IRB does not approve research studies; it certifies the principal investigator's compliance with guidelines for the ethical treatment of human research subjects. The IRB considers the design and data-gathering procedures of the study in its review.

1. Prior to determining level of application and filing the appropriate forms, the principal investigator completes a web-based training program in human research subjects' protections through the Collaborative Institutional Training Initiative (CITI).

2. The principal investigator, in consultation with the faculty research supervisor, determines the level of risk to the proposed research study's participants and completes the appropriate IRB application (Full, Expedited or Exempt).

3. The faculty research supervisor reviews the application and works with theprincipal investigator to ensure all questions are answered fully and accurately. Only complete applications will be reviewed by the IRB.

4. The principal investigator attaches appropriate approval documents, a Conflict of Interest Disclosure Statement, and documentation of successful CITI training completed by the principal investigator and faculty research supervisor.

5. The faculty research supervisor signs the application, verifying that the study has academic merit, meets the requirements for IRB certification, and that IRB application has been prepared in accordance with the guidelines specified in this Handbook.

6. The faculty research supervisor forwards the application to the IRB Chair (IRB@westcliff.edu) for logging and forwarding to the assigned IRB member for review.

7. The IRB chair determines if the level of the application is correct, reviews it if it is an Exempt or Expedited application, and forwards Full IRB applications to the IRB Committee for review at the monthly IRB meeting with the required voting quorum.

8. Exempt or Expedited applications can take up to 10 business days for review. Full applications may take up to 60 days for review not including revisions. Deficient applications will be returned to the faculty research supervisor and principal investigator for revisions.

9. The cover page of the IRB application contains certification conditions. Once the application is certified, a copy of the signed cover page is returned to the faculty research supervisor and principal investigator. The original signed application is retained in a secure file in campus administrative offices or a secure share point.

10. Upon completion of the study, the principal investigator completes a Project Completion Report (Appendix L), which is submitted to the IRB Chairperson. The form is filed with the principal investigator's original IRB application. The IRB Chairperson signs the principal investigator's Doctoral Research Approval Form (DRAF) indicating this form has been filed and/or sends an email acknowledging the filing of the form.

SECTION TWO: ADMINISTRATION AND GOVERNANCE

Membership of the IRB

Campus IRB Members

Each campus IRB shall have at least five members, with varying backgrounds, who will review research activities commonly conducted by the institution. The IRB shall be sufficiently qualified, through the experience, expertise, and diversity of its members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The composition of the IRB should reflect the university's commitment to diversity, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to certify the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas.

1. The IRB shall include at least one member whose primary concerns are in scientific areas and one whose interests are in non-scientific issues. Meetings cannot be held unless there is at least one member present whose main interest is in non-scientific issues.

    a. No IRB may consist entirely of members of one profession or one gender.

    b. All colleges and schools at the university campus should be represented on each IRB.

2. At least one of the members present must have no affiliation with Westcliff University other than serving on the IRB.
    a. Affiliated members include but are not limited to (a) individuals who are part-time employees, (b) current students, (c) members of any governing panel or board of the institution, (d) paid or unpaid consultants, and (e) volunteers working at the institution on business unrelated to the IRB.
    b. Unaffiliated members include but are not limited to, individuals whose only association with Westcliff University is that of a client or subject.
3. An IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

4. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

5. Campus IRBs may have a student for a member, but no IRB is required to have a student member. A student member cannot be also counted as a representative of his or her current department or field of study, nor as an outside member.

Campuses may use a variety of procedures to identify members. The IRB is responsible for perpetuating itself within the guidelines of the Handbook. The board may invite new members, and colleges or departments may designate a representative (as a designee of the chairperson), who will review the applications of that college. The chairperson may solicit participation with an eye to the guidelines above. New campuses may initiate an IRB by appointing a temporary IRB Chairperson.

Exceptions to any of the rules listed above must be requested by the campus IRB chairperson, approved by the Westcliff University Chief Academic Officer, and noted in written correspondence to be maintained by the campus IRB.

Authority of the IRB

Campus IRBs review proposals of research projects to be conducted at the single campus level. The initial review process involves four primary areas of responsibility for IRBs in terms of their authority to:

1. approve, request modification, or disapprove research activities;
2. ensure informed consent requirements are met and documented, or waiver of informed consent is appropriate and documented, as relevant;
3. notify investigators of their determinations; and
4. conduct continuing reviews of research.

Responsibilities of the Campus IRBs

Campus/Online IRBs review all research conducted by anyone affiliated with the campus. To implement their responsibilities, the campus IRBs establish their own calendar and procedures for the review of applications for certification of compliance as described in this handbook. The campus IRB announces its responsibilities and holds meetings to train principal investigators and their research supervisors in the processes and procedures for review of campus research projects.

In addition to reviewing all research by anyone affiliated with the campus, a campus IRB may also review research from another Westcliff campus when it possesses expertise not available on the originating campus or assurances (e.g., Federal-wide Assurance or Department of Defense Addendum) that would significantly facilitate the timely review of research from the originating campus. In such instances, the reviewing IRB shall maintain oversight over the reviewed research until the submission of a project completion report and accompanying IRB acknowledgement.

For application review decisions, each campus IRB is autonomous. The decisions of the local IRB are not subject to review or appeal. Annually, each IRB files a Letter of Assurance with the unit's chief academic officer, indicating that the IRB is duly constituted according to established guidelines and that it will conduct its reviews in accordance with the guidelines.

Responsibilities of the IRB Chairperson

Each IRB shall designate a chairperson using a process determined by each campus. Each IRB is encouraged to appoint a Vice Chairperson, responsible for carrying out the chairperson's duties when the chairperson cannot do so. With the approval of the full IRB, the chairperson shall:

1. conduct the meetings of the IRB;
2. maintain a record of all IRB members for the unit, including current curriculum vitaes;
3. invite new board members, as needed;
4. assign certification authority to the members;
5. maintain and acknowledge filing of all project completed reports; and
6. maintain a record of the proceedings of the IRB meetings, including agendas, actions of the IRB, and the certification logs of the members.

Governance of the IRB

Self-Governance

The IRB is self-governing. No other group or individual may interfere with its decision-making process or overrule its decisions. Unless otherwise agreed upon, the IRB retains authority over all matters related to its responsibility to assure the protection of research participants. Policies and procedures governing Westcliff University IRBs may be changed only by the university IRB, except for procedural details unique to each campus, which may be changed by the IRB of that campus at a regular meeting and approved by the national IRB Chair. Links to pertinent federal law related to governance are found in Appendix O

Functions and Operations

IRBs must follow written protocols for IRB Functions and Operations per the Federal Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4) and (5)(i) as well as 21 CFR 56.108(a). In order to fulfill its requirements, each IRB shall:

1. Conduct the initial and continuing review of research and report its findings and actions to the investigator and the institution;

2. Secure access to meeting space and sufficient staff to support the IRB's review;

3. Prepare and maintain a current list of the IRB members (See Appendix M)

4. Review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas for full review, Level 3, applications. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Additionally, IRBs must establish and follow written procedures to:

1. Determine which projects require review more often than annually and which projects need verification (from sources other than the principal investigator) that no material changes have occurred since previous IRB review.

2. Facilitate prompt reporting to the IRB of proposed changes in a research activity.

3. Ensure that investigators conduct research activities in accordance with the terms of their IRB certification until any proposed changes have been reviewed and approved by the IRB (except when necessary to eliminate apparent immediate hazards to the subject).

4. Require prompt reporting to the IRB, appropriate institutional officials, the department or agency head of funding (if applicable), and the Office for Human Research Protections (if FWA) in the event of:

    a. unanticipated problems involving risks to human subjects or others;

    b. instance of serious or continuing noncompliance with the applicable HHS regulations or the requirements or determinations of the IRB; and

    c. suspension or termination of IRB certification.

Finally, the IRB is responsible for ensuring that all of the following requirements are satisfied.

1. Risks to subjects are minimized by using procedures that are consistent with sound research design, that do not expose subjects to risk unnecessarily, and that use procedures already being performed on the subjects for diagnostic or treatment purposes, when appropriate.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or solely economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented or appropriately waived (see elements of informed consent section).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

IRB Compliance Audits

Any reported significant deviation in activities previously certified by the IRB must be investigated by the IRB as an issue of noncompliance with certification requirements. Likewise, when the IRB has reason to suspect noncompliance that was not reported by the investigator (e.g., participant complaints made directly to the IRB, past instances of noncompliance), an investigation is also conducted.

Investigations of noncompliance. In cases of suspected or reported noncompliance with IRB certification, an ad hoc subcommittee of the IRB will be appointed by the chairperson to investigate alleged noncompliance. The subcommittee will be composed of the IRB chairperson and any other IRB member whose presence is deemed essential. The chairperson shall brief the full IRB at the next scheduled meeting (or at a specially convened meeting) on the findings of the investigation. The IRB will determine whether there was, in fact, a violation of regulatory or institutional policies.

Procedures for resolving noncompliance. In cases where the IRB determines a violation did occur, then the IRB will outline the restrictions, conditions, or other actions that are necessary to resolve the noncompliance and identify procedures to prevent future occurrences. The principal investigator and his or her research supervisor will be notified in writing of the requirements or conditions necessary to ensure compliance with the restrictions, conditions, or decisions of the IRB. Every effort will be made to ensure the confidentiality of all aspects of the investigation and any subsequent IRB actions relating to the incident(s).

Notification and consequences of noncompliance. When appropriate, University administrators (e.g., Dean, VPAA) will be informed of acts of noncompliance. If the research involved external funding, or if the campus currently holds an institutional Federal-wide Assurance (FWA), the Office for Human Research Protections (OHRP) and any granting agency (e.g., APA Minority Fellowship Program) receiving the assurance shall also be informed, as appropriate. Additionally, student investigators may be referred to the Student Conduct Committee of Westcliff University and subject to the sanctions deemed appropriate by that committee, up to disqualification of the study and dismissal from Westcliff University.

Meetings of the IRB

Yearly Organizational Meeting

Each IRB must conduct an annual organizational meeting at which time the members of the IRB agree to comply with the guidelines and procedures established for the IRB and sign a Letter of Assurance to be submitted to the unit's chief academic officer. At its annual organizational meeting, each campus IRB shall constitute itself for the current academic year. At this meeting, the IRB will:

1. Admit new members and dismiss members who wish to terminate their service on the IRB.

2. Select a chairperson from among its membership, per campus protocols.

3. Review applicable parts of *Title 45 of the Code of Federal Regulations*, ethical guidelines published in the *Belmont Report*, and other applicable state and federal laws, rules, and university regulations to discuss changes, if any, that have been made to these rules and regulations.

4. Direct all new members to complete the training program for new IRB members. The Westcliff University IRB share point has information about available training opportunities).

5. Determine a schedule of meetings for the current academic term to be made available to the campus.

6. Assign specific IRB members to review IRB application and with authorization by the IRB Chairperson for these members to certify exempt and expedited applications.

Regular Meetings of the Full IRB

While a fixed monthly meeting date is desirable, each IRB shall establish a calendar of full board meetings appropriate to the campus and university calendar. The IRB must schedule sufficient meetings to conduct business in a timely manner and conduct business according to the criteria set by federal and university regulations. The IRB follows Robert's Rules of Order (Robert, et al., 2011) in all procedures and meetings. The primary purpose of monthly meetings is to:

1. review any applications that may be subject to IRB review requirements;
2. determine the level of review required for an application;
3. report on exempt and expedited reviews by IRB members;
4. approve the log of exempt and expedited applications, including the primary reviewer's decision, to be recorded in the IRB minutes;
5. conduct a review of any full review (Level III) IRB applications for certification;
6. review cooperative research applications involving a joint certification review; and
7. conduct other business of the IRB as needed and appropriate

While exempt and expedited applications may be reviewed on a continuous basis by the IRB chairperson or the chairperson's designee, full IRB review applications must be certified by the IRB at scheduled monthly meetings. To prepare members for full review application, prior to the IRB meeting, all members should receive with the meeting agenda the:

1. documents submitted to the IRB for review (e.g., protocol, informed consent form, recruitment materials);

2. designation of primary reviewer; and

3. description of possible actions the convened IRB can take (including determination if population is vulnerable to coercion). If vulnerable participants are being recruited, the committee should review precautions included to protect the participants' rights and welfare.

If a campus cannot convene a minimum five-member committee to review full (Level III) applications, the chair of the host campus will consult with the National IRB to form an ad-hoc committee for the express purpose of reviewing the Level 3 application(s).

When an application involves cooperative research, subject to review by another qualified IRB, the campus IRB may review possible arrangements, where applicable, for a joint certification review, allowing one IRB to accept the decision of the other IRB to avoid duplication of effort. The campus IRB determines and documents the effective date of initial certification. If applicable, it also sets the continuing review date, including determination of verification source as well as rationale for the review (e.g., vulnerable population, investigator experience, novel experimentation) which is recorded in the minutes and in the log. A communication plan is determined for notification of approval of the application or reasons for disapproval along with process for obtaining approval.

Participation of outside consultants. If the IRB determines it lacks sufficient expertise in an area of research that is the subject of a research project submitted for certification, the IRB may include outside consultants in its deliberations at its discretion, either during a scheduled IRB meeting or a separate meeting convened for this purpose. The consultant must be chosen based upon his/her expertise in the research field and its use of human participants for research. Consultants may not vote on the submission under consideration. The no vote condition does not apply to the ad-hoc full (Level III) review committees formed between the campus and National IRBs.

Abstention of IRB members with a conflict of interest. A member of the IRB may not certify compliance of a research proposal for which the IRB member has a direct interest either as an investigator or as a dissertation, CRP committee member, sponsor, or faculty research supervisor of a student's project. No IRB may have a member participate in the IRB's initial or continuing review of any project of which the member has a conflicting interest, except to provide information requested by the IRB.

Meeting Quorum

A majority of the IRB members of record shall constitute a quorum for the purposes of conducting the business of the full IRB, whether held in person, by teleconference, videoconference, or other method. A quorum of members (>50 %) is required at full board meetings and lack of a quorum prohibits taking official action at its meeting.

At the beginning of each IRB meeting, members should certify for the record that they have no conflicts of interest in any research project currently under consideration. If any member is a co-investigator, or otherwise has a conflict of interest with a research project, he or she must be excused from voting.

