Everything You Wanted to Know About IRB

Presented by The Office of Research Integrity

What is Human Subjects Research?

- A *human subject* is defined by the Code of Federal Regulations (CFR) as "a living individual about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.“
- *Research* is defined in the Code of Federal Regulations (CFR) as "a systematic investigation designed to develop and contribute to generalizable knowledge."

Examples

- Interviews
- Surveys
- Focus groups
- Secondary data analysis
- Analyzing medical records
- Testing interventions
- Clinical Trials

Is It Human Subjects Research?

Classroom Exemptions: these are related to any class project or assignment which involved human participants but for the purpose of teaching. These projects must not be presented, nor include minors or vulnerable populations, and have no video or audio recordings. This is not considered Human Subjects Research but is required to be submitted to the IRB for review and exempt determination.

Secondary Data Analysis: these entail projects where previously collected data is analyzed and published. This includes but is not limited to medical chart data, publicly available data, databases, data from a previous work intended for different review, and course evaluations or instruction for the purpose of research.

Not Human Subjects Research

Evaluations of an employee, course, program, or service where the evaluations are not designed to lead to generalizable knowledge. This includes surveys designed to enhance a program or course.
This is assumed that there will be no publication or presentation on the evaluation data outside of the original department.

Review Types

Exempt Review

This is for projects that are no more than minimal risk and are exempt from more detailed review.
Exempt research still needs IRB review.

Examples:
- surveys
- educational research in a classroom
- secondary data review

Expedited Review

This is for projects that are no more than minimal risk but are non-exempt. This also includes minor changes to approved projects.

Examples:
- collection of audio/visual recordings
- interviews
- clinical studies
- those determined non-exempt by IRB
- amendments to current protocols with no additional risk

Full Board Review

This is given to projects which could be more than minimal risk and may involve vulnerable populations. This also includes those that are determined by the IRB to not fit exempt or expedited categories.

Example:
- research with those under 18 or disabled groups
- sensitive research questions

Does It Require IRB Review?

Dr. Red is teaching a “History of WKU” class this Fall would like his students to conduct research on the community's perception of WKU in Bowling Green. This project will be conducted by the students, but the only presentation will be within the class. He wants each student to develop their own survey. Which of the following does Dr. Red need to do?

A. Submit a Continuing Review form for his other IRB application titled “Perceptions of WKU in age groups across Kentucky”
B. Nothing- this is not human subjects research and does not require an application
C. Submit a Classroom Exemption Form through IRBNet for IRB approval
D. Submit a Human Subjects Application though IRBNet



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C. Submit a Classroom Exemption Form through IRBNet for IRB approval

D. Submit a Human Subjects Application though IRBNet

Dr. Red must submit a Classroom Exemption Form as well as Student Code of Conduct Forms for each student participating in IRBNet. These projects will be given an exempt determination.



How Do I Complete an IRB Application?

Blank applications can be found on our Human Subjects Page or within IRBNet in Forms & Templates

- **Complete the first sections with your PI, Co-PI, and basic project information.**
  Be sure to complete all questions and add any key personnel.

- **Section A- Summary**
  This is a brief overview of your project. This should include hypothesis, research questions, and the proposed activities, no more than half a page.

- **Section B- Selection Criteria**
  We have developed specific targeted questions for this section on what we are looking for including how many participants you plan to recruit, where recruitment will occur, how it will occur, how you will contact participants, inclusion and exclusion criteria.

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- **Section C- Informed Consent**
  Describe your consent process. Where will it occur, how will consent be obtained, and what format (informed consent or implied consent) you will use. Do not include your consent document in this section.

- **Section D- Procedures**
  Step by step guide of how the research will be conducted from participant recruitment to study close.

- **Section E- Confidentiality**
  Describe how confidentiality is maintained, even if it you do not collect personal information. How incentive sign up will be maintained separate from responses should also be detailed here.

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- **Section F- Risks**
  Describe any potential risks. Even uncomfortable questions can be considered a risk. It is recommended to always mention this as a potential and that no participants have to answer any questions that make them uncomfortable.

- **Section G- Benefits**
  Incentives should be descriptive such as $25 online Amazon gift card. Indirect benefits should be outlined here as well.

- **Section H- References**
  Specific measurement tools or diagnostics are helpful to put here for review.

Now What??

Complete your Consent Form (not needed if the project is secondary data analysis)

Consent Templates can be found within IRBNet in Forms & Templates as well as on our Human Subjects Page.



Informed Consent

Used when there is direct interaction with particpants, interventions, interviews, and audio/visual recording.

This includes the actual signature of the participant and a witness (the person obtaining consent.

Example: I am conducting interviews over Zoom for a research project and I plan on recording the interviews so I am able to trascribe the interaction for data analysis.
- This requires an infomed consent

VS

Implied Consent

These forms are used when there is only survey interaction with participants.

Consent is “implied” based on the continuation of the survey.

Example: I am sending out a survey for my research project to students on campus with a Qualtrics link. The consent document will show up first and the participants action of clicking next to the survey implies their consent.
- This requires an implied consent

What Consent Do I Need?

Dr. Integrity is conducting a research project on how students, faculty, and staff feel about green spaces on campus. This will be composed of confidential surveys as well as a 60 minute follow up interview with willing participants. What kind of consent(s) does Dr. Integrity need?

A. Just an informed consent for the entire research study
B. Both an implied consent for the survey and an informed consent for the interview
C. An implied consent at the beginning of the survey that mentions the interview in the procedures
D. Just a recruitment script



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Dr. Integrity will need both consent types. An implied consent for the survey and then an informed consent for the interview. This is to ensure that participants are consenting to