



APPLICATION FOR APPROVAL FOR USE OF HUMAN
PARTICIPANTS IN RESEARCH

It is the policy of Indiana Wesleyan University that no activity involving human subjects research be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).

Please carefully edit and proofread before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator(s).

Proposals must be submitted electronically to IRB@indwes.edu as a Microsoft Word document. The IRB cannot adequately review proposals or supporting documents submitted as PDFs, JPGs, Google Docs, HTML, etc. Principal investigators and faculty advisors (if applicable) must sign applications. To electronically sign, include your IWU email address and IWU ID number at the appropriate location(s).

Time Frame for Review

Proposals should be submitted as early as possible prior to the intended date for commencement of research activities. Some proposals may require a Board meeting. Approval can usually be granted within two to three weeks of receipt of the application; however, the IRB does not guarantee approval within a certain period of time from submittal of application. Factors that affect approval time include the level of review, quality of the proposal, complexity of the proposal, the extent and magnitude of comments from the Board and the completeness and timeliness of the response to the Board's review by the researcher.

REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN SUBJECTS

Effective July 1, 2017, all investigators, research advisors, and other participants who contribute substantively to the development or execution of a project must successfully complete the CITI Program's Human Subjects Research course (for most persons this is the "Social & Behavioral-Basic/Refresher" course). A copy of the certification of completion of the training must be included with the proposal (unless one is on file with the IRB).

If you have not yet completed the human subject protection training, the online CITI Human Subjects Research training course can be accessed at the following url: <https://www.citiprogram.org>. Once you are on the page, click the "Register" button located on the top right of the page and proceed to Step 1. There is no charge for the course. IWU pays an annual subscription fee to cover all IWU community members.

- **Step 0 (Pre-Step):** Click the "REGISTER" button. Do NOT click the "LOG IN THROUGH MY INSTITUTION" button.
- **Step 1: Select Your Organization Affiliation:** Start typing "Indiana Wesleyan University" and the name will appear in the drop-down menu. Click on "Indiana Wesleyan University" and then check the box to AGREE to the "Terms of Service," etc. Check the "I affirm that I am an affiliate of Indiana Wesleyan University" box. Click the "Continue to create your CITI program Username/Password." Do NOT agree to the "Independent Learner Registration" in the box below.
- **Step 2: Enter your "Personal Information"** (first and last name, email address). Click on the "Continue to Step 3" button.
- **Step 3: Create Your Username and Password,** and choose a security question and provide an answer to the security question. Click on the "Continue to Step 4" button.
- **Step 4: Country of Residence:** Start typing "United States" and the name will appear in the drop-down menu. Click on "United States" and then click on the "Continue to Step 5" button. answering questions regarding gender, etc.
- **Step 5: Click on the "No" button** for all three questions. Click on the "Continue to Step 6" button.
- **Step 6: Information:** Only three of the blanks have to be filled in: IWU email address, department and role in research (e.g., student researcher – undergraduate, co-investigator, etc.) Click on the "Continue to Step 7" button.
- **Step 7: Select Curriculum:** For most persons completing an IRB proposal or acting as Faculty Advisor, you only need to answer Question 1, "Human Subjects Research." Under Question 1, choose the "Social and Behavioral Research Investigators" button, scroll to the bottom of the page, and click "Complete Registration." (You can always add other courses, e.g. Responsible Conduct of Research, Conflict of Interest, etc. at a later date if you so desire.)
- **Next Step: Click the "Finalize Registration" button.** The next screen will say, "Your registration has been completed successfully." Under "Institutional Courses," you will see "Indiana Wesleyan University" with a button to the right that says "View Courses." By clicking on the "View Courses" button, the next screen will show your "Active Courses," "Courses Ready to Begin," and "Completed Courses." Click the "Start Now" button in the "Social & Behavioral Research-Basic/Refresher" box to begin the course. The next screen will be an Assurance Statement. Check the "I agree to the above..." statement and click the "Submit" button. The next screen "Required Modules" lists the 11 required modules. Click on the "Start" button for each module to complete the course. "Supplemental Modules" do not have to be completed unless required by the IRB or your faculty advisor.
- **Later: If you want to add another course,** log in and you will be directed to the "Welcome" page. Under "Institutional Courses," click the "View Courses" button. The

next page, under “Indiana Wesleyan University” shows your “Active Courses,” “Courses Ready to Begin,” and “Completed Courses.” Continue to scroll down to the “Learner Tools for Indiana Wesleyan University” box and click on the “Add a Course” link. This will take you to a page titled “Select Curriculum.” Click the button under the question related to the course you want to register for and then click “Submit” at the bottom of the page. That takes you back to the page that includes your courses including the one that you just added.