Special attention must be paid to ensure that a quorum is not lost during a meeting. If a member abstains from voting, or is excused due to a conflict of interest, a quorum of total members must remain for certification of full reviews. If not, the research project under review cannot be certified. In addition, if during the meeting, the number of members present falls to a level below that required for a quorum, the meeting must be adjourned as no official action can be taken. The voting record shall be recorded in meeting minutes for this purpose.

Documentation of IRB Actions and Activities

Required Records

All applications for certification documentation and forms received by the IRB (including amendments, continuing review forms, and project completion report) will be appropriately filed with original application documents submitted by the principal investigator. In compliance with OHRP in the Department of Health and Human Services (45.46.115), each IRB will retain records for at least three years after completion of the research.

Records of all business conducted at monthly meetings of the IRB shall be kept in a secure location by the chairperson. Records shall include agendas and minutes of the business meetings, including attendance and the votes by members present on each decision (to document no conflicts of interest and a majority vote by the board, including the nonscientific member). Minutes will also include discussion of controverted issues and final decisions.

The IRB will document, by vote, decisions to require any continuing review of less than a year. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing, which will be kept on record.

Annual reports, required forms, and records of IRB applications shall be managed through the logging procedure described below, including copies of all correspondence. In addition, the signature page of CRPs or the Dissertation Research Approval Form (DRAF) requires the signature of the IRB chairperson, verifying the receipt of the project completion report. For principal investigators who are not students, IRB records may be maintained in print or electronic form in a separate file controlled by the IRB chairperson. Annual reports from the campus IRBs will be submitted to the campus president or designee and the National IRB chairperson. Annual reports from the National IRB will be submitted to the University's Chief Academic Officer.

All records (hard copy and/or electronic copy) shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable

manner. Data retention practices for each protocol should be governed by the guidelines of the protocol's appropriate discipline, funding source or governmental regulations should they exceed the three-year requirement for records retention noted above.

Logs and Tracking Procedures

Each IRB shall maintain a log that tracks each application from the beginning to the end of the review process (see example in Appendix N).

1. The principal investigator, in consultation with his or her faculty research supervisor, prepares and signs an application for certification of compliance appropriate for the procedures of the study.

2. IRB members review exempt and expedited applications. A copy of each month's application transactions from the log/tracking system is submitted to the IRB chairperson as part of the monthly IRB meeting. If the logging procedure is electronic, appropriate conveyance procedures are developed by the IRB.

3. If the IRB member determines that the level of application is completed incorrectly, the member returns the application to the principal investigator and faculty research supervisor with a Letter to Correct IRB Application Deficiencies (Appendix G), logging the review date and subsequent return of the corrected application.

4. If a full review (Level 3) application is received, the IRB member submits a written request to the IRB chairperson to include the application on the agenda of the next available monthly meeting for review. The member also distributes copies of the application to all IRB members before the meeting with a transmittal memo requesting their review.

5. Once an application has been certified, the IRB Chairperson, or designee, copies the application cover page and makes a copy of the complete application to return to the faculty research supervisor along with the original copy to be returned to the principal investigator.

The monthly application transactions from the log/tracking system is maintained by the IRB Chairperson.

Letter of Assurance

At the conclusion of the annual organizational meeting, each IRB shall prepare and file with the Chief Academic Officer for that unit a Letter of Assurance that details the:

1. Composition of the IRB Members - This list identifies members by name, earned degree, representative capacity, experience (i.e., board certifications, licenses, etc.) sufficient to describe each member's chief anticipated contributions to IRB deliberations, and employment or other relationship between each member and the institution (e.g., full-

time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

2. Meeting Schedule - IRBs will conduct regular meetings appropriate to the campus and university calendar and sufficient to conduct business in a timely manner); and

3. Signed Acknowledgment - The letter of assurance is signed by each IRB members signifying agreement to abide by the guidelines set forth in this document. Electronic signatures are acceptable.

Campus IRB's should forward a copy of the Letter of Assurance to the National IRB chair. In situations when the Chief Academic Officer of a unit is a member of the National IRB, the Letter of Assurance should also be filed with the Westcliff University Vice Chancellor of Academic Affairs. Changes to any of the elements of the Letter of Assurance shall be reported in a subsequent letter. The Letter of Assurance is kept current with the IRB or institution, eliminating the previous requirement of reporting changes in IRB membership to OHRP when the existence of an assurance approved by HHS for federal-wide use is accepted. The final rule also eliminates the requirement that an institution designate one or more IRBs on its FWA.

SECTION THREE: IRB REVIEWS AND CERTIFICATION

To ensure the protection and ethical treatment of human participants, and to comply with federal and state laws, Westcliff University requires that, prior to initiation, all research projects be reviewed, and a determination of compliance be made by the Westcliff University IRB. A review of a research project by the IRB is initiated with an IRB application (Appendix A, Appendix B, or Appendix C) and is concluded by a Project Completion Report (Appendix L).

Purpose of an IRB Review

The purpose of the IRB review of a proposed research project is to certify compliance with Westcliff University research standards for the protection of the rights and welfare of participants in research projects. To this end, the background, purpose, and methodology of proposed research projects are reviewed to determine potential physical, psychological, social, and legal risks to the proposed research participants, the protection of their confidentiality and the adequacy of their informed consent. All principal investigators must follow the guidelines for collaboration with participants and other stakeholders as noted in the *Publication Manual of the American Psychological Association* (7th ed.), the *Belmont Report*, and their professional code of conduct (see Appendix O). The Board does not ordinarily review scientific design but may do so if the design of the study could affect the risk-benefit ratio.

Benefits of an IRB Review

A review by the IRB offers benefits to investigators and the institution. It certifies that the investigator's research project is in compliance with ethical guidelines and with state and federal rules and regulations. Additionally, the review may bring to the attention of an investigator ethical factors that may not have been sufficiently considered. Further, the IRB review and certification demonstrates and documents the institution's commitment to the protection and ethical treatment of human participants.

Studies Requiring an IRB Review

Research Involving Human Data

Each principal investigator proposing a research project involving human data, large or small, must request IRB review and acquire certification that the proposed research project complies with the guidelines set forth below for the protection of human participants. This policy applies, regardless of source of funding and location of study, to all research studies or pilot studies conducted by or on (a) faculty, staff, students, or employees of Westcliff University or (b) Westcliff University as an institution. This policy applies to research performed for conference presentations or poster sessions as well.

Exceptions for review are those research activities conducted internally by Westcliff University for self-review or those conducted by faculty or staff members where the research has no relationship to his or her Westcliff duties or affiliation and in certain class assignments and projects.

Research Conducted at the Place of Employment

Proposals to conduct research at the principal investigator's place of employment are carefully reviewed because of the risk of a dual relationship that the principal investigator may have with the research participants; that is, there may be perceived bias against, or perceived coercion of, participants during the research process. In writing the proposal, principal investigators must clearly address any conflict of interest that such studies can present, including their relationship to participants.

Investigators are strongly urged to avoid the use of participant pools of convenience (see Conflict of interest section). Additionally, Westcliff University strongly discourages the use of other Westcliff University students or employees for clinical or dissertation research (see Westcliff University Students and Employees as Research Participants section). Internal research conducted at Westcliff University for purposes such as program review, departmental or institutional assessment, and university accreditation do not require IRB review.

Class Research Projects

Most class assignments do not fall within the definition of research, per se, because the focus is on gathering information for journalistic/educational purposes as opposed to collecting data for a research project that may lead to research publication or presentation. Such examples include:

1. in-class or out-of-class informal interviews used for class purposes typically do not require IRB review[3]; and

2. activities designed to train students in research methods in the normal classroom setting usually do not fall within the federal definition of research.

On the contrary, some research conducted by students as part of their class assignments as well as class research conducted by professors in their work with students may be subject to IRB review. Such examples include:

1. original research completed in preparation for a conference presentation or poster session.

2. graduate theses, CRPs, research projects, and dissertations.

The examples above are clearly understood as research and fall within the IRB purview when human participants are involved.

The course instructor has the responsibility for ensuring that the student is educated on the general principles of research ethics, human participant protection, and investigator training. Faculty and students may contact the IRB to discuss the assignment and obtain assistance in

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[3] IRB certification may be needed in the case of a sensitive topic, vulnerable population, or other conditions requiring protection of human participants. See the questions developed as criteria for assessing whether Class Research Projects require IRB certification within this discussion.

determining if review is needed. To provide guidance to faculty members, the IRB has developed the following criteria to determine whether classroom assignments require IRB Certification:

1. Are the participants from a vulnerable population such as children, prisoners, or individuals with impaired decision-making ability?

2. Does the assignment require use a protected setting (e.g., prison, nursing home, hospital, school)?

3. Does the assignment focus on sensitive topics (e.g., alcohol or drugs, depression or suicide, learning disabilities, abortion, AIDS, HIV, sex, sexually transmitted diseases, eating disorders, psychological inventories)?

4. Does the assignment include audiotaping or videotaping?

5. Will participants be directly identified through the assignment?

6. Will the data be formally presented to any audience outside of the class?

7. Will the research extend beyond the realm of the classroom environment?

8. Does the assignment require the use of proprietary or privileged information that is not publicly available?

If the answer to any of the above questions is "Yes," the project must be reviewed by the IRB. When in doubt, faculty research supervisors should consult with their local IRB board to ensure compliance.

Research Anticipating Human Involvement

Certain types of activities are planned and initiated with the knowledge that human participants will be involved, without definite plans for their involvement. Examples of such proposed activities are:

1. training programs in which individuals or projects remain to be selected or designed;

2. research pilot or developmental studies in which the involvement of human participants depends on such things as the completion of survey instruments;

3. prior studies that have already been certified to conform; and

4. general support programs of which selection of the project is the responsibility of the institution or program administrator.

In consultation with the investigator's supervisor, the appropriate anticipated level of review application is to be submitted to the IRB with as much information as is available. The

application must include assurances that additional information will be submitted when developed, and in the case of training grants, that all trainees will submit individual applications if human participants are used.

Levels of IRB Review and Certification

The principal investigator, after completing CITI training and in consultation with his or her faculty research supervisor, assesses the risk-to-benefit ratio of the research and completes an IRB application at the appropriate level (exempt, expedited, or full review) based on the following descriptions.

Studies Qualifying for Exempt (Level 1) Review

Westcliff University reserves the Exempt (Level 1) for research projects with minimal risk to human participants. Research projects for which there is no human participant interaction (e.g., meta-analysis, literature review) undergo this limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information.

Sensitive topics and vulnerable participants (e.g., children, patients, individuals with impaired decision-making ability, and prisoners) do *not* qualify as exempt research. Likewise, international studies do not qualify for exempt IRB review. The IRB makes the final determination about whether a proposal is Exempt. Two weeks may be required for processing after receipt of a *complete* application. One IRB member's (the Westcliff University campus representative or the IRB Chairperson) signature is required.

Exempt level research includes the following.

1. no-risk, routine educational tests (see educational practices below), surveys, interviews, or observation of public behavior unless identities of participants can be ascertained;

2. the use of information that is publicly available or recorded without identifiers;

3. secondary research using information collected by the Federal Government for other purposes and not subject to certain privacy laws;

4. secondary research using information covered by HIPAA protections and without identifiers that will benefit as a public service; and

5. taste and food quality evaluations and consumer acceptance studies.

Unless otherwise required by law or by department or agency heads, research activities are exempt in the following categories:

Educational Practices. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education

instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The exemption is retained to allow for the conduct of education research that may contribute to the important public good of improving education, consistent with the principle of beneficence.

To qualify for the exempt category for educational practices, research must meet the following conditions:

1. *Setting:* The exemption retains the condition that the research activity takes place in established or commonly accepted educational settings because otherwise IRB review would be warranted for such research activities being conducted in unconventional settings.

2. *Procedures*: Research that *only* includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior (including visual or auditory recording) that does *not* involve an intervention, if the data are recorded anonymously.

3. *Benign Behavioral Interventions:* For adult participants only (children are never exempt), in conjunction with the collection of information through verbal or written responses (including data entry) or audiovisual recording, the research may be exempt if subjects agree to the intervention and information collection, and if the following criteria are met.

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.

    d. For the purpose of this provision, *benign behavioral interventions* are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

    Provided that all such criteria are met, examples of benign behavioral interventions could include having the subjects (a) play an online game, (b) solve puzzles under various noise conditions, or (c) decide how to allocate a nominal amount of received cash between themselves and someone else. For example, a research study comparing test performance of test takers in quiet or noisy surroundings would qualify for this exemption. Also,

subjects could be asked to perform cognitive tasks and audiovisual recording could be used to collect the data, without any educational test, survey, or interview procedure occurring, and this research would be considered exempt.

This exemption is based on the assumption that the potential risks raised by this category are largely informational and that subjects are aware of them, and thus, the most important role that an IRB might play with respect to reducing potential harm is to ensure the application of privacy safeguards. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Secondary Research. Secondary research for which consent is not required may be considered exempt. Secondary research may use identifiable private information, if at least one of the following criteria is met:

1. The identifiable private data are publicly available.

2. Information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

3. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of "health care operations" or "research" for "public health" activities.

    a. HIPAA provides protections in the research context for the information that would be subject to this exemption (e.g., clinical records), such that the additional application of Common Rule requirements for consent should be unnecessary in those contexts. Under HIPAA, these protections include, where appropriate: (a) requirements to obtain the individual's authorization for future; (b) secondary research uses of protected health information; or (c) waiver of that authorization by an IRB or HIPAA Privacy Board.

    b. This provision introduces a clearer distinction between when the Common Rule and the HIPAA Privacy Rule apply to research in order to avoid duplication of regulatory burden. The HIPAA protections are adequate for this type of research, and it is unduly burdensome and confusing to require applying the protections of both HIPAA and an additional set of protections. The exemption permits the use of private identifiable information for secondary research conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the information originally

involved a collection that adheres to the federal standards for safeguarding privacy as described in this part of the exemption.

c. For archival studies, any previously obtained broad consent document is a required part of the researcher's application packet if identifiable information is still attached. The IRB is within its rights to ask about the provenance of *any* given data set when there are concerns and may request a copy of the consent when relevant to a given application's determination.

Studies Subject to Expedited (Level 2) Review

The expedited review process is used to review certain categories of research involving minimal risk to human participants. Any research in which human participant interaction is anticipated falls under this level unless risk to participants is more than minimal. Most studies with direct interaction or intervention with human participants will fall into this level. Thirty days may be required for processing after receipt of a complete application. One IRB member's (an experienced IRB member or the IRB Chairperson) signature is required.

