IRB Initial Submission Application Worksheet

Key:

Italics: explanatory text

Yellow highlight: information everyone needs to complete

Gray highlight: instructions about when additional questions need to be completed

Teal highlight: information you may need to complete, depending on previous answers

Section 1

Submitter: [the system will enter this]

Project Title: [enter your project title]

Estimated Project Start Date: *NOTE: You may not begin your research until you obtain IRB approval.* [enter start date]

Estimated Project End Date: [enter end date]

Primary Research Site: *The primary research site is the physical location where the interaction with the subjects will take place and the data will be collected. If the project has more than one research site, you must designate one as the primary research site. NOTE: For most research sites other than Whitworth you will need to supply a Site Permission Letter.*

[select one from drop-down:

Community Organization
Corporation
External Medical Clinic
K-12 Education
Online
Other
Other College or University
Whitworth University]

If you selected "Other":

Other Primary Research Site: [enter the kind of site]

Are there additional research sites? [yes/no]

If you selected "Yes":

Please list any additional research sites: [enter additional research sites]

If for “Primary Research Site” you selected “Community Organization”, “Corporation”, “External Medical Clinic”, “K-12 Education”, “Other”, or “Other College or University”:

Attach Site Permission Letter(s) for all research sites for which this is a requirement.
Click here to access the Whitworth Site Permission Letter template.
*Site permission letters are **required** for External Medical Clinics, K-12 Education, Other College or University*
*Site permission letters are **recommended** and **may be required** for Community Organizations, Corporations, and Other sites.*

[upload attachment(s)]

Principal Investigator: [enter the name of the principal investigator; the system will find the profile]

PI Department: [select the PI’s department from drop-down]

PI Status: [select one: Student/Faculty/Staff]

If you selected “Student”:

Faculty Assurance: [enter the name of the faculty assurance; the system will find the profile]

If you selected “Faculty”:

Please make sure that your CITI training is current; this application will not be able to be approved unless the CITI training is current and will remain current through the initial approval period.

Does anyone in addition to the PI need to sign off on this application (e.g., Co-Principal Investigator): [yes/no]

If you selected “Yes”:

Additional Signator: [enter the name of the additional signator; the system will find the profile]

Will there be any other Whitworth team members working on this project? [yes/no]

NOTE: Other team member could include: Co-investigator, Coordinator, Research Assistant, and/or Research Team Member

If you selected “Yes”:

Additional Whitworth Investigators: For each investigator complete the following:

Name: [enter the name of the investigator; the system will find the profile]

Role: [select one from drop-down: Co-Investigator/Consultant/Research Team Member]

Save: [click save to add the investigator to the form]

Will there be any Non-Whitworth team members working on this project? [yes/no]

If you selected “Yes”:

Non-Whitworth Investigators: For each investigator complete the following:

First Name: [enter the first name of the investigator]

Last Name: [enter the last name of the investigator]

Email: [enter the email of the investigator]

CITI Certificate: [upload the appropriate CITI certificate for the investigator]

Save: [click save to add the investigator to the form]

Is the primary responsibility for the study subject to the Whitworth IRB only? [yes/no]

For example: If the project has IRB oversight from an external IRB, will the Whitworth IRB rely on that IRB? If so, select "No".
NOTE: If the project has IRB oversight from an external IRB and the Whitworth IRB will rely on that IRB, you will need to attach, at a minimum, a draft of the reliance agreement from the external IRB.