What is IRB Approval?

The Institutional Review Board (IRB) consists of a diversity of faculty members from Indiana Wesleyan University (IWU) and at least one member from the community. The IRB is responsible for ensuring that all IWU research complies with the school's ethical standards as well as federal regulations. IRB approval is required before collection of any data involving living individuals, including pilot data. Approval is typically granted for a period of one year and is renewable.

Who Should Use this IRB Application Form?

This application should be completed by all students and faculty members who are conducting research projects of any scope involving collection or analysis of data from living individuals (whether from surveys, interviews, observation, student or employee work products, or records of any type). The only categories of research that do not need to be submitted for IRB approval are literature reviews, hypothetical research designs, and faculty projects that are completely independent of IWU resources, participants, and funding (including presentation and publication of results).

Research projects conducted by administrators or staff of IWU or external researchers are also under the purview of the IWU IRB, as per federal regulations.

Study Title _____

_____ Date

Check One:

_____ Faculty-Staff Research

_____ Student Research

Division(s)/Department(s):

Principal Investigator 1:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

Principal Investigator 2:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

Principal Investigator 3:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

Principal Investigator 4:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

Principal Investigator 5:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

(Add lines for Additional Investigators)

Research Advisor 1:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)

Research Advisor 2:

- CITI Certificate (Attached)
- CITI Certificate (On File with IWU IRB)



CHECKLIST AND ASSURANCES

IRB Proposal Checklist:

(Mark all items that have been completed. Enter "N/A" where Not Applicable.)

- _____ 1. Completed and Signed Proposal Title Page
- _____ 2. Detailed Description of the Proposal
- _____ 3. All required forms
 - _____ a. Consent form(s)
 - _____ b. Letters of permission (if applicable)
 - _____ c. Copies of all survey instruments to be used

By electronically signing this form:

I certify that the information provided in this application is complete and accurate.

I understand that misrepresentation of the research described in this IRB application may constitute non-compliance with federal regulations and/or academic misconduct.

I certify that all known conflicts of interest have been disclosed.

I agree to provide proper surveillance of this project to ensure that the rights and welfare of the human subjects are protected. I will report any problems to the IRB.

I agree that the research will not take place without the receipt of permission from any cooperating institutions, when applicable.

I agree that modifications to the research as submitted will not take place without prior review by the IRB.

I agree to send to the IRB electronic copies of all signed consent forms in one electronic file at the completion of the study.

I agree to retain all other study documents (hard copy or electronic) for a minimum of three years after close of the study.

I agree that all activities will be performed in accordance with all applicable federal, state, and local laws, and Indiana Wesleyan University policies.

Electronically sign this form by typing in your IWU email address (provides authentication for electronic signature and, thus, must match the IWU email address on file with Indiana Wesleyan University).

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Principal Investigator 1:

Principal Investigator 2:

Principal Investigator 3:

Principal Investigator 4:

Principal Investigator 5:

(Add lines for Additional Investigators)

RESEARCH ADVISOR'S* ASSURANCE (REQUIRED FOR STUDENT PROJECTS)

*The research advisor must be an IWU faculty or staff member. The advisor is considered the responsible party for the ethical performance and regulatory compliance of the research project.

As the Research Advisor, I certify that the student investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular research in accordance with the approved protocol.

I agree to meet with the investigator on a regular basis to monitor research progress.

Should problems arise during the course of research, I agree to be available, personally, to supervise the investigator in solving them.

I will ensure that the investigator will promptly report incidents (including adverse events and unanticipated problems) to the IRB.

If I will be unavailable, for example, on sabbatical leave or vacation, I will arrange for an alternate faculty member to assume responsibility during my absence, and I will advise the IRB by email of such arrangements.