In addition to meeting the general eligibility criteria described previously, the research must also meet the certification criteria as follows:

1. The risks to participants for participating in the research must be reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be gained.

2. Participant selection must be fair.

3. Informed consent will be sought and documented unless a waiver of consent or documentation of oral consent has met the criteria.

4. The plan to collect and monitor data assures participant safety.

5. Procedures provide for the privacy of participants and for maintenance and disposal of confidential data.

Studies Subject to Full (Level 3) Review

A full IRB review is required for research projects that entail sensitive or risky research topics or methodologies or involve vulnerable participants (i.e., vulnerability to coercion and undue influence) in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research. Vulnerable participants (e.g., children, individuals with impaired decision-making ability, prisoners, and persons under court supervision) require full IRB review in a full board meeting. These applications must contain extensive detail describing procedures designed to protect vulnerable participants. A majority of IRB members must certify the proposal, verified by the minutes of the monthly IRB meeting, and the IRB Chairperson signs the cover page. Sixty days may be required for processing after receipt of a complete application.

Cooperative Research Activities

The IRB has special requirements for the review and certification of proposals involving cooperative activities. Cooperative activities are those in which Westcliff University faculty, staff, employees, or students, seek access to human participants at one or more cooperating institutions, or when investigators from cooperating institutions seek access to human participants at Westcliff University.

1. If an investigator from a cooperating institution desires to obtain direct access to any person at Westcliff University, the study must first be reviewed by the dean of the college most closely associated to the discipline area of the research, and a Westcliff University faculty member must be listed on the research project request.

2. If a Westcliff University faculty, staff member, employee, or student wishes to collect data from an outside agency, the principal investigator is responsible for submitting a letter granting permission to do such from an authorized member of the cooperative institution.

3. If the cooperating agency has its own IRB, Westcliff University faculty, staff, employees, and students may need to negotiate which institution will grant the IRB Certification or accommodate requests made by an outside IRB. In some cases, a single certification may suffice between cooperative agencies.

Multi-Campus Cooperative Research

In cases where cross-campus research involves multi-campuses (more than two campuses), the application must be filed with Westcliff's National IRB.

- The National IRB chair convenes a subcommittee from the National IRB to review the application. For most national requests, the convened subcommittee will include the chairpersons of the campus sites where the proposed research will take place.

- For full review applications at the national level, a quorum of the members of the national IRB reviews the application at their next regularly scheduled meeting.

Once certification is obtained at the national level, campus VPAAs will be notified and research may commence. Local certification is not required for protocols certified at the national level.

Dual-Campus Cooperative Research

In cases where cross campus research involves only two campuses, the IRB application and certification is conducted by the originating campus with permission granted from the cooperating campus.

- If students from only one college are being solicited for participation, the college dean will review and approve the request to conduct research with their campus,

- If students from more than one college are being solicited, the college deans, VPAA, and regional director of HR of the host campus (if required) will review and approve the request to conduct research with participants at their campus.

The VPAA and HR director forward approval to the applicant's home campus IRB chairperson, the faculty research supervisor, and the principal investigator. The principal investigator includes all letters of permission as an appendix in the original application or as an amendment if the principal investigator is seeking to expand the participant pool from the original campus.

The principal investigator includes all letters of permission as an appendix in the original application or as an amendment if the principal investigator is seeking to expand the participant pool from the original campus.

Westcliff University Students and Employees as Research Participants

Westcliff University strongly discourages students from using archived data of the University and from engaging other members of its community (students or employees) in graduate research, dissertations, theses, capstones, or similar research projects. The University reserves the right to prohibit access to WU member pools and/or archived data; yet, there are occasions when such access to WU membership pools or archived data for research may be warranted. In such cases, Westcliff University utilizes the following procedures, as adapted from *Guidance for Enrolling University Students as Research Subjects* published by the University of Texas at Arlington
(n.d.).

Westcliff University Students as Participants

According to the IRB guidelines published by the Office for Human Research Protections of the U.S. Department of Health and Human Services (n.d.):

> The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community)... An alternative way to protect against coercion is to require that faculty-investigators advertise for subjects generally (e.g., through notices posted in the school or department) rather than recruit individual students directly. As with any research involving a potentially vulnerable subject population, IRBs should pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated. (Students section, para. 2)

In addition, potential conflicts of interest may arise, especially when graduate students are using WU based membership pools to complete a clinical research project or dissertation. These potential individual conflicts of interest may impinge upon researcher objectivity and heighten the use of undue influence to complete a clinical research project or dissertation.

Faculty and graduate student researchers should eliminate or reduce undue influence or coercion on students to participate in their research projects. The following guidelines are offered to assist departments, faculty, and graduate students who engage in research projects in which students

will be asked to be research participants.

- Students should be of the age of majority (18 years old). Research involving minors (under 18 years of age) as participants (e.g., 16 or 17-year-old college students) in most instances requires a signed parental (or legal guardian) consent, as well as the signed assent of the student. Some types of research may qualify for a waiver of consent (parental permission).

- Generally, researchers may not access classroom performance evaluations, grades, and information in a (current) student's records without prior written permission from the student, regardless of the access an investigator may have in his/her academic role.

- When research activities to be conducted by the students are not part of the required class activities, the principal investigator should arrange to have the data collected by an independent third party outside of active class time. This safeguards confidentiality of participants so the instructor nor investigator knows which students participated. Likewise, it safeguards identifiable data and identity of participants for any purpose until grades have been reported.

- When course credit or extra credit is offered to students who participate in research as part of a course requirement, students are to be provided alternatives to fulfilling the research component (e.g., short papers, special projects, book reports, brief quizzes on additional readings, research seminars, or completing a similar project). Alternative projects must be comparable in terms of time, effort, and educational benefit as research participation to ensure that students are not being coerced into becoming participants. Alternatives offered to student participants need prior IRB approval. Departments seeking to use student participant pools and offering projects including pre- and/or post-testing also require IRB approval if tests are not part of the assigned curriculum.

- Solicitation of volunteer participants for research must be conducted in a non-coercive manner. To avoid undue influence, participants should be recruited by a public announcement (i.e., paper or electronic format, including social media) that should include a clearly written description of what students are expected to do and how much time is required for participation. In addition to being provided with the traditional information and consent forms, the participant should also be provided with the name and contact information of a neutral third party to contact should the participant feel coerced at any time during the process.

- When possible, researchers should avoid data collection during regular class meetings. When study participation consumes a significant portion of a class session, loss of instructional time for both participants and non-participants may be considered a loss of

benefits. When research participation is expected during the same session that participation is invited, students may be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day's class.

- Since there are special risks of confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks in the consent of students to participate. The plan for handling consent forms and research data should be designed to minimize the risk that confidentiality will be breached (e.g., signed consent forms can be collected and filed separately from the anonymous test instrument). When instruments call for the disclosure of information that participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

- The use of mass testing (classroom scenario) is strongly discouraged. When possible, students should be permitted to access web-based research-related activities. Using applications that permit students to register for participation outside of the view of others (at the time and place of their choosing) is also recommended.

- Like other research volunteers, students who become research participants must be permitted to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion. In general, it is favorable to give credit if the participant withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.

- If the research is one where data are collected from a group project or videotape of the group interaction, each student's consent is necessary for the use of that data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded.

- When deception is used, students have the right to full disclosure as soon as possible. Two consenting presentations are required, the first of which will normally take place during the pretesting period; the final informed consent is presented at the debriefing. When possible, a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the participants until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected. During the debriefing, students must be provided an opportunity to decide whether the researcher(s) can use the data collected.

- Research conducted by graduate students in a class taught by the researcher, or in a class where the research assists or grades is subject to the same restraints described above.

- Archival data that belongs to Westcliff University is proprietary information. Even though the use of archival data without personal identifiers most often falls under the exempt IRB application category, securing permission to access WU archival data follows the same processes as access to membership pools.

Westcliff University Employees as Participants

When Westcliff University graduate students intend to use employees of Westcliff University, the Office for Human Research Protections of the U.S. Department of Health and Human Services (n.d.) advises, "The issues with respect to employees as research participants are essentially identical to those involving students as research participants: coercion or undue influence, and confidentiality" (Employees section, para. 1).

Westcliff University requires training directly related to this topic by IRB members, graduate faculty who supervise clinical research projects and/or doctoral research studies and administrators who would grant access to such participant pools or data sources.

Proprietary Information

Disclosure of proprietary information or trade secrets can lead to harm, including competitive disadvantage, compromise of economic interests, and breach of confidentiality. For this reason, employees must be mindful of company interests when granting access to internal information, erring on the side of caution in all cases.

Process

When a principal investigator needs access to membership pools or archival data within Westcliff University, the investigator must first submit the study for review to the college dean. This is true regardless of whether the investigator is soliciting member pools or data from a single program within a college at a single campus or is soliciting member pools from across Westcliff University or sister schools. The additional permissions that must be secured vary by college number, and type of member pools that need to be accessed. See the Cooperative Research Activities section of the IRB Handbook for additional information details and requirements.

Research at the International Level

In cases where international research will be conducted by a Westcliff Universitystudent, the guidelines established by the OHRP at the U.S. Department of Health and Human Services are followed. The guidelines can be found at: http://www.hhs.gov/ohrp/international/index.html.

Research at the National Level

In cases where research is requested at the national level, the principal investigator files an application with the chairperson of Westcliff University's National IRB and the National IRB will review the materials, certifying when possible. At the national level, if a principal investigator seeks to use Westcliff University students, class practices, or related educational materials, the permission process involves three steps:

1. The study must be approved by national college dean. If more than one college is involved, both deans must provide approval.

2. The study must be approved by University's Chief Academic Officer (CAO). If a principal investigator seeks to use Westcliff University employees or business practices at the national level as part of a study, permission must be obtained from the university's Vice President of Human Resources (VPHR), in consultation with the CAO. In the principal investigator's request for permission, the principal investigator must explain in detail the purpose and procedures of the study and what is being requested from the campuses or university. The CAO or VPHR will then approve or deny the request in writing.

3. With the national college dean and University CAO approvals of the study, the researcher will send the IRB application to the national IRB. The National IRB will convene a committee with representatives from each campus that is a part of the proposed study. On behalf of the National IRB, this committee will either certify protocol or return to researcher and chair for revision and reapplication.

National applications that do not contain the required written permissions will be denied. Please note that OHRP cautions against research using participant pools of convenience and the IRB strongly discourages researchers from using Westcliff students unless the student population is relevant and appropriate for the research question proposed and that Westcliff students receive direct benefit for participating in the study. Internal research conducted by Westcliff University at the national or local levels for purposes of program review, departmental or university assessment and academic program or university accreditation do not require IRB review as these practices do not fall under the definition of research per the Common Rule.

Research at the Campus Level

When research is conducted at the campus level, national review is not required. The process is similar as mentioned in the previous section but applies to research conducted at the campus level. For Clinical Psychology programs, the principal investigator must secure written permission from the VPAA and the program dean of the campus, and when required, the director of HR to conduct the study. Again, requests to use Westcliff University's students, staff, educational or business practices, or faculty as research participants are strongly discouraged and only approved when the research provides a specific benefit to those being studied.

SECTION FOUR: CONSENT OF PARTICIPANTS

Navigating the IRB process quickly and efficiently is important to all involved, and the informed consent process can seem like a daunting component of the process. As such, Westcliff University provides a sample informed consent form (Appendix E) that captures the federally required elements of informed consent for the great majority of studies conducted by WU students. It is the expectation that students will use this model to develop their informed consent letters. In the few cases where additional or special elements justify deviation from this model, the IRB will work with students and their faculty research supervisors to ensure the appropriate and required elements are included. The following sections detail the consent process, required elements of informed consent letters, special consent procedures, and the review process by the Westcliff University IRB.

Informed Consent Purpose and Process

Before involving a human participant in research, an investigator shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative. The goal of the informed consent is to present a concise and focused presentation of the key information that will assist the prospective participant (or legally authorized representative) with an understanding of the reasons why one may or may not choose to participate in the research and to provide an opportunity to discuss that information.

Ethical practice and law require that a participant's consent be intelligent, knowing, and voluntary. It is essential that consent to participate in a research project be obtained under circumstances where a participant has (a) reasonable time to listen to investigators' explanations; and (b) the participant's physical, mental, or psychological state does not impede comprehension of information or the ability to make rational and non-coerced choices. To ensure the validity of consent where other than minimal risks are involved, the initial presentation to the participant should precede execution of the consent form by several hours or days.

Investigators should make every effort to avoid using participants whose capacity for competence to give consent is limited (e.g., impaired decision-making ability, medication, severe debilitation, pain). Such participants should be thought of as non-consenting. Most persons under the age of 18, or persons judged legally incompetent due to impaired decision-making ability, are legally incapable of consent and their legal guardians must be petitioned for permission or consent on their behalf.

Investigators must allow a minor or legally incompetent participant the right to refuse to participate in the study even when guardian approval has been secured. Parents cannot sign away a minor's right to choose to participate, and minors must give their assent (even if parental consent is obtained). The investigator must provide minor participants with a separate form—called an agreement (or assent) form—written to the minors' level of understanding. Investigators must obtain and document the assent of minors and legally incompetent persons to participate in the research project.

Principal investigators must provide potential participants with informed consent documents written in simple, first person language at the reading level of the participants and in the native language understandable to the participant (or the participant's legally authorized representative). If participants do not read the native language in which the form is written, or if there is no written native language, then terms must be written in a translated informed consent document in their native language or explained verbally in detail in their native language. Verbal consent must be documented and witnessed by another party who can speak the native language.

The consent process promotes respect for participants and enables them to decide the protection level afforded them in the research project. The informed consent process increases transparency so potential subjects have information about how their private information may be used. Prospective participants will be told whether identifiers may or may not be removed from their private information and used for future research, if this could be a possibility. Principal investigators are responsible for ensuring that participants, or their representatives, are given sufficient opportunity to consider whether to participate and must seek to avoid coercion (implied, overt, or covert) or undue influence. To comply with changing requirements, the IRB, at its discretion, has the authority to alter these requirements or waive the informed consent process.

Elements of Informed Consent

Every investigator at Westcliff University must obtain the informed consent of any potential human participant of research before that person participates in research. Information provided to potential participants or their representatives must be in language that is understandable to the participant or participant's representative. The beginning portion of the informed consent must be organized and presented in a way that facilitates the participant's comprehension and does not merely provide a list of isolated facts. As such, it is prudent to present the information that is most important to participants before presenting other information.