If you selected "No":

Will this study receive/has this study received IRB approval through another organization?
Please indicate status below: [Yes, already have approval/No, but awaiting approval from another organization/No, not applicable]

If you selected "Yes, already have approval":

Attach External IRB Approval Letter: [upload attachment]

Attach External IRB Approved Application: [upload attachment]

Please attach a draft of the Reliance Agreement form the external institution (this does not yet need to be signed): [upload attachment]

Will any external IRBs rely on the Whitworth IRB for oversight? [yes/no]

If you selected "No" to "Is the primary responsibility…" OR "Yes" to "Will any external IRBs":

External IRB Name: [enter the name of the external IRB]

External IRB FWA#: [enter the Federalwide Assurance Number of the external IRB]

External IRB IORG#: [enter the IRB Organization Number of the external IRB]

Please indicate the funding source:

[select all that apply:

Corporate Funding
County Funding
Federal Funding
Municipal Funding
No Funding

Private Funding
State Funding
Whitworth Endowment Funding
Whitworth New Faculty Funding
Whitworth Summer Research Funding]

Name of Funding Source/Sponsor: [enter the name of the funding source or "No Funding"]

Section 2

Estimated Level of Risk: *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.* [select one: Minimal risk/Greater than minimal risk]

Additional Project Information:

[select all that apply:

The project uses deceit
The subjects are all children (under 18 year old)
The subjects are all prisoners
The subjects all have impaired decision-making ability
The subjects are all unhoused persons
The subjects are all minorities
The subjects are all over 70 years old
Other
None of the Above]

If you selected "Other":

Please describe the other additional project information: [enter the other additional project information (this would normally be information about the anticipated subjects that would help the IRB determine if they required additional protections)]

Section 3

Briefly describe the purpose and relevant research support for your project: *State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project.* [enter purpose statement]

Data Collection Methods:

[select all that apply:

Chart Review
Device
Drug
Focus Group

Interview
Medical/Therapeutic Technique
Non-prescription Medications, Supplements, Etc.
Observation of Public Behavior
Questionnaire
Use of Existing Data]

If you selected "Focus Group", "Interview", "Medical/Therapeutic Technique", or "Questionnaire":

Briefly describe data collection methods or instruments; if these are standard instruments in your discipline, please explain: [enter description]

Attach Data Collection Instruments: [upload attachment(s) of any surveys, interview protocols, focus group scripts, or other data collection instruments to be used]

If you selected "Device", "Drug", "Medical/Therapeutic Technique" or "Non-prescription Medications, Supplements, Etc.":

Attach Drug/Device Literature Review: [upload attachment with literature review for any drugs, devices, or medical/therapeutic techniques used in the research; also attach product brochures for drugs and devices]

Number of Subjects: *NOTE: For number of subjects, enter the estimated maximum number of subjects.* [enter the number of subjects]

Describe your subject population (age, gender, special conditions/requirements) and where they will be recruited: [enter description of subject population]

If under "Data Collection Methods" you selected "Drug", "Focus Group", "Interview", "Medical/Therapeutic Technique", "Non-prescription Medication, Supplements, Etc." or "Questionnaire":

Recruitment Methods: describe how you will recruit subjects for your study: [enter description of recruitment methods]

Attach Recruitment Materials: [upload attachment(s) of any recruitment materials, such as flyers, recruitment scripts, language for emails, text, or online postings]

Describe how you will prevent coercion and undue influence while recruiting subjects: [enter description (e.g., how potential subjects' identities will be kept private, how potential subjects will not feel undue pressure to participate, e.g., from a teacher/instructor)]

Describe the study design, including the sequence and timing of all study procedures. What will the participants be asked to do? [enter description of study design]

Please explain in detail the setting in which you will meet with subjects to conduct the research; address any concerns about protecting privacy of subjects. *For example: will others be able to hear interview responses? If so, why is that appropriate?* [enter explanation of setting]

Describe the risks and inconveniences to participants. *Note: all studies entail some risk; if the risks are not greater than the subjects would encounter in their everyday activities, indicate that the risk is 'not more than minimal'.* [enter description of risks]

How will you protect personally identifiable data? *It is recommended that, unless otherwise needed, subject data will be coded to remove all identifying information that could affect confidentiality or anonymity during data analysis and dissemination. Only the research investigators and faculty supervisor should have access to collected data. All hard copy data should be stored and locked in a secure area. Electronic data should be password protected/encrypted. Upon completion of the study, all coded data, without identifiers, must be kept for three years and then properly disposed of (i.e. deleted if electronic or shredded if there are hard copies). No identifying information should be held after coding of the data is complete and verified.* [enter description of protections]