Electronically sign this form by typing in your IWU email address (provides authentication for electronic signature and, thus, must match the IWU email address on file with Indiana Wesleyan University).

Research Advisor 1:

Research Advisor 2:

Date:

Detailed Description of the Proposal

(Use as much space as necessary to type your information in the space under each box.)

Section 1: Purpose of the Research

This statement should be easily understood by reviewers with no prior knowledge of the area of study. The statement should be brief but long enough for reviewers to understand the purpose of the project. What are you trying to learn from the study? Avoid all jargon.

Section 2: Methodology

Please describe the steps that will be taken to complete the project. Provide enough detail so that reviewers will understand how the study participants will be involved. Include information about the study population that will be sampled. Explain how the privacy and confidentiality of each participant will be protected. Explain how the data will be stored, e.g. in a locked filing cabinet in a locked office or on a secure server. State that electronic copies of all signed consent forms will be sent to the IRB in one electronic file at the completion of the study. State that all other study documents (hard copy or electronic) will be retained for a minimum of three years after close of the study by the principal investigator. Remember to attach survey instruments if applicable and permission to use copyrighted survey instruments when applicable.

Section 3: Participant Recruitment Strategy

Discuss in detail how subjects will be approached to participate in the research. What recruitment methods will be used to select subjects? Will all participants be 18 years of age or older?

Section 4: Potential risks involved and methods of minimizing risks, inconveniences, or discomforts

What risks may participants face? Remember that just because a study is anonymous does not mean that the participants will not face risks. What will be done to alleviate discomforts? Is there someone the participants can speak with if they so desire about discomforts they may experience while being part of the study? What are the costs to participants to be in the study, e.g. loss of time, travel expenses, etc.?

Section 5: Anticipated benefits and importance of gained knowledge

Are there any benefits that participants will receive for being in the study? Note: Payments to research subjects for participation in the study are not considered benefits. What does the study add to scholarship and knowledge?

Section 6: Known Conflicts of Interest

Does the Principal Investigator, Research Advisor, or anyone else involved in the research, have an equity interest in a company that is a sponsor of the research or owner of products being evaluated in the research. Does anyone involved in the research have a financial interest in a particular outcome of the research? Is there any other circumstance that might cause the investigator(s) to be unduly biased toward a particular outcome of the research? If a conflict of interest is recognized, does the research design adequately protect human subjects and study integrity from bias? If there are no known conflicts of interest, state so in this section.

Section 7: References

Please cite the literature that you have used to develop your proposal.

All required attachments:

Research Participant Consent Form

Consent for Participation in an Electronic Survey (if applicable)

Survey instrument(s) / Interview Questions (if applicable)

Copies of CITI Completion Report(s)

Consent Form for a Minor to Participate (if applicable, request a template from the IRB)

Assent Form for a Minor to Participate (if applicable, request a template from the IRB)

RESEARCH PARTICIPANT CONSENT FORM BACKGROUND INFORMATION

An informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

We recommend the use of the following template to create the informed consent document(s) for your study. Please note:

1. New Federal regulations now require that research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:
 - a. Identification of the project as a research study and that participation is voluntary
 - b. Purpose of the research, duration of participation, and a description of research procedures
 - c. Foreseeable risks or discomforts, if any
 - d. Expected benefits to subjects or others, if any
 - e. Alternative procedures or treatments that might benefit the subject
(Note: applies primarily to clinical research)

Many IRB studies have brief consent documents (2 or 3 pages) that meet the new federal requirement without the need for a separate key information section. However, if your project is complex or involves numerous research procedures, the above-listed summary of key information is required for federally-sponsored projects and strongly recommended for all others.

2. Additional instructions or sample text are provided in boxes.
3. Before you submit your consent document, delete this cover page and boxes. The finished document should reflect what the potential subject will read.

For questions about informed consent, please contact the IRB at irb@indwes.edu. For more information on plain language go to <https://www.plainlanguage.gov/>.