Generally, the informed consent letter must be written in the first person ("I") of the participant (e.g., "I understand that I will participate in a research study."); however, statements such as, "I agree to what has been verbally described" are not acceptable. The investigator must describe the study and its procedures in writing at the participant's reading level on the informed consent document. (Word processing programs such as Microsoft Word can provide an estimate of the reading-level of documents.) The opening paragraph should:

1. state that it is a research study conducted by the principal investigator (student's name) and affiliation (e.g., doctoral student in the College of Education at Westcliff University, Orange County campus);

2. provide sufficient details for participants to be informed as to the purpose and objectives of the study (e.g., if the study is part of degree requirements, this must be clearly stated);

3. describe where the study will be conducted and the expected duration and dates;

4. explain that their participation is voluntary and the nature of participant's participation;

5. include the facts that a participant will need to make a decision to participate; and

6. summarize the circumstances in which a waiver or alteration of the requirements of informed consent are permitted (i.e., research involving public benefit and service programs conducted by or subject to the approval of state or local officials)[5].

In general, the expectation is that this initial presentation of the key pieces of information will be a relatively short summary of information explained in greater detail later in the consent form. No informed consent may include any exculpatory language through which the subject or the legally authorized representative waives or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. An explanation should be included of whom to contact about the research and the research participant's rights, especially if research-related injury or unanticipated event occurs.

Westcliff University informed consent form(s) comply with the federally required elements of informed consent, and also include additional elements beyond federal regulations. The following elements are included (or may be added for special circumstances, as applicable) in the Westcliff informed consent form(s).

1. Describe the procedures to be followed, including any that are experimental.

2. Identify the anticipated number of participants.

3. Denote the approximate amount of time participation will take (i.e., hours, days, weeks) and where the procedures will occur.

4. Explain any risks (e.g., psychological, emotional, physical), however slight, and how those risks will be mitigated. For most expedited IRBs and some full IRBs, the risks will be minimal.

5. Postulate any benefits to the person participating and available alternative procedures. If there are not any direct benefits for participation, indicate this also. Do not claim future benefits to society or benefits to the investigator.

6. Specify compensation (monetary or psychological benefits), schedule of payments, and compensation in the event of withdrawal from the study. (Note that compensation, monetary or otherwise, is not permitted in Westcliff University doctoralresearch.).

7. Include a statement informing participants about the confidentiality of their medical records, grades, exam scores, or other personal documents (if such will be examined or used).

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[5] This requirement applies to all informed consents except for broad consent.

8. Provide contact information for the principal investigator, faculty research supervisor, and IRB chairperson in the event subjects require additional answers to pertinent questions about the research or the research subjects' rights. Specify whom to contact in the event of a research-related injury.

9. For survey, questionnaire, or other similar measurements, include a statement informing participant(s) that they may refuse to answer (without loss of benefits to the participant) any questions that make them feel uncomfortable. If not answering questions would cause the principal investigator to have to withdraw the participant from the study, note this and any resulting consequences of being withdrawn, in the consent form.

10. For sensitive topics (e.g., depression, sex, AIDS/HIV, drug or alcohol abuse, suicide, abusive behavior, minor abuse) the investigator must include sources where the participant can obtain assistance, such as counselors, treatment centers, or hospitals. It should also emphasize the plan of action for identified behaviors involving the risk of injury to self or others and for compliance with State and Federal reporting laws.

11. If appropriate, a statement should be included to inform participants that detected minor abuse will be reported to the proper authorities.

12. Include a statement that the participant can withdraw from the study; have the audiotaping, videotaping, or any electronic media discontinued at any time; refuse to answer particular questions; and that such withdrawal will not affect any treatment, employment, benefits, or the like, as applicable. Specify the consequences or lack of consequences for withdrawing, (i.e., there will not be loss of benefits, grades, payment, treatment, course credit, employment, etc.).

13. Describe anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's original consent, and what effect this termination would have on any benefits, payment, treatment, course credit, etc.

14. Describe the level of confidentiality of the study (e.g., confidential or anonymous--it cannot be both). Explain how the investigator will maintain confidentiality of records and data (e.g., coded responses or secure storage). *Anonymous* means that the information provided cannot be connected to the participant. *Confidential* means that the information provided by the participant may be connected to the participant. Confidentiality cannot be guaranteed, as some situations (i.e., subpoena) will override a promise of confidentiality made by a researcher.

15. Permission for recording, specifying how and by whom the records will be used, must appear in the consent form if recording will be part of the protocol. The investigator must let the participants know how long the records will be kept, how the information will be kept secure, and how the records will be destroyed or erased. If a participant refuses to be recorded, but still may participate in the study, a separate form must be developed stating the options with a signature line for each option. For example, if a participant refuses to complete an electronic survey, the participant could be given the option of a paper copy.

If a participant refuses videotaping, the person may permit notetaking. If the study includes the videotaping of classrooms, the investigator must provide options to people who do not wish to participate or be videotaped, such as allowing them to sit out of the videotape range, at the back of the classroom, or permitting them to leave the room. (Note: A separate Audio-Videotape release form should only be used in cases of deception studies in which participants are not informed that they have been audiotaped or videotaped until after their participation, or if the participant can still participate without being audiotaped or videotaped.)

16. Include a statement, if appropriate, that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.

17. List any costs the participant may incur while participating in the research (e.g., parking fees, travel costs, medical costs, and loss of work time).

18. Explain that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be communicated to the subject.

19. Specify whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

20. Disclose whether possible future research using information stripped of identifiers (or with identifiers in the case of broad consent) is applicable.

The basic elements of consent apply to all research of which identifiable private information is collected. Based on the investigator's plans, the informed consent form and process must inform subjects that either one of the following conditions apply.

1. Identifiers might be removed from the data and that the non-identified data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the representative, if this might be a possibility.

2. The subject's data collected as part of the research, from which identifiers are removed, will not be used or distributed for future research studies. This information can usually be provided in a brief statement.

Oral informed consent may be certified by the Westcliff University IRB in some cases if all elements of consent are given and the consent is witnessed or, in certain cases, audio or video taped. A transcript of the oral consent process must be provided to the Westcliff University IRB and must be given to the participant if he/she requests a copy. If the statement is longer than one page, each page must contain specific identifying details so that, in effect, the participant's signature is immediately below the statement of understanding. Consent forms with more than one page should be initialed and dated by the participant on each page, and the pages should be numbered (e.g., page 1 of 2 pages).

It is assumed that the consent form is only part of the total consent process in which the investigator, perhaps using the written consent form as an outline, describes all facets of the research and addresses the participant's questions. The investigator is responsible for ensuring that research participants understand the research procedures and risks. Failure of the participants to ask questions should not be construed as understanding on the part of the participant or be seen as voluntary agreement to participate.

Special Consent Procedures

Oral Consent

In most cases, written consent is required; however, on rare occasions, oral consent may be considered more appropriate. For such research, the investigator must submit in writing to the IRB chairperson (a) the information that is to be presented to participants orally, (b) an explanation of why oral consent is considered more appropriate, and (c) a request for a waiver of the requirement for written consent (see Appendix F for a Model Oral Consent Form). When this method is used, there must be a witness to the oral presentation.

Electronic Media Consent

Note that the definition of *written* or i*n writing* does not preclude the possibility that consent forms could be in media other than paper or electronic formats and still meet the requirements of the Common Rule. Electronic research methods require participant consent. For the purposes of this guidance, electronic informed consent (eIC) refers to the use of electronic systems and processes that may employ multiple electronic media to convey information related to the study and obtain informed consent (e.g., text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, and card readers). Informed consent may be gained with a descriptive paragraph that contains words to the effect that by self-administering the electronic survey the participant is providing approval. The electronic transmittal letter should contain all elements of a formal informed consent document, and should conclude with wording such as, "I have read the transmittal email/letter detailing the purpose and procedures for this research, and I am completing this survey as evidence of my consent to be a voluntary participant in this research project." Research using multiple electronic media can incorporate all components into one informed consent form signed electronically, or, as in the case of the electronic survey, consent is given when the participant chooses to complete the instrument (see 45 CFR 46).

As in other modalities of informed consent, the consent form must ensure protection of the rights, safety, and welfare of the participant, facilitate the participant's understanding of the information presented in the consent, and documentation of that process. If asked during an inspection, the researcher should be able to produce evidence of the participants' consent. The same guidelines that apply for on-site research apply to the electronic environment. Therefore, the electronic informed consent must include a process that facilitates the subject's comprehension of the information and allows adequate opportunity for the subject to ask questions and consider whether or not to participate (see 45 CFR 46.116) as well as the

opportunity to ask questions during the study or withdraw from participation at any time. Any eIC should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

Use of eIC may supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study. For example, some subjects may prefer one method over another. Other subjects may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. Therefore, subjects should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process. Moreover, in some circumstances, it may be appropriate for investigators or study personnel to assist subjects in using the eIC technology. For example, study personnel may help the subject navigate the consent by clicking on links for the subject. However, the principal investigator must also avoid the possibility of coercion.

The investigator is responsible for ensuring that legally effective informed consent is obtained before that subject takes part in the study (see 45 CFR 46.116). Whether part or all of the eIC process takes place on-site or remotely, the responsibility for obtaining informed consent remains with the investigator and any trained study personnel to which responsibility has been appropriately delegated. The investigator cannot delegate authority to obtain informed consent to the electronic system.

The consent process may take place at the study site when both the investigator and subject are at the same location, or it may take place remotely (e.g., at the subject's home or another convenient venue) where the subject reviews the consent document in the absence of the investigator. The eIC materials may be provided for both on-site and remote access. If the entire process takes place at the study site, the study personnel can personally verify the subject's identification, review the eIC content, answer questions about the material, have follow-up discussions, and witness the signing of the eIC.

If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see [21 CFR 11.100(b)]). Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods. OHRP recognizes that it may not be possible or necessary for all types of research covered by 45 CFR part 46 to verify that the person signing the informed consent is the subject or the subject's LAR who will be participating in the research study. OHRP encourages investigators to apply a risk-based approach to the consideration of subject identity. For example, social behavioral minimal risk research will not typically warrant such verification. In addition, informed consent may be waived for minimal risk research meeting the requirements at 45 CFR 46.116(d).

The investigator should have methods in place to ensure that the electronic informed consent process allows subjects the opportunity to consider whether or not to participate and to ask questions about the study before signing consent as well as at any time during the subject's involvement in the research. This may be accomplished by in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing, or a live chat with a remotely located investigator or study personnel. When live chat or video conferencing is used during the electronic informed consent process, investigators and study personnel should remind subjects to conduct the electronic informed consent discussion in a private location to help ensure privacy and confidentiality.

Subjects should be given a description of how and when they will receive answers to their questions, and they must be provided information on how to contact an appropriate individual for pertinent questions about the research and their rights and whom to contact in the event that they sustain a research-related injury (see [45 CFR 46.116(a)(7)]).

To assist the subject in understanding the material, the electronic informed consent may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The electronic informed consent should be appropriate for the intended audience, taking into consideration the subject's age, language, and comprehension level.

The electronic informed consent may contain various methods to help an investigator assess the subject's understanding of the information being presented during the electronic informed consent process. For example, the eIC may include optional questions at any time during the eIC discussion that can be used to help educate the subject about the information presented, as well as assess the subject's understanding of the informed consent materials. Such optional questions and other methods may be used as tools to gauge subject comprehension of key study elements and highlight areas where the subject might need further explanation and discussion before signing the informed consent to enter the study.

OHRP regulations permit the flexibility of using electronic and paper informed consent methods independently or in combination throughout the course of the study. Thus, amendments to the electronic informed consent do not need to be electronic in nature and can instead rely on more traditional means, such as paper-based amendments or postal mail, for conveying and transmitting the information to the subject.

OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted. IRBs, investigators, and sponsors should consider such issues as how the electronic signature is created and whether the informed consent or permission document can be produced in hard copy for review by the subject upon request. IRBs, investigators, and sponsors may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements, including a secure signature and time stamp. A copy of the informed consent must be provided to the person signing the form. The copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion.

Note that if the electronic informed consent uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in any printed paper copy, if one is provided.

If the entity holding the subject's personal information is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Public Law No. 104-191) or acting as a business associate of a HIPAA-covered entity, the requirements in the HIPAA Privacy, Security, and Breach Notification Rules apply (see 45 CFR 160 and 45 CFR 164). For example, the subject's information within an electronic system must be encrypted, unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable and appropriate equivalent measure.

The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization. This requirement also applies where a HIPAA authorization is obtained electronically.

HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations (see [21 CFR Part 11]). The Global and National Commerce Act (E-Sign Act; Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form.

The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and web-based presentations, which the subject will receive and view during the electronic informed consent process. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy (see 45 CFR 46.109). OHRP recommends that an investigator discuss plans for using electronic informed consent with the IRB before finalizing development of the electronic informed consent ensure that the IRB agrees that such a format may be used for the applicable research for obtaining informed consent.

The IRB should also review any optional questions or methods used to gauge subject comprehension of key study elements. The IRB should also review the usability of the electronic informed consent materials to ensure that they are easy to navigate. If the program uses hyperlinks to convey study-related information, IRBs should review the contents to which subjects are referred in order to determine if the study-related information that has been supplied is accurate and appropriate. Because websites are often modified over time, IRBs must maintain the version of the website information that contains the study-related information that the IRB reviews and approves, either electronically or as a hard copy (see 45 CFR 46.115).

Broad Consent

Broad consent constitutes permission for the storage, maintenance, and secondary research use of identifiable private information. The consent form must provide a general description of the types of future research that may be conducted with identifiable private information with the

participant's permission. This “reasonable person” standard is consistent with the interpretation that the Office for Civil Rights provided for authorization obtained from an individual for the use or disclosure of protected health information for future research purposes. For example, in the final rule, it is required that broad consent include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and a statement that such results may not be disclosed to the subject must be included in the broad consent. Broad consent will often be sought with the expectation that specific secondary research studies using identifiable private information will be exempt. In these cases, the specific secondary research study will still need to undergo IRB review and approval, and it is expected that the IRB would consider what subjects were told in the broad consent regarding the return of research results. Developing a broad consent requires additional guidelines not contained within this handbook but accessible via 45 CFR 46.

