WESTCLIFF UNIVERSITY
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Standard Operating Procedure

SOP 13	Communicable Diseases Transmission Based Precautions	Effective Date 1/1/2023

PURPOSE

Proposed research may at times involve contact with communicable diseases. Researchers and human subjects' protection is vital to prevent and manage potential communicable disease transmission. The purpose of this policy is to provide information and resources to researchers and reviewers to promote safety and protection in circumstance that may include exposure to said diseases.

DEFINITIONS

Communicable diseases, also known as *infectious* or *transmissible diseases*, including Coronavirus disease (COVID-19), are illnesses that result from the infection, presence, and growth of pathogenic (capable of causing disease) biologic agents in an individual human or other animal hosts.

POLICY

In a focused effort to eliminate or reduce the potential for disease transmission and spread, all protocols (and their deviations) that may increase a participant(s) risk of exposure to a communicable diseases are banned.

SACHRP allows protocol deviations to immediately eliminate or reduce an apparent hazard to the safety of research participants or others—including exposure to communicable diseases. Such deviations must be requested using the Modification Form.

Essential Research Activities (ERAs) provided they comply with university policies and:

- IRB requirements;
- research/practicum protocols;
- local, state, national, and international safety policies;
- regional, state, and local laws governing research population(s); and
- CDC (or relevant government authority) guidelines

If regional, federal, state, or local laws prohibit in-person contact, data collection should be conducted remotely using remote/virtual visits, telephony, or other accepted virtual modalities. HIPPA (https://www.cdc.gov/phlp/publications/topic/hipaa.html#privacy-rule) requirements may

encourage using services such as https://doxy.me/, https://explore.zoom.us/en/healthcare/, https://www.goto.com/healthcare, or https://vsee.com/.

PROCEDURE

- Researcher submits application to IRB for review and approval identifying nature of study and potential risks/hazards along with proposed methods for amelioration.
- IRB Reviews application noting any areas of concern related to and as stated in the above policy.
- IRB reviewer returns reviewed application to researcher with comments including notations of deviations and other areas of concern.
- Researcher modifies application to reflect compliance with reviewer observations.
- Researcher submits *Modification Form* to request deviations as appropriate.
- Researcher re-submits modified application to IRB for further review and approval.

RESPONSIBILITIES

The primary investigator accepts responsibility for:

- reviewing all guidelines regarding communicable diseases pertinent to protocol(s) and research proposal;
- reviewing all guidelines regarding communicable diseases pertinent to protocol(s) and research proposal. The primary investigator is charged with working with their local and international colleagues, if required, to keep up to date with policies and directives from national or local governments and collaborating institutions and their IRBs;
- considering participant and site statuses pertinent to protocol(s) and research proposal;
- adding any new paragraphs and documents to describe and support the planned remote recruitment, consent, and data collection instruments;
- applying required guidelines to proposed research criteria;
- Submitting a completed IRB application and supporting documentation; and
- after obtaining IRB approval(s) are responsible for learning, acknowledging, and strictly adhering to all pertinent guidelines.

IRB reviewers accept responsibility for:

- understanding all guidelines regarding communicable diseases pertinent to protocols and to incoming research applications as described in this policy;
- reviewing incoming research applications for adherence to guidelines and protocols as described in the proposed research;

- identifying areas discrepant with approved policies and guidelines and noting them in the reviewer comments sections;
- guiding the primary investigator by offering insight into areas that are noted as deficient and suggesting corrective actions; and
- disallowing/not approving research to continue should observed deficiencies not be satisfactorily corrected.

Research is an integral part of the educational process and allows scientists to develop new theories and ideas that shape and add value to our society and our everyday lives. Research is not intended to bring harm to the researchers or subjects by unintentionally causing transmission of health threatening disease. To that end, researchers own the responsibility, to the extent possible, to ensure their work has mechanisms in place that offer safety and protection to their subjects and themselves

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
Brett Gordon	IRB Chair
	IO

DISCLAIMER

The University reserves the right to modify or amend sections of this SOP at its sole discretion.