RESEARCH PARTICIPANT CONSENT FORM

Use this informed consent for studies beginning January 21, 2019 or later

Title of Project: _____
Principal Investigator's Name(s): _____
Research Advisor's Name(s): _____
Academic Division/Department: _____

Section 1: Purpose of the Research

This statement should be easily understood by individuals with no prior knowledge of the area of study – avoid all jargon. It is best that the first person be used consistently throughout each section of the informed consent document rather than just cutting and pasting from other sections of the proposal. For example, begin sentences with “I understand that...” or “I acknowledge that....” The goal is to make sure the potential human subject completely understands the study and the nature of her or his involvement. Consistently using the first person in the consent form will help comprehension.

Section 2: Specific Procedures to be Used

This should include each step of the procedure the participants would either observe or experience.

Section 3: Duration of Participation

This should inform the potential participants of the amount of time (number of days/hours) they will need to commit to the project (including travel time).

Section 4: Risks to the Individual

Each study has some amount of risk. If the risk is minimal or similar to that of everyday life, state that “the risk is minimal or similar to that of everyday life.” If the respondent is asked to answer personal questions, e.g. about self-concept, emotions, or health conditions, note that this can cause discomfort. The fact that a study is anonymous does not preclude risk. When applicable, note that if there

is a chance you may become privy to information that must be reported, such as child abuse, child neglect, elder abuse or intent to harm self or others, this must be disclosed as a risk to participants.

Section 5: Benefits to the Individual or Others

Benefits refer to direct benefits to the participants. They need to be clearly stated. Not all studies will have direct benefits to the participants and if this is the case, it needs to be stated as so. Compensation is not a benefit.

Section 6: Compensation

If there is compensation, it needs to be listed here; it is not to be considered a benefit. Put N/A in this section if not applicable.

Section 7: Extra Costs to Participate

This may include, but is not limited to, transportation costs for travel to the site of research, costs of medicine, etc. If there is no cost to the participant, state that fact.

Section 8: Injury or Illness

This should explain what the plan is for any medical situation that may occur during the research process. Explain who will be contacted and what the participant's rights are in terms of medical compensation. A plan for medical care should also be included.

Section 9: Confidentiality

Explain how the privacy and confidentiality of each participant will be protected. Include where, how, and for how long documents related to this study will be kept and how they will be eventually disposed. Explain how the data will be stored, e.g. in a locked filing cabinet in a locked office or on a secure server. State that electronic copies of all signed consent forms will be sent to the IRB in one electronic file at the completion of the study. State that all other study documents (hard copy or electronic) will be retained for a minimum of three years after close of the study by the principal investigator. Include the process of keeping audio/video media confidential (if applicable).

It also needs to be stated if confidentiality is limited. For example, if you are meeting in focus groups, other group members may not keep information

confidential even when instructed to do so. Also, there may be some information that is brought to light that you are required, by law, to report. If subjects will be paid, the statement, "I understand that my name, social security number and address may be provided to the business office of Indiana Wesleyan University for the purpose of facilitating payment to me for participating in this study," should be included in this section as well.

Section 10: **Voluntary Nature of Participation**

Explain how a participant would withdraw from participating without any penalty. If there is any circumstance that would make withdrawing difficult, that must be explained. If a participant is an employee who is part of a study related to the participant's work, include a statement to the effect that willingness to participate or not participate in the study and decision to withdraw from the study will have no effect on the person's employment. Similarly, if the participant is a student who is part of a study related to his or her education site, include a statement to the effect that "willingness to participate or not participate in the study and my decision to withdraw from the study will have no effect on my standing at the institution of higher education where I am enrolled." Include the following statement in Section 10 of the consent document.

I do not have to participate in this research project. If I agree to participate, I can withdraw my participation at any time without penalty.

Section 11: **Release**

All consent forms must include the following release statement.

I participate of my own accord in this research project and release any claim to the collected data, research results, publication in any form including thesis/dissertation, journal article, conference presentation or commercial use of such information or products resulting from the collected information.

Section 12: **Contact Information**

Insert Investigator's name(s) and email addresses. Also, for student research, include the research advisor's name and contact information.

If I have any questions about this research project, I can contact:

If I have concerns about the treatment of research participants, I can contact the Institutional Review Board (IRB) at Indiana Wesleyan University, 4201 South Washington Street, Marion, IN 46953. (765) 677-2090.