Screening, Recruiting, or Determining Eligibility

An IRB may approve a research proposal in which an investigator will obtain information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2. The investigator will obtain identifiable private information by accessing records.

The approval of the principal investigator’s committee is required for procedures used to gain participant approval. Except as described above, investigators may not enroll human participants in research unless they have obtained the legally effective, written, informed consent of the participant (or the participant’s legally authorized representative) prior to enrollment of the participant in the research or in the case of an approved waiver of informed consent. This includes research using internet surveys and other electronic data-gathering technology.

Waivers of Informed Consent and Assent

Waiver of Consent

Under certain conditions, the IRB may waive the requirements for obtaining informed consent, certify a consent procedure that does not include all elements of informed consent previously listed, or alter some or all of the elements of informed consent previously listed. In such cases, a statement will be provided that identifies the conditions under which the waiver will be applied and justification as to why the waiver is appropriate for the research (including how the decision is consistent with the principles in the Belmont Report). Conditions that may be considered for a waiver include the following.

1. The research involves no more than minimal risk to the participants and involves only procedures that do not normally require written consent.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3. The research could not practicably be performed without the waiver or alteration, and, whenever appropriate, the participants will be provided with a summary of pertinent information after participation so as to prevent deception.

4. If the research involves using private identifiable information, the research could not practicably be carried out without using such information in an identifiable format.

5. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases where consent requirement is waived, the IRB may require the investigator to provide the participants or legally authorized representatives with a written statement regarding the research. The conditions of the waiver must appear in the minutes of the IRB meeting in which the waiver was approved.

Waiver of Assent

In the case of children and minors, both the parent/guardian and child/minor must sign, or where age or developmentally appropriate, give oral consent. A witness should sign the consent in cases of oral consent. Assent may be waived under the following conditions.

1. The minor or children involved in the study are so limited in capability that they cannot be reasonably consulted.

2. The prospect of direct benefit to the health or wellbeing of a minor is available only through the context of the research.

3. The waiver meets the same criteria for the waiver or alteration of consent for adults.

Documentation of Informed Consent for IRB Review

Informed Consent documents are reviewed as part of the IRB certification process. Signed consent forms are maintained by the principal investigator and the IRB. The IRB retains all files related to an IRB application for three years following the conclusion of the research project (or longer if a greater time is specified by the grant or foundation funding agreement for the research, as part of the maintenance of confidentiality of the research participants)

Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed

consent form. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

SECTION FIVE: IRB APPLICATION AND REVIEW PROCESS

Faculty research supervisors, in accordance with their campus IRB procedures, will decide whether the IRB application is submitted before or after the dissertation proposal defense. In either case, before any data are gathered, the investigator must first obtain a certification of compliance. Failure to follow this guidance is a violation of federal law and Westcliff University policy. It may result in the investigator's research being disqualified, as well as other disciplinary consequences, such as dismissal from the university.

The process for submitting completed applications may vary between Westcliff University campuses (e.g., some may require the submission of multiple copies of the application; others may require the submission of an electronic application). Nonetheless, all Westcliff University campuses require the principal investigator to submit a completed application with faculty research supervisor's approval, current date, and the required documentation described below.

Preparing the IRB Application

All IRB application documents must be typed. All formatting and spacing should conform to the current edition of the APA Publication Manual unless as specified in this Handbook. Applications and all materials submitted to the Westcliff University IRB should be carefully prepared and fully completed (e.g., leaving an area blank, or "N/A" answers are not permitted).

The appendices of this Handbook contain applications and documents to be used in the application and certification process. Forms have been formatted for electronic completion (fillable PDFs). The forms can be completed and signed using the Adobe Reader software, available as a free download from the Adobe website. Alternatively, students may print the form and complete type it manually.

General Guidelines

The principal investigator and faculty research supervisor should consult to determine the level of certification appropriate to the content and procedures of the proposed research project. See Levels of IRB Review and Certification for a description of research that qualifies for Exempt (Appendix A), Expedited (Appendix B) or Full (Appendix C) review.

In completing the application, principal investigators should adhere to the following general guidelines.

1. Save the appropriate application or form and on your computer or other storage device.

2. You may use text from your research proposal to answer questions. Include only text that directly answers the IRB protocol. Do not reference your proposal or attach your proposal to the application.

3. Future tense language is appropriate since the study has not yet been conducted. Check all spelling, grammar, and style.

4. Answer every question on the application using complete sentence. “N/A” is not an acceptable answer for any question.

5. Incomplete applications will be returned to the investigator, extending the timeline for review and certification.

6. Principal investigators should communicate with the IRB through their faculty research supervisors (i.e., do not contact an IRB member directly to inquire about the status of your application.

Required Documents

Principal investigators should refer to the sample IRB application, checklists, and other helpful resources designed to aid students in the completion of the application (see Appendix O). Included with each IRB application are critical documents, pertinent to the research that must also be reviewed by the IRB. As applicable, each IRB application should include the following attachments.

CITI completion reports. CITI training must be successfully completed by the committee, and a copy of the CITI completion report/certificate of the principal investigator, research supervisor, and committee member should be attached to the application (see Collaborative Institutional Training Initiative (CITI) section for more information).

Conflict of interest disclosure statement. A principal investigator may have a conflict of interest when factors (e.g., financial, personal gain, personal relationships) could potentially bias the investigator’s judgment regarding the welfare of study participants or the integrity of the research. Conflicts of interest can be construed as a research risk. Investigators must disclose any conflicts of interest to the IRB, study participants, and any publications resulting from the research. A Conflict of Interest form (Appendix D) must be submitted with all IRB applications. The IRB will review the potential conflict and determine whether the investigator has minimized the risks involved and provided for the disclosure of such information to the participants. Annually, this disclosure must be updated, as the IRB research project is renewed or amended. All investigators must comply with the conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest. Failure of the principal investigator to do so could result in forfeiting IRB certification.

Research site approval letter. If data are being collected from another institution (e.g., hospital, school, clinic, business), a signed letter (preferably on letterhead) must be attached from the appropriate official of the institution granting permission to conduct the study. Such approval is required even in cases where only archival data will be collected from the institution.

Certification from another institution. In the case that the institution where the study is to be conducted has its own IRB and requires certification from that IRB, the investigator must submit the certification letter from that institution’s IRB.

- In rare instances, another institution may require Westcliff University certification before granting its own certification (see Appendix H). In such cases, contingent certification may be requested of the Westcliff University IRB, pending permission from the other institution. The final letter from the institution must be received before the research may proceed and the Westcliff University certification is finalized.

- In cooperative research, only one institution needs to certify the protection of human participants for a research project per agreement between the institutional IRBs.

Most often, the other institution will request a letter from Westcliff University with such information as the (a) applicant's affiliation with Westcliff University (i.e., student), (b) title of the research study and the circumstance for which it is being conducted (e.g., dissertation research), and (c) name and contact information of the faculty research supervisor.

Informed consent and assent documents. Depending on the type of consent/assent being used, this information may take the form of a formal informed consent document, an information sheet containing the elements of consent, a letter or video/website to accompany online surveys or email surveys, or a copy of a script used to obtain verbal consent. (See Appendix E for a sample consent form.) Further guidelines for creating a consent document are detailed in the Informed Consent section of this Handbook. In addition to consent or assent documents, if research will be conducted with minors, any agreement documents used with minors must also be attached.

Research study materials. Copies of all material provided to participants must be submitted with the application. Such materials include but are not limited to the following examples, as applicable:

- recruitment materials,[6]
- instruction forms,
- instruments[7] (e.g., surveys, questionnaires),
- coding form or description of coding process (e.g., use of NVivo software),
- interview protocol and questions, and
- debriefing instructions.

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[6] Recruitment materials (e.g., advertisements, announcements, fliers, scripts) must contain the (a) contact information of the principal investigator (i.e., name, phone number, email address); (b) purpose of the study; (c) eligibility requirements for participants; (d) description of benefits and possible risks; (e) compensation, if applicable; (f) location and duration of the study; and (g) where and to whom the recruitment materials will be conveyed.

[7] Permission letters or emails must be attached from the owner/developer of any survey or other instrument granting the applicant permission to use and/or amend the instrument as part of the research. In the case of large instruments (e.g., standardized tests) or electronic instruments and databases, a description of the instrument should be included.

Permission for use of previously collected data. If using archival data, the investigator must submit a letter from the owner of the data granting the investigator permission to use it. The letter must include an assurance that the data were initially collected in an ethical manner and that participants gave their consent for their information to be used for research purposes. The Westcliff University IRB may request a copy of the original consent form. If requesting an exempt review, the permission letter must also state that the data will be stripped of all identifying information before it is provided to the investigator or that broad consent was given to use private identifiable information for future research without specific consent.

The IRB Review Process

Steps of the IRB Review

The completed application and accompanying documents should be thoroughly reviewed by the faculty research supervisor prior to submission to the IRB. For a research project conducted as part of a student's academic work, at least one member of the Westcliff University faculty[8] (serving as faculty research supervisor or dissertation chairperson) will evaluate whether the project has scientific merit and whether the research project conforms to IRB submission guidelines. The faculty research supervisor will provide feedback and suggestions to the principal investigator regarding changes that are needed to improve the application. Such feedback is aimed to help the principal investigator comply with certification standards of the IRB. Once the faculty research supervisor is satisfied with the quality and completeness of the IRB application, the review process will begin as described in the following steps.

Initial review by the faculty research supervisor. Upon determining that the project has both merit and has been prepared according to guidelines, the faculty research supervisor will sign the cover sheet that is part of the application. Faculty research supervisors are encouraged to use the IRB application checklist as a device for assuring the completeness of the application prior to submission to the IRB.

Submission and logging of the application. The faculty research supervisor forwards the signed application and accompanying documents to the IRB chairperson, member, or designee who logs the application and forwards it to the IRB member with authority to review.

Review by designated IRB member. The designated IRB member reviews the application and determines whether the level of the presented application is correct. If the application requires a Full (Level 3) review, the member makes a written request to the IRB Chairperson to place the application on the agenda of the next monthly meeting. The member distributes copies of the Level 3 application to all IRB members to review prior to themeeting.

Certification or resubmission. If the application level is correct, the IRB member reviews the application and has authority to certify Exempt (Level 1) and Expedited (Level 2) applications. If the IRB member determines that the information on the application is not correct

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[8] Core faculty must perform this evaluation for programs with accreditation requirements.

or the application is incomplete, the member notes the deficiencies to be corrected and logs the application and action or returns the application to the IRB Chairperson or designee to log the application and action. Once logged, the deficient application is returned to the principal investigator and faculty research supervisor for revision, including the notations describing the deficiencies.

Responding to a request for revision. Following a Westcliff University IRB review, the investigator may be asked to edit and revise the application or include additional information. In such cases, the revised application should: (a) be completed in a timely manner (i.e., within 30 days); (b) include a list of the changes made and/or highlight such changes within the document; and (c) include the original memorandum of the changes requested. The revised application should be returned to the faculty research supervisor who should review it prior to resubmission. When satisfied with the revisions, the faculty research supervisor forwards the revised application to the IRB chairperson, member, or clerk for logging and forwarding to the appropriate IRB member.

Filing of the application. The cover to the application (Appendix A, Appendix B, or Appendix C) contains certification conditions. Once an application is certified, a copy of the signed cover page is returned to the faculty research supervisor and principal investigator. The original application (with the original attachments and signatures) and the original IRB signatures is placed in an appropriate and secure file in campus administrative offices or on a secure share point.

Criteria for IRB Certification

Certification of IRB applications includes an evaluation of the risks and benefits of the research to participants. The IRB evaluates only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). It does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

To certify compliance with Westcliff University research standards for the protection of participants, the IRB shall determine that all of the following requirements are satisfied.

Minimal risk. Risks to participants are minimized by procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk, and when appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes.

Reasonable risk. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably be expected to result.

Equitable selection of participants. In making this assessment, the IRB considers the purposes of the research and the setting in which the research will be conducted. The IRB is particularly cognizant of the special problems of research involving vulnerable populations when

some or all of the participants are likely to be vulnerable to coercion or undue influence. Vulnerable populations include children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons. Additional safeguards are required in the study to protect the rights and welfare of these participants. In addition, the pool should also consider equitable recruitment of participants that does not target economically or educationally disadvantaged individuals and is not a convenience sample that is not representative of the population. Participant selection must be appropriately reviewed by the principal investigator and the faculty research supervisor as well as the IRB (or designated authorizer) of the research setting prior to submission for Westcliff University IRB review.

Additionally, regulations require the IRB to review the:

1. adequacy of protections for the privacy of participants;

2. confidentiality[9] of identifiable private information;

3. documentation of consent or that a waiver of documentation is appropriate, in accordance with the federal regulations outlined in the Informed Consent section of this Handbook. Informed consent will be sought from each prospective participant, or the participant's legally authorized representative (LAR), in accordance with, and to the extent required by, federal, state, and/or local guidelines. Informed consent will be appropriately documented, in accordance with and to the extent required, by those guidelines. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

4. sufficiency of provisions to protect the privacy of subjects and to maintain the confidentiality of data in the way private identifiable information is stored.

The regulations generally require all of these determinations to be made for any study that must undergo IRB review.

Outcomes of an IRB Review

The IRB shall review and have authority to approve, require modifications (to secure approval), or disapprove any research activity covered by this policy, including exempt research. The review of an Application for IRB Review and Certification of Compliance may result in one of the following outcomes:

Certified. The application is certified as written (signed cover sheet).

Contingently certified. The research application or the procedures for the protection of the research participants described in the application are deficient in one or more minor areas. A

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[9] In Exempt applications, a limited IRB review requirement is needed to satisfy exemption determinations (see Studies Qualifying for Exempt (Level 1) Review) including broad consent for storage, maintenance, and secondary research use of private identifiable information, if applicable.

memorandum (Appendix G) is attached to the application that specifies deficiencies or changes that must be completed and documented prior to beginning the research. For these deficiencies, the IRB chairperson or designated reviewer can, upon reviewing the principal investigator's response(s) to the required changes, certify the research proposal on behalf of the IRB.

Interim certification. If it is essential for a full IRB (Level 3) review study to begin prior to the next scheduled monthly meeting of the IRB (e.g., a patient with an unusual disorder suddenly becomes available for study and might suffer adversely by delay), the investigator may request interim certification. The investigator, through his or her faculty research supervisor, presents to the IRB chairperson a complete, signed application and a written request for interim certification, including the appropriate reasons the research should begin before the next scheduled IRB meeting. The IRB Chairperson or designee, in consultation with at least one other IRB member, will decide on the emergency interim compliance application. If granted, interim certification is limited to the time until the next IRB meeting is held for review of the application by the full IRB. Interim compliance certification is neither appropriate, nor will it be granted, for purposes of meeting a grant or academic deadline or for the convenience of the applicant.