Study employs deception to mask the true purpose. [yes/no]

> If you selected "yes":
>
> Please create and attach a debriefing statement that will be used to explain the deception to subjects: [upload attachment of debriefing statement]

Could your project present a risk to persons with pre-existing health conditions such as diabetes or heart conditions? [yes/no]

> If you selected "yes":
>
> Please attach a health screening form: [upload attachment of health screening form]

Section 4

Will there be an inducement for subject participation? [yes/no]

> If you selected "yes":
>
> Please explain what inducement will be used for participation and why. [enter explanation]

Consent Waiver Status:

> *Full waiver of Consent: No informed consent will be obtained (i.e., no identifying information will be collected)*
>
> *Partial Waiver of Consent: Certain required elements of consent are requested to be waived (NOTE: this waiver is to be used under special circumstances only; contact the IRB Chair or Administrator for details)*
>
> *Waiver of Signed Consent: A consent form will be provided, but collection of signatures are requested to be waived (e.g., collection of anonymous data)*
>
> *Note: Consent waivers are governed by Federal regulations and subject to IRB approval*
>
> [select all that apply: Full Waiver of Consent/No Consent Waivers/Partial Waiver of Consent/Waiver of Signed Consent]

If you selected “Full Waiver of Consent”, “Partial Waiver of Consent” or “Waiver of Signed Consent”:

Please explain why the Full or Partial Waiver of Consent, or Waiver of Documentation of Consent (waiver of signatures) is requested: [enter explanation]

If you selected “Waiver of Signed Consent”:

Will you be using a script or informational page on a survey to present consent-related information? [yes/no]

If you selected “yes”:

Please attach the consent script or information page: [upload attachment]

If on “Consent Waiver Status” you selected “Full Waiver of Consent”, “Partial Waiver of Consent” or “Waiver of Signed Consent”:

Why is the study considered to be minimal risk? [enter explanation]

If on “Consent Waiver Status” you selected “Waiver of Signed Consent”:

Does a breach of confidentiality constitute the principal risk to participants? *Consider the risks associated with a breach of confidentiality and how risks will be minimized because of the waiver of signed consent.* [yes/no]

Would the signed consent form be the only record linking the participant to the research? *Consider this in relation to the procedures to protect privacy/confidentiality.* [yes/no]

Does the research include any activities that would require signed consent in a non-research setting? *For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.* [yes/no]

If on “Consent Waiver Status” you selected “Full Waiver of Consent” or “Partial Consent Waiver”:

How will the waiver affect the participants’ rights and welfare? *The IRB must find that participants’ rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.* [enter explanation]

If on “Consent Waiver Status” you selected “No Consent Waivers”, “Partial Waiver of Consent”, or “Waiver of Signed Consent” AND on “Data Collection Methods” you selected one of “Device”, “Drug”, “Focus Group”, “Interview”, “Medical Therapeutic Technique”, “Non-presecription Medications, Supplements, Etc.”, or “Questionnaire”:

Describe how you will obtain informed consent including who will obtain consent, where and when it will be obtained, and how much time participants will have to make a decision: [enter description]

Consent Type:

To access the Adult Consent Template, click here.

To access the Parental Consent Template, click here.

To access the Child Assent Template, click here for elementary and here for middle/high school.

[select all that apply: Adult consent (all subjects over the age of 18)/Parental consent/Child assent (required for age 7 and above)]

How will important information be returned to the participants? *If information will not be returned to participants, please explain why. For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.* [enter explanation]

Attach Informed Consent Form(s): [upload attachment(s)]

Attestation

By submitting this application, I attest that the application is complete and accurate to the best of my knowledge: [check the box "I Attest"]

Submission

Submit: [click the button "Submit"]