I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT DOCUMENT, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO PARTICIPATE IN THIS PROJECT.

Participant's Signature: _____

Participant's Name (Type or Print): _____

Date: _____

Investigator's Signature: _____

Date: _____

Note to Investigators: See following pages for additional instructions.

Additional instructions for the Research Participant Consent Form:

You may also need to obtain dated consent for specific activities when those activities are **optional**. Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

Consent to be Audio/Video Recorded

I agree to be audio/video recorded.

YES _____ **NO** _____

Signature

Date

Consent to Use Data for Future Research

I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information. (Note: This separate consent is not necessary if you will only store and share de-identified data.)

YES _____ **NO** _____

Signature

Date

Consent to be Contacted for Participation in Future Research

I give the researchers permission to keep my contact information and to contact me for future research projects.

YES _____ **NO** _____

Signature

Date

Participant to Initial and Date All Non-Final Pages

* Please note that all consent forms that are longer than one page must provide a place for the participant to initial and date all non-final pages. A format such as the following may be added to the bottom of each non-final page:

I have read this page _____ (initials here)
Continue to next page.

Electronic Consent

Some studies allow for electronic consent, e.g. when potential participants are solicited through an email or social media. In that case, the preamble/cover letter/email should include all of the information contained in the above informed consent document template.

Additionally, the following clause or similar wording as befits the proposal shall be included in electronic informed consent documents if participants will take an electronic survey: “The survey is designed not to collect e-mail addresses or Internet protocol (IP) addresses. To further maintain confidentiality of the survey, please do not include your name or any other information by which you can be identified in any of the comment boxes in the survey.”

Under no circumstances shall electronic informed consent be used for studies that include children under the age of 18 years.

An example of an electronic consent preamble template follows. Revise appropriately to fit your study, if applicable.

CONSENT FOR PARTICIPATION IN AN ELECTRONIC SURVEY SAMPLE

Hello, we are conducting research about.... If you want to participate, please read the following consent document.

I certify that I am over the age of 18 and am participating in this survey of my own freewill. I recognize that some or all of the questions contained in this survey may be of a sensitive nature and may cause discomfort. I understand all survey answers will be held in strict confidence and may be used by the researchers for future publications.

I understand that the purpose of the research is to

I authorize (PI Names) of the Indiana Wesleyan University College/ School/ Division/ Department of ... program and any designated research assistants to gather information regarding my responses to questions asked on this survey. This survey will ask about understanding and perceptions of ... and will take approximately ... minutes/hours to complete. If I agree to take part in this study, I understand that I will be asked to complete the survey questions listed on the following pages. I understand that my responses will be utilized for research and may become part of a published journal article or scholarly presentation.

I recognize that I will not receive monetary compensation for participating in this survey. Conversely, there are no monetary costs to me for participating.

I certify that my participation in this survey is wholly voluntary and recognize that I may withdraw at any time. I understand that I am free to skip any question I do not feel

comfortable answering. There is no obligation for my participation and I may withdraw at any time.

I understand that (PI names) will be available for consultation should I have any additional questions regarding the research being conducted.

I understand that the answers given to this survey will be maintained by the researcher for a period of no less than three years after the close of the study. The researcher will store all paper copies of surveys in a locked and secured filing cabinet. Additionally, paper copies of surveys and release forms may be digitized and stored electronically on a password-protected hard drive.

I release any claim to the collected data, research results, publication of or commercial use of such information or products resulting from the collected information.

If I have any questions or comments about this research project, I can contact:

- PI's name(s) and contact information, or
- Research Advisor and contact information.

If I have concerns about the treatment of research participants, I can contact the Institutional Review Board (IRB) at Indiana Wesleyan University, 4201 South Washington Street, Marion, IN 46953. (765) 677-2090.

The survey is designed not to collect e-mail addresses or Internet protocol (IP) addresses. To further maintain confidentiality of the survey, please do not include your name or any other information by which you can be identified in any comment boxes that may be included in the survey.

BY CLICKING ON "CONTINUE," I ACKNOWLEDGE THAT I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO CONSENT TO MY PARTICIPATION IN THIS SURVEY.