Not certified. The research application or the procedures for the protection of the research participants described in the application are significantly deficient in one or more areas. A memorandum (Appendix G) is attached to the application that specifies deficiencies or changes that must be completed prior to beginning the research. For these deficiencies, the IRB chairperson or designated reviewer can, upon reviewing the principal investigator's response(s) to the required changes, certify the research proposal on behalf of the IRB.

Notification of IRB Decisions

Generally, the principal investigator and faculty research supervisor are notified of IRB decisions with the receipt of a signed copy of the application. Requests for revisions will be sent to both the principal investigator and the faculty research supervisor. IRB certification of compliance is logged by the IRB chairperson, member, or clerk and serves as official documentation that the research project has been certified. This documentation can be used for the dissertation proposal defense depending on campus procedures.

Appeal of IRB Decisions

If a principal investigator wishes to contest an IRB decision, he or she may make a written request to the IRB chairperson to reconsider. No further appeal is available. No faculty member or administrator may conduct or approve a research project involving human participants that has not been certified by the IRB as in compliance with applicable ethical and legal standards.

Events and Actions that may Follow IRB Certification

Amendments to the Research Project

On occasion, the principal investigator may find it necessary or prudent to make a change in the research plans proposed at the time of IRB certification. Requests to change or modify a Westcliff University IRB certified research project, consent form, or any other document related to an IRB certified research project must be made in writing by the principal investigator using an the IRB Amendment Form (Appendix J). This form should be submitted with any supporting materials necessary. If making changes to existing documents (e.g., instructions, consent forms), the investigator should submit two copies of the revised documents, with one copy noting where

the changes were made using bold, strike-through, and/or highlighted text and provide an explanation of the changes that were made on the Westcliff University IRB Amendment Form.

Requests to amend a certified research project are submitted to the IRB through the faculty research supervisor. The designated IRB member processes the request and determines whether the amendment or modification changes the direction of the research. If not, the research may proceed as amended.

In the event that the amendment and/or modification significantly alters the original certification of the research (e.g., change from archived data to gathering data from research participants), the principal investigator must submit a new IRB application. To accommodate accelerated data gathering procedures, the principal investigator, through his or her faculty research supervisor may submit the new application to the IRB chairperson and request interim certification to gather data under the strict supervision of the faculty research supervisor. Amendment forms, documents, and IRB applications are attached to the principal investigator's original IRB documents and appropriately filed.

Adverse Events

Westcliff University policy requires principal investigators to report promptly any significant deviation (accidental or otherwise) or adverse event (regardless of severity) related to the conduct of research, regardless of the severity. An *unanticipated problem* or *adverse event* is defined as any potential for harm or risks to participants or others.

Investigators should use the Adverse Event Report Form (Appendix K) to report the event to the Westcliff University IRB within 10 days of the incident. The report should include any and all supporting information needed to disclose the incident. Incidents in which participants are harmed, or have otherwise adverse reactions to the research proceedings, must be immediately reported to the Westcliff University faculty research supervisor and IRB, regardless of the level of the initial IRB review. Failure to report an adverse event is considered an act of noncompliance, subject to the actions and consequences described previously in this Handbook.

All reports of adverse events are reviewed by the IRB chairperson or designated reviewer at the next convened IRB meeting. Westcliff University takes the position that any activity involving humans has the potential for a problematic incident. The risk of such incidents is controlled for within the procedures planned by the principal investigator, but may still occur. The principal investigator is responsible for planning for possible incidents and for describing appropriate procedures in case an incident should occur. Being prepared to follow an employer's institutional procedures or school district procedures already in place constitutes appropriate planning. If the research is FWA certified, the IRB chairperson must notify the Office for Human Research

Protection (OHRP) after the IRB has reviewed the report and determined if appropriate action has been implemented to respond to the incident.

Suspension of Certification

The Westcliff University IRB has the authority to suspend a project at any time for justifiable reasons (e.g., failure to comply with applicable state or federal regulations, adverse reactions to a study procedure or activity, continued noncompliance of protection of human participants, or the inability to complete the study within the certification period). If the research involves external funding or if the campus currently holds an institutional FWA, OHRP and any granting agency receiving the assurance must be informed of any suspension of certification. In the event of serious or continued noncompliance, the IRB will summarize the noncompliance and IRB action in IRB minutes.

Request to Continue IRB Certification

IRB certification is typically valid for one year. No human participant research may take place after the initial certification expiration date unless or until certification for continuation (i.e., recertification) is granted[10]. It is the responsibility of the principal investigator to request an extension of certification in a timely manner. Failure to adhere to these guidelines will be considered an act of noncompliance and the principal investigator could have his/her research and/or funding suspended.

A request for Continued Certification of Compliance (Appendix I) for full review research projects will normally occur during the eleventh month of a year-long certification period and the subsequent certification period will begin during that month. Continuing review for subsequent years normally occurs every 12 months, with the certification period always beginning on the last day of the month in which the research project is reviewed. This procedure ensures compliance with federal requirements and ensures that research projects are reviewed at least annually. Time intervals for continuing reviews shall be made at the discretion of the Westcliff University IRB, based on the risk to the participants, but shall occur no less than annually.

Eligibility for continuing review. Effective January 2019, continuing review is no longer a requirement for studies that undergo exempt or expedited level review (unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects). Further, continuing review is no longer required for full review studies that were initially reviewed by a convened IRB when the research has progressed to the point where all that remains is only (a) analysis of the data already collected (including analysis of identifiable private information); or (b) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. If an IRB chooses to conduct a continuing review even when these conditions are met, the rationale for doing so must be documented.

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[10] See Eligibility for continuing review section for research that does not require continuing review.

Completing a request for continued certification. A request for continued certification of compliance (Appendix I) is submitted by the principal investigator through his or her faculty research supervisor to the IRB with a copy of the original application. In the request, the principal investigator will report the condition of the research project, to include (a) whether the study was initiated or whether the research should be terminated; (b) any conditions that may have changed[11] (e.g., changes in the informed consent form or other modifications to the study); and (c) any adverse events[12] regarding human participants in the investigation.

IRB review of continuing certification. The Westcliff University IRB Chairperson or designee will review the form and any other documentation submitted by the principal investigator as part of the continuing review report. The original Westcliff University IRB application and a written status report of the research project and other supporting documents are distributed to Westcliff University IRB members and placed on the next available meeting agenda. After the full board meeting, the certification for continuation is signed by the IRB chairperson and returned to the principal investigator and faculty research supervisor. Those research projects qualifying for and receiving continuing certification are reported to the IRB in a separate section of the agenda.

Continuing review more often than annually. There are situations when the risks associated with a particular research project are such that continuing review should take place more frequently than annually. These risks include the possibility of death, severe injury, major damage or loss, or outcomes that may result in negative publicity for the participants involved. In such cases, the Westcliff University IRB may specify that the principal investigator report to the IRB at a shorter time interval or after a specified number of participants are enrolled. The IRB may request the principal investigator to report the observed effects of the research activities and how the participant(s) responded to the research interventions. The IRB will determine whether continued and active monitoring of the research project is warranted and, if so, it will specify the period for monitoring.

Project Completion Report

The last step in the IRB process is submission of the Project Completion Report (Appendix L), by the principal investigator at the conclusion of the research project in accordance with federal regulations. The form is completed after the final defense and is submitted as part of the final dissertation/CRP paperwork required before degree conferral. For other research activities, it is submitted at the conclusion of the research project. Submission is the responsibility of the principal investigator and faculty research supervisor.

The Project Completion Report is filed with the principal investigator's original IRB application. Once a Project Completion Report is filed, the IRB Chairperson will reply with an acknowledgement of filing (e.g., signed Doctoral Research Approval Form or acknowledgement

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[11] Any changes to the research project must be reviewed and certified by the IRB.

[12] Adverse events must be reported upon occurrence, as required.

by email). Records relating to research conducted shall be retained for at least three years after completion of the research. The institution or IRB may maintain the records in printed form or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency and institution auditors at reasonable times and in a reasonable manner.

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APPENDICES

Many of the appendices that follow (i.e., forms, applications) include an active link to a fillable PDF version of the appendix. The PDF forms and resources can also be accessed from the Westcliff University IRB Resources website.

APPENDIX A

Exempt (Level 1) Application for IRB Certification of Compliance

No or Minimal Risk

This level of application is reserved for research meeting exempt category specifications. See the Levels of IRB Review and Certification section of the IRB Handbook for a description of review levels.

Exempt Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*

2. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*

3. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB)-- then written permission from the participating institution's IRB must be attached to your IRB application.*

4. *If you are conducting research outside of the United States, you may not file at the Exempt level.*

The attached Application for Certification of Compliance contains (check all that apply):

- ☐ Institutional Permission Letter (where data are held) or documentation of ability to use data
- ☐ Letter(s) of Informed Consent (may be needed if there is a question about original use of data)
- ☐ Conflict of Interest Disclosure Statement
- ☐ CITI Completion Report for principal investigator, faculty research supervisor, and committee member
- ☐ Signatures of the principal investigator and faculty research supervisor

Application for IRB Review and Certification of Compliance

Exempt (Level 1) Cover Sheet

IRB# _____

Date Logged: _____

Use this form for research involving Exempt (Level I) Research No or Minimal Risk

(Review by one or more IRB Members — May lead to Expedited or Full review)

Principal Investigator/Researcher's Name:_____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, Applied Research, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number:_____Email: _____

Faculty Research Supervisor's Name: _____

Telephone Number:_____Email: _____

College: ☐ Counseling, Psychology, and Social Sciences ☐ Clinical Psychology

☐ Education ☐ Graduate School of Business and Management ☐ Health Sciences

☐ Law ☐ Other (specify): _____

Program of Study:_____ Degree _____

Project Proposed Start Date:_____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator _____ _____
Date

Approval/Signature of Faculty Research Supervisor_____ _____
Date

IRB Certification Signature_____ _____
Date

The above named research project is certified for compliance with Westcliff University's requirements for the protection of human research participants with the following conditions:

1. Research must be conducted according to the research project that was certified by the IRB.

2. Any changes to the research project, such as procedures, consent or assent forms, study design, or addition of participants, must be reported to and certified by the IRB.

3. Any and all adverse events or reactions must be reported to the IRB immediately (see Appendix K).

4. When the study is complete, the investigator must complete a Project Completion Report.

5. Any correspondence will be directed to the principal investigator and faculty research supervisor (if applicable) and include the assigned IRB research project number and the project title.

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NOTES:

- *Please complete this cover and the application in detail. Every question must be answered. Please type your answers.*
- *Attach the appropriate documents and submit the entire application with supporting materials under the cover of a completed Application Checklist to the faculty research supervisor for review and approval prior to submitting to the IRB.*
- *Do not proceed with any research work with participants until IRB certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, or other element of the project that impacts participants, the IRB must be notified in writing with the appropriate form (see Appendix J).*
- *Please allow 30 days after receipt of a complete application for processing.*
- *DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION*

Application for IRB Review and Certification of Compliance

Exempt (Level 1) Application

No or Minimal Risk

Read and complete the following statements: If you answer "no" to any of the statements, your research does NOT qualify for Exempt status. (If your project does NOT qualify for Exempt status, complete an Expedited or Full application, based on risk/benefit ratio to participants).

a. A literature review ☐ Y ☐ N

b. Broad consent granted in prior research study that allows secondary research using original data with private individual information ☐ Y ☐ N

c. Routine educational tests, survey or interview procedures or observation of public behavior ☐ Y ☐ N

d. Secondary research use of information that is publicly available or recorded without identifiers ☐ Y ☐ N

e. Secondary research use of information collected by the Federal Government for other purposes and subject to certain privacy laws ☐ Y ☐ N

f. Secondary research use of information covered by HIPAA protections ☐ Y ☐ N

Completely answer the requested information. (N/A is not acceptable for any question). Do not attach your research proposal – answer the questions as stated. Begin typing in the gray boxes.

1. Identify the study site(s): _____

2. Provide a brief but detailed summary of the project, including methodology. Specify all information related to the purpose of the study, recruitment of participants, procedures with participants, and measures and materials for gathering data.

   _____

3. Describe the involvement of human participants in the research project.

   _____

4. Describe required institutional approvals or other approvals (parental approval as necessary according to institutional policy).

   _____

5. Describe how confidentiality will be maintained. Be specific, including the use of secondary documents, audio/video tapes, etc. Describe procedures for the safekeeping and disposal of information stored electronically.

   _____

6. Describe why this project fits the Exempt level of risk.

   _____

7. Describe review by institutions outside of Westcliff University, if applicable. (Attach copies of permission letters, IRB certifications, and any other relevant documents).

   _____

Attach any other required forms, including the CITI completion certificate for principal inv*estigator, faculty research supervisor, and committee member, the principal investigator's Conflict of Interest form, instruments, institutional permission, etc., related to this study. Failure to do so will result in delayed processing of the application.*

APPENDIX B

Expedited (Level 2) Application for IRB Certification of Compliance

Minimal Risk

This level of application is reserved for research projects with minimal risk. See the Levels of IRB Review and Certification section of the IRB Handbook for a description of review levels.

