

	IRB Response	
	Yes	No
Is the study <i>exempt</i> ?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Human/Nonhuman Research</b>		
Will the study involve (human) participants?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Required Paperwork/Applications/Forms</b>		
CITI, or equivalent, certificate	<input type="checkbox"/>	<input type="checkbox"/>
Completed IRB Application	<input type="checkbox"/>	<input type="checkbox"/>
Completed consent form(s) appear in an appendix.	<input type="checkbox"/>	<input type="checkbox"/>
All instrumentation, protocols, recruitment letters, permissions, correspondence, and other documentation appear in appendices. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Completed proposal Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Supporting documentation Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Basic IRB Application Evaluation</b>		
The Purpose of the Study, Supporting Literature, and Locations of Research appear to support generalizable research of value to stakeholders. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Funding should be <i>internal</i> or <i>unfunded</i> . If externally funded, IRB shall request additional information. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The study is not subject to FDA regulations, involve prisoners, or utilize HIPAA or other protected information. If identifiers exist, then IRB shall request a sample dataset and offer advice on removing identifiers. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The study poses, at most, <u>minimum (minimal) risk</u> to participants. Minimal risk means that 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. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Are <u>risks minimized</u> ? If so, how? If not, how could risks be minimized? Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Sampling offers a sound chance to collect the required data using a suitable sample. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Is the selection of subjects equitable? See <u>45CFR46.111(a)(3)</u> . Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Minors, prisoners, university employees, and tribal populations are excluded. If tribal populations are included, then IRB shall request permission forms and other relevant information. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Exclusions are unbiased and naturally delimit the sample. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Recruiting and compensation do not rely on gifts, rewards, bribes, or other social or economic incentives. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The written consent process is ethical and fits the participants and study. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>

There are no conflicts of interest. See <a href="#">Financial Conflict of Interest: HHS Guidance (2004)</a> . Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
IRB Application is (electronically) signed and dated. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Confidentiality and Protections</b>		
Process in place to maintain participant confidentiality—whether the collection is in person and/or virtual as well as during and after concluding the study. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Investigator manages, maintains, and secures all data. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Justice and Privacy Considerations</b>		
Are privacy and confidentiality adequately protected? Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
(If applicable) Might the payment constitute undue influence to participate for economically-disadvantaged subjects <a href="#">45CFR46.111(b)</a> ? Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Informed Consent and Safety</b>		
The consent form is complete and easy to understand. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The study utilizes a sound and simple consent process. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Consent is completed before collecting data. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent process manages special data such as video, audio, and images. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
HIPAA and/or other protected data is not collected. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
Consent remains mindful of the safety of participants, investigators, and relevant parties. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
There appears little, or no chance, of errors in the administration of the consent process. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
There appears little, or no chance, for the realization of threats to the safety of the participants, investigators, and relevant parties. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent form clearly discusses potential risks and benefits of being in the study. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent form explains how data will be protected, including a statement about keeping records in a secure location for an extended duration. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent form reports all relevant contact information. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent form makes clear that participation is voluntary. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>

The consent form has a clear/easy-to-use (digital or inked) signature line. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The consent form utilizes the template consent form appearing in the dissertation template. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Integrity Check</b>		
The information in the application matches (or agrees with) the proposal and supporting documents. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
The information in the consent form and process matches (or agrees with) the proposal and supporting documents. Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>

**Reviewer Determination**

The IRB reviewer issues the following determination:

<input type="checkbox"/>	The application and all documentation are APPROVED.
<input type="checkbox"/>	The application and all documentation require revision and review (see <i>Reviewer Comments</i> )
<input type="checkbox"/>	The application and all documentation are DENIED and have been referred to the IRB Chair (see <i>Reviewer Comments</i> ).

**Reviewer Comments**

The IRB has determined the following given the above requirements:

- The dissertation proposal meets all requirements. **IRB approval number is \_\_\_\_\_.**  
The investigator may now collect data per the IRB-approved proposed study.
- The dissertation proposal does not meet the above requirements (see checklists and comments).
- Usually, the inclusion of tribal populations (as indicated on the application) requires a denial of the study. However, upon review of the study, the interview questions, and the scope of the study, IRB believes such inclusion is acceptable for this study.
- You have been approved to use protected information/data. However, IRB may request to review your data (in all forms) to ensure compliance with the rules for de-identification. Further, IRB will review your completed dissertation to ensure no identifiers appear within the completed dissertation.
- Currently, you are exempt from most IRB rules because you are conducting nonhuman research. However, if you need to include people via interviews or surveys, at a later date, please inform IRB immediately to ensure IRB compliance.