Expedited Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*

2. *Please be advised that research projects involving interaction with human participants must have an Informed Consent form(s) attached. If a minor or individual of any age with impaired decision-making ability is involved, parent/legal guardian permission must be included.*

3. *Parental permission does not negate the child's right to choose not to participate.*

4. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*

5. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB) -- then written permission from the participating institution's IRB must be attached to your IRB application.*

6. *If you are conducting the research outside of the United States, attach a letter of assurance that you will abide by the laws and regulations of the governing bodies that preside over the location where the research is being conducted.*

The attached Application for Certification of Compliance contains the following (check all that apply):

- ☐ Institutional Permission Letter (where research is taking place)
- ☐ Assurance of Adherence to Governmental Regulations concerning Human Subjects (if research project is conducted outside the US)
- ☐ Letter(s) of Informed Consent
- ☐ Data gathering instruments: observation, interview, survey, other
- ☐ CITI Completion Report for principal investigator, research supervisor, and committee member.
- ☐ Conflict of Interest Disclosure Statement
- ☐ Signatures of the principal investigator and faculty research supervisor

Application for IRB Review and Certification of Compliance

Expedited (Level 2) Cover Sheet

IRB# _____

Date Logged: _____

Expedited Review (Level 2) Application, Minimal Risk

(Review by one or more IRB Members—May lead to Full IRB Review)

Principal Investigator/Researcher's Name:_____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, Applied Research, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number:_____Email: _____

Faculty Research Supervisor's Name: _____

Telephone Number:_____Email: _____

College: ☐ Counseling, Psychology, & Social Sciences ☐ Clinical Psychology

☐ Education ☐ Graduate School of Business and Management ☐ Health Sciences

☐ Law ☐ Other (specify): _____

Program of Study:_____ Degree _____

Project Proposed Start Date:_____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator _____ _____
Date

Approval/Signature of Faculty Research Supervisor_____ _____
Date

IRB Certification Signature_____ _____
Date

The above-named research project is certified for compliance with Westcliff University's requirements for the protection of human research participants with the following conditions:

1. Research must be conducted according to the research project that was certified by the IRB.

2. Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.

3. Any and all adverse events or reactions must be reported to the IRB immediately (see Appendix K).

4. The research project is certified for the specific period noted in this application; any collection of data from human participants after this period is in violation of IRB policy.

5. When the study is complete, the investigator must complete a Project Completion Report.

6. Any correspondence will be directed to the principal investigator and faculty research supervisor (if applicable) and include the assigned IRB research project number and the project title.

****

NOTES:

- *Please complete this cover and the application in detail. Every question must be answered.*
- *Please type your answers.*
- *Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the faculty research supervisor for review and approval, prior to submitting to the IRB.*
- *Do not proceed with any research work with participants until IRB Certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, site, or other element of the project that impacts participants, the IRB must be notified in writing with the appropriate form (see Appendix J).*
- *Please allow 30 days after receipt of a complete application for processing.*
- *DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION*

Application for IRB Review and Certification of Compliance

Expedited (Level 2) Review Application

Minimal Risk

(Review by one or more IRB Members— May lead to Full Review)

Research with minors, prisoners, individuals with impaired decision-making ability, fetuses, in vitro fertilization, and/or individual or group studies where the investigator manipulates the participant's behavior, or the participant is exposed to stressful or invasive experiences do not qualify for Expedited status.

Please completely answer the requested information. (N/A is not acceptable for any question.) DO NOT attach your research proposal – answer each specific question in the area provided. Begin typing in the gray boxes.

1. Purpose of the study: _____
2. Provide a brief but detailed summary of the study's methodology (Specify all information related to recruitment, study procedures, measures and materials): _____
3. Participant Demographics:
    a. Anticipated sample size :_____
    b. Special ethnic groups (describe):_____
    c. Institutionalized or other protected group: ☐Y ☐N If yes, describe: _____
    d. Age group: _____
    e. General state of health: _____
    f. Other details to describe sample group. _____
4. Will deception be used in the study? ☐Y ☐ N (If yes, describe) _____
5. Will audio or videotapes be used in the study? ☐ Y ☐ N (If yes, describe) _____
6. Confidentiality protection issues (pertains to audio and video as well as written documents.) _____
    a. What precautions will be taken to ensure the privacy and anonymity of the participants (e.g., closed doors, private rooms, handling of materials where participants' identify could be discovered, etc.)? _____

b. What specific precautions will be taken to safeguard and protect participant's confidentiality while handling the data (audio/video/paper) both in principal investigator's possession and in reporting the findings (e.g., coding, removal of identifying data, encrypting recordings)? _____

c. Describe procedures where confidentiality may be broken by law (e.g., minor abuse, suicidal intent). _____

7. Review by institutions outside of Westcliff University ☐ Y ☐ N (Attach copies of permission letters, IRB certifications, and any other relevant documents). _____

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent (see Elements of Informed Consent section). _____

9. If written or oral informed consent is required, describe the manner in which consent will be obtained. _____

10. Describe any possible physical, psychological, social, legal, economic, or other risks to participants. _____

    a. Describe the precautions taken to minimize risk to participants. _____

    b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies). _____

11. Potential benefit of the study:

    a. Assess the potential benefit(s) of the study for the participants: _____

    b. Assess the potential benefits(s) to the professional community: _____

Attach any other required forms, including the CITI completion certificate for principal investigator, faculty research supervisor, and committee member, the principal investigator's Conflict of Interest form, instruments, institutional permission, etc., related to this study. Failure to do so will result in delayed processing of the application.

APPENDIX C

Full Review (Level 3) Application for IRB Review and Certification of Compliance

Full (Level 3) Review: High Risk

Full Review (Level 3) Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*

2. *Please be advised that research projects involving interaction with human participants must have an Informed Consent Form(s) attached. If a minor or individual with impaired decision-making ability of any age is involved, parent/legal guardian permission must be noted and included.*

3. *Parental permission does not negate the child's right to choose not to participate.*

4. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*

5. *If that institution requires a review by its Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB) --, then written permission from the participating institution's IRB must be attached to your IRB application.*

6. *If you are conducting the research outside of the United States, attach a letter of assurance that you will abide by the laws and regulations of the governing bodies that preside over the location where the research is being conducted.*

The attached Application for Certification of Compliance contains (check all that apply):

- ☐ Institutional Permission Letter (where research is taking place)
- ☐ Assurance of Adherence to Governmental Regulations concerning Human Subjects/Participants (if research project is conducted outside the United States)
- ☐ Letter(s) of Informed Consent
- ☐ Parent/Guardian Permission Letter (must have provision for written signature)
- ☐ Oral Statement of Assurance (used with minors or participants with no written tradition)
- ☐ Data gathering instruments (i.e., observation, interview protocol, survey instrument, etc.)
- ☐ Conflict of Interest Disclosure Statement
- ☐ CITI Completion Report for principal investigator, faculty research supervisor, and committee member
- ☐ Signatures of the principal investigator and faculty research supervisor

Application for IRB Review and Certification of Compliance:

Full Review (Level 3) Cover Sheet

Full IRB Review (Level 3) Application, High Risk (Full Board Review)

IRB# _____

Date Logged: _____

Principal Investigator/Researcher's Name:_____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, Applied Research, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number:_____Email: _____

Faculty Research Supervisor's Name: _____

Telephone Number:_____Email: _____

College: ☐ Counseling, Psychology, & Social Sciences ☐ Clinical Psychology

☐ Education ☐ Graduate School of Business and Management ☐ Health Sciences

☐ Law ☐ Other (specify): _____

Program of Study:_____ Degree _____

Project Proposed Start Date:_____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator _____ _____
Date

Approval/Signature of Faculty Research Supervisor_____ _____
Date

IRB Certification Signature_____ _____
Date

The above named research project is certified for compliance with Westcliff University's requirements for the protection of human research participants with the following conditions:

1. Research must be conducted according to the research project that was certified by the IRB.

2. Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.

3. Any and all adverse events or reactions must be reported to the IRB immediately (see Appendix K).

4. The research project is certified for the specific period noted in this application; any collection of data from human participants after this period is in violation of IRB policy. Any study continuing beyond the deadline must submit Continuing Certification of Compliance Form.

5. When the study is complete, the investigator must complete a Project Completion Report.

6. Any correspondence will be directed to the principal investigator and faculty research supervisor (if applicable) and include the assigned IRB research project number and the project title.

****

NOTES:

- *Please complete this cover and the Application in detail. Every question must be answered. Please type your answers.*
- *Attach the appropriate documents and submit the entire application package under the cover of a completed Application Checklist to the CRP/Dissertation Chairperson.*
- *Do not proceed with any research work with participants or data gathering until IRB certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, or other element of the project that impacts participants, the IRB must be notified in writing with the appropriate form (see Appendix J).*
- *Please allow up to 60 days after receipt of a complete application for processing.*
- *DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION.*

Application for IRB Certification of Compliance:

Full Review (Level 3) Application

Full IRB Review (Level 3) Application, High Risk or Involving Vulnerable Populations

Vulnerable populations include children, prisoners, and individuals with impaired decision-making ability.

Please completely answer the requested information. (N/A in not acceptable for any question). DO NOT attach your research proposal – answer each specific question in the area provided.

Begin typing in the gray box.

1. Purpose of the study: _____

2. Provide a brief but detailed summary of the project, including methodology. (Be specific and be sure to include all information related to recruitment, study procedures, measures and materials): _____

3. Participant Demographics:

    a. Anticipated sample size: _____

    b. Special ethnic groups (describe): _____

    c. Institutionalized protected group: ☐ Y ☐ N If yes, describe: _____

    d. Age group: _____

    e. General state of health: _____

    f. Other details to describe sample group: _____

4. Will deception be used in the study? ☐ Y ☐ N If yes, describe: _____
_____

5. Will audio or videotapes be used in the study? ☐ Y ☐ N If yes, describe: _____

6. Confidentiality protection issues (pertains to audio and video as well as written documents.)

    a. What precautions will be taken to ensure the privacy and anonymity of the participants (e.g., closed doors, private rooms, handling of materials where a participant's identify could be discovered, etc.)? _____

b. What specific precautions will be taken to safeguard and protect subject's confidentiality while handling the data (audio/video/paper) both in principal investigator's possession and in reporting the findings (e.g., coding, removal of identifying data)? Describe procedures for the safekeeping and disposal of information stored electronically. _____

c. Describe procedures where confidentiality may be broken by law (e.g., minor abuse, suicidal intent). _____

7. Review by institutions outside of Westcliff University/name of the campus. (Attach copies of permission letters, and any other relevant documents). _____

8. Informed Consent and Assent (attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent. _____

9. If written or oral informed consent is required, describe the manner in which consent and/or assent will be obtained for each level).

a. Adult participants (18 years and older – written consent required unless impaired decision making ability requires legally assigned representativeconsent). _____

b. Minor participants (under 18 – parent/guardian consent and participant assent required). _____

c. Institutionalized participants (parent/guardian/conservator consent with appropriate participant assent). _____

10. Describe any possible physical, psychological, social, legal, economic, or other risks to participants. (Attach another page if needed. ☐) _____

a. Describe the precautions taken to minimize risk to participants. _____

b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies). _____

11. Potential benefit of the study:

a. Assess the potential benefit(s) of the study for the participants: _____

b. Assess the potential benefits(s) to the professional community: _____

Attach any other required forms, including the CITI completion certificates for principal investigator, faculty research supervisor and committee member, the principal investigator's Conflict of Interest form, instruments, institutional permission letters, etc., related to this study. Failure to do so will result in delayed processing of the application.

APPENDIX D

Conflict of Interest Disclosure Statement

After reading the Code of Business Ethics and Conduct and description of a Conflict of Interest in the Westcliff University IRB Handbook, I have identified below any areas where I foresee a possible conflict of interest and described my plan for mitigating risk.

Conflict of Interest or Potential Conflict of Interest	**Yes**	**No**	**Actions taken to minimize threats posed by the conflict of interest. (Complete for all questions answered "Yes.")**
I am recruiting participants from a Westcliff facility	☐	☐	_____
I am recruiting participants who do business with Westcliff facility	☐	☐	_____
I am recruiting participants from my place of employment.	☐	☐	_____
I am recruiting participants from my family or close friends.	☐	☐	_____
I am recruiting participants from my (or a friend's) students.	☐	☐	_____
I hold a position of authority over my potential participants.	☐	☐	_____
Other – Describe: _____	☐	☐	_____
Other – Describe: _____	☐	☐	_____

I have reviewed the Code of Business Ethics and Conduct and description of a Conflict of Interest in the Westcliff University IRB Handbook and have disclosed above any potential conflicting interests that might influence or be perceived to influence how I professionally conduct my research study or certify that I have no conflicting interests that might influence or be perceived to influence how I professionally conduct my research study.

Name:_____ Date: _____

Signed: _____

APPENDIX E

Sample Informed Consent Form

(Header: Insert Name of Study, Principal Investigator(s), Page XXX of YYY)

This research is being conducted by XXXXX, a student in the XXXXX College at Westcliff University-XXXXX completing a (insert a choice: Clinical Research Project/thesis/dissertation/ applied research project) to fulfill the requirements of a XXXX degree. You are being invited to participate in this research study consisting of XX participants.

The title of this study is XXXXX.

- I understand that the purpose of this study is XXXXX *(Describe in plain English, or lay person's terms, at the reading level of the participants).*
- I was asked to participate in this study because XXXXX.
- If I agree to be in this study, I will be asked to XXXXX *[INCLUDE any experimental procedures or interventions].*
- I understand that participation in this study will take XXXXX *(State total amount of time and how many meeting times if more than once).*
- The risks associated with this study are XXXXX. *[DESCRIBE risks, however slight, and how those risks will be mitigated]. Include contact information for help.*
- The benefits of participation are XXXXX. *[NOTE: If there are no direct benefits for the participant, indicate this information. Do <u>not</u> include eventual benefits to society or personal benefits to the investigator –summarize items 10 & 11 in application].*
- I will receive XXXXX compensation for participating in this study. *[IDENTIFY monetary or other incentives or NO compensation].*

(Choose one of the two choices below as appropriate.)

1. The information I provide will be treated confidentially, which means that nobody except (principal investigator's name) will be able to tell who I am. *Note:* If there are others who will have access to confidential information (e.g., a coding person, chair, committee member) include this here. In most cases, use the role of the individual/individuals rather than the names.

2. The information I provide will be anonymous. No one, including the investigator, will be able to connect the information that I have provided in this study with my name.

    a. The records of this study will be kept private. No words linking me to the study will be included in any sort of report that might be published.

b. The records will be stored securely and only (principal investigator's name) will have access to the records.

c. I have the right to get a summary of the results of this study if I would like to have them by contacting (principal investigator) at (email address). *[If results are to be published at a secure Internet site, include URL here]*.

I understand that my participation is voluntary. If I do not participate, it will not harm my relationship with XXXX. If I decide to participate, I can refuse to answer any of the questions that may make me uncomfortable or for any other reason. I can quit at any time without affecting my relations with the university, job, benefits, etc.

I can contact ***(****principal investigator and committee chair, email addresses and phone number)* with any questions about this study. If I contact the researchers, I understand that anonymity cannot be guaranteed; however, confidentiality will be protected.

I understand that this study has been reviewed and certified by the Institutional Review Board, Westcliff University – *(insert location)*. For problems or questions regarding participants' rights, I can contact the Institutional Review Board at *(Insert contact info of IRB Chair)*.

I have read and understand the explanation provided to me and I have had all my questions answered to my satisfaction. I have printed or have been provided a copy of this informed consent. By signing this document, I am giving my voluntary consent to participate. (*In the case of electronic or anonymous surveys*, *change the "By signing this document…" wording to*: By continuing with the study, I am giving my voluntary consent to participate.)

Broad Consent *(insert only if applicable)*

☐ By checking this box, I consent to allow the private information that I provided in this study to be stored, maintained, and used without my specific permission/consent in future research (if possible, identify or estimate the period the information may be used). The information obtained in this study that might be used for future research studies includes (insert information here). I understand that the results from these other studies may not be available to me, since others who use my information may not know how to reach me to provide the results.

Name of Participant (printed) _____

Signature of Participant:_____Date: _____

Signature of Principal Investigator:_____Date: _____

Note: If the study requires video or audio recording the following must also be inserted.

☐ I_____(printed name) agree to be video/audio recorded for the purpose of this study. _____(signature) _____(date)

☐ I_____(printed name) do NOT agree to be video/audio recorded for the purpose of this study._____(signature) _____(date)

If seeking consent for a child or individual with impaired decision-making capacity to participate:

Print Participant's Name: _____

Relationship to Participant (identify the relationship) _____
If parent, a custodial parent must sign.

Legal Guardian (if applicable) appointed by: _____

Minor assent: I_____ (name) agree to *(participant states in own words what he/she expects to do and)* checks one: ☐ Yes ☐ No

Child's Signature (if applicable):_____

Note: All informed consent statements should be designed to meet the needs of each individual research project and /or sample group and are therefore subject to change as needed.

Approval by parents does not sign away or negate the right of children to refuse to participate.

Some research may require that a separate assent form be completed by the child. Each child's assent form must contain the above elements in language at the level of participant's understanding, state that participation is voluntary, and permit the minor to refuse to participate.

Additional factors to take into account. Note: Do NOT include the following directions in the final consent form.

- Include the URL for the participant to proceed to the electronic site for data collection (e.g., Survey Monkey).

- Include a statement informing participants if their medical records, grades, exam scores, or other personal documents will be examined or used. A separate release of information may be required per FERPA or HIPAA requirements.

- For sensitive topics, the investigator must include sources where the participant may obtain assistance for possible risks. Emphasize the plan of action for behaviors involving danger of risk to self or others.

- Where appropriate, a statement should be included indicating that detected minor abuse (or other situations, where applicable by state or federal laws, such as vulnerable adult abuse, HIV status) will be reported to the proper authorities.

- Include a description of anticipated circumstances under which the participant's participation may be terminated by the investigator.

APPENDIX F

Model Oral Consent and Instructions

This model summary statement is also required for oral consent and is used in conjunction with the oral consent form. Both forms are generic and are designed to be adapted for most research studies. If researching with children younger than 18 years of age, please be sure to include a minor assent statement (i.e., NAME agrees to participate in the study. Please mark one____Yes ___No).

Model Oral Instructions to Participants Involved in Research

Signed copies of this form must be retained on file by the Principal Investigator and the process witnessed.

ORAL CONSENT FORM

Title of Project:

Principal Investigator:

Faculty Supervisor:

Explanation of Research Project:
[1 paragraph maximum.]

Explanation why oral consent is needed:

[ACTION: Brief explanation why oral and not written consent needs to be obtained by the principal investigator.]

Script: *[ACTION: The wording used to secure consent (summary of procedures and purpose) - see sample scripts.].*

Please explain in your own words what will happen to you as a participant in this study:

[ACTION: ***Interviewer***] Participant was able to restate the study in own words Yes____ No____

If you want to talk to anyone about this research project, please contact the principal investigator and/or faculty supervisor for this study.

[ACTION: Provide contact information for researcher & supervisor]

If you have questions about your rights as a research participant, please contact the IRB Chair.

[*ACTION: Provide contact information*]

If you agree to be in this study, please let us know by saying YES.

[ACTION: ***Interviewer***] Please circle: YES or NO

_____

[ACTION: ***Interviewer: Please END here.***]

[If YES] Thank you for your agreement in participating in this study. Next, I would like to obtain your agreement to tape-record my questions and your responses.

If you agree to be **recorded**, please let us know by saying YES.

[ACTION: ***Interviewer***] Please circle: YES or NO

Minor assent: I (NAME) agree to be in the study: circle one (yes) (no).

_____ _____

Participant's Name (Written by the Investigator) Signature of Investigator

_____

Investigator's Signature

_____

Witness Signature

_____ _____

Place Date and Time

APPENDIX G

Letter to Correct IRB Application Deficiencies

IRB MEMORANDUM
Westcliff University

Date: _____

To: _____, Principal Investigator

_____, Faculty Research Supervisor

From:_____, IRB Member

Re: Incomplete Application for IRB Certification

This application needs to be completed and/or revised for the following reasons:

☐ Original Institutional Permission Letter missing or unsigned (required on letterhead)
Comments: _____

☐ Letter of Informed Consent missing or needs revision
Comments: _____

☐ Missing signatures _____

☐ Question(s) not answered/ not complete or unclear
Comments: _____

☐ Missing attachment (e.g., interview protocol /survey instrument, Conflict of Interest Statement, etc.)
Comments _____

When the revised application is completed, please sign/initial and date upon return to the IRB Chairperson or administrative assistant for logging.

APPENDIX H

Letter to Institutions Requesting Westcliff University Certification

Westcliff University Letterhead

Chairperson, Institutional Review Board
[Insert name of Institution]
[Insert Mail Address and/or email address]

Dear IRB Chairperson:

[Insert name] is a student at Westcliff University working on his/her [insert dissertation, applied research study, clinical research project] under the supervision of Dr. [insert name], his/her faculty research supervisor in the [insert college name].

The Westcliff Institutional Review Board has certified the IRB application of [insert principal investigator's name] as of [insert date].

Please contact me if you have questions regarding the certification process. I can be reached by email at [IRB Chair's email address] or by phone at [IRB Chair's business number].

Thank you for your consideration.

Sincerely,

IRB Chairperson,
Westcliff University, [insert campus name]

APPENDIX I

Request for Continuing Certification of Compliance

Type and submit to the Institutional Review Board all requested information and materials. Each item must be completed or described as not applicable.

Date of this Submission: _____

IRB Research project #:_____

Date of Original Certification: _____

Principal Investigator: _____

Faculty research supervisor: _____

Title of Project: _____

1 ☐ The study was not initiated and has been cancelled (specify cancellation date): _____

2 A renewal of the research project is requested for the following conditions:

a ☐ Renewal of proposal or research project with no changes. The research project has not yet been begun but will be carried out as previously certified.

b ☐ The research is in progress and no changes in research project have been made regarding human participants.

c ☐ The research project is now modified. (Any changes to the research project must be reviewed and Certified by the IRB before being initiated.) Please attach certification amendment forms.

3 Have there been any adverse events regarding human participants in your investigation?

4 ☐ Yes ☐ No If yes, attach the Adverse Event form (Appendix K) to this application.

I/We certify that the above statements and attachments concerning this research are true.

_____ _____ _____
Principal Investigator Name Signature Date

_____ _____ _____
Faculty Research Supervisor Name Signature Date

APPENDIX J

Amendment to Original IRB Certification

Submit to the Institutional Review Board all requested materials.

Please type in the following information regarding your study. Each item must be completed or indicated as non-applicable (N/A):

IRB Research project #:_____

Date of Original Certification:_____ Date of Amendment Submission: _____

Principal Investigator:_____ Email: _____

Faculty Research Supervisor:_____ Email:_____

Title of Project: _____

1. Describe proposed changes to the research project:
   a. Revision to research project that impacts human participants: _____
   b. Revision to consent documents: _____
   c. Other (including change of research supervisor) Specify: _____
2. How have the requested changes affected the level of risk involved for participants? _____
3. Attach a complete copy of the original application and/or consent form(s) and include a revised copy with all additions/revisions/changes highlighted or in bold type.

Principal Investigator Statement of Assurance
I certify that the above statements and attachments concerning this research are true.
I understand that I cannot initiate any changes in the certified protocol/research project before I have received re-certification and/or complied with all contingencies made in connection with that approval.

_____ _____
Signature of Principal Investigator Date

Research Faculty Supervisor
I acknowledge and assure the Westcliff University/XXXX Institutional Review Board that I am aware of the existence and status of this research activity and I agree to the statements made in the original IRB application and these revisions including the Statement of Assurance.

_____ _____ _____
Faculty Research Supervisor Signature Date

_____ _____ _____
IRB Chair or Designee Signature Date

APPENDIX K

Adverse Event Report

Type in all text boxes and submit to the Institutional Review Board, including all requested documents.

An Adverse Event refers to any problem, circumstance or occurrence that was not anticipated or accounted for in the original IRB application and that may have a negative impact on the research participants.

IRB Research project #: _____

Date of Original Certification: _____

Adverse Event Submission Date: _____

Principal Investigator: _____

Faculty research supervisor: _____

Title of Project: _____

Date(s) of Event(s): _____

Describe the Adverse Event(s): _____

Attach a summary of all circumstances related to this event. This summary must include a statement describing this unanticipated problem and its relationship to the participants in the study certified by the Westcliff University IRB. All hospitalization and/or medical treatment (including mental health) must be reported. If the problem has not been resolved, please describe progress toward an expected resolution of this problem and prevention of further incidents. You will need to keep the IRB informed of any updates. Your IRB Project Completion Report will not be finalized until IRB approves resolution of the problem(s).

Include all notifications, correspondence, and other related materials for this unanticipated problem from the study sponsors, researchers, study sites and/or participants.

I/We certify that the above statements and attachments concerning this research are complete and true.

_____ _____
Principal Investigator Signature Date

_____ _____
Faculty Research Supervisor Signature Date

_____ _____
IRB Chair or Designee Signature Date

APPENDIX L

Project Completion Report

(Use for notification of completion for research projects certified by a Westcliff University IRB)

Type in all text boxes and submit to the Institutional Review Board.

1. General Information

   Principal Investigator:_____ Telephone: _____

   Address: _____

   College:_____

   Email: _____

   Faculty Research Supervisor: _____ Telephone: _____

   Email:_____

2. Title of Project and IRB number: _____

3. Date of Completion _____

1. Significant findings (as presented to participants):

   _____

_____ _____
Principal Investigator's Signature Date

_____ _____
Faculty Research Supervisor's Signature Date

_____ _____
IRB Chair or Designee's Signature Date

APPENDIX M

IRB Letter of Assurance Example

Westcliff UNIVERSITY
Irvine Campus

TO: Dr. John Doe, President
Westcliff University, Irvine Campus September 04, 2018

INSTITUTIONAL REVIEW BOARD LETTER OF ASSURANCE

At its organizational meeting on September 4, 2018, the undersigned agreed to comply with the guidelines and procedures established for the IRB as outlined in the Westcliff University Institutional Review Board Handbook.

Members of the Westcliff University/Irvine Campus Institutional Review Board for 2018-2019:

Name and Degree	Signature	Position	Representative Capacity	Affiliation
Jane Smith, PsyD		Chairperson	Georgia School of Professional Psychology	Faculty
Bill Jones, PhD		Member	Graduate School of Business and Management	Faculty
Mark Rogers, PhD		Member	College of Counseling, Psychology, and Social Sciences	Faculty
Lucy Dunn, EdD		Member	College of Education	Faculty
Art Barnes, EdS		Member	Undergraduate Programs, Non-Scientific Member	Faculty
Reese Ward, MBA		Member	Non-Affiliated with Westcliff University	External

The IRB will convene on the third Thursday of each month at 2:00 PM PST in Room 204 of the Irvine Campus. Meeting dates are scheduled as follows:

- September 4, 2018
- October 3, 2018
- November 6, 2018
- December 4, 2018
- January 8, 2019
- February 5, 2019
- March 5, 2019
- April 9, 2019
- May 7, 2019
- June 4, 2019
- July 9, 2019
- August 6, 2019

APPENDIX N

Example of IRB Log

Below represents an example of an IRB log. It may be copied, pasted, and adjusted. Use of an Excel spreadsheet to develop and maintain the log is recommended.

IRB#	DATE APPLICATION RECEIVED	FILING LEVEL	PRINCIPAL INVESTIGATOR	FACULTY RESEARCH SUPERVISOR	DATE CERTIFIED	RESEARCH TITLE	RESEARCH COMPLETION REPORT DATE

Note. This format can be modified to record additional activities and actions, including incident reports, or additional actions to be tracked, such as:

- IRB Reviewer (for exempt and expedited review levels)
- Date Assigned
- Resubmission Date (for applicants that need to revise their application);
- Certification Date;
- Amendment Date

APPENDIX O

Additional Resources

The following list contains active hyperlinks. The links may open on a different page or download a document at the bottom of your screen. If you have difficulty accessing a link, then right click on the title (link), select "copy hyperlink," and paste it directly into your browser.

- Westcliff University IRB Resources
  Fillable PDF versions of IRB applications and forms (appendices A-L of this Handbook) as well as examples and other resources including the websites listed below.
- Alphabetical List of IRB Resources published by OHRP
  Indexed listing of IRB resources from the Office for Human Research Protections
- American Counseling Association Code of Ethics
  Ethical and Professional Standards published by the ACA Governing Council
- Ethical Principles of Psychologists and Code of Conduct
  American Psychological Association
- Belmont Report
  Principles and guidelines for the ethical issues that arise from human subjects research
- Collaborative Institutional Training Initiative (CITI)
  Web-based training for (Basic) Human Subjects Research (Social and Behavioral Focus)
- Common Rule (45 CFR 46)
  Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)
- Educational Resources for IRB Members
  A collection of videos and readings for IRB members published by the OHRP.
- Educational Resources for Principal Investigators
  A collection of videos and readings for principal investigators published by the OHRP.
- Electronic Signatures in Global and National Commerce Act of 2000 (E-Sign Act) Pub. L. 106-229 as it pertains to use of electronic signatures for informed consent
- Health Insurance Portability and Accountability Act of 1997 (HIPPA)
  Pub. L. 104-191 as it pertains to informed consent of participants.
  IRB Guidebook
  Published by the OHRP
- Office for Human Research Protections (OHRP)
  Provides information, regulations, and resources for the protection of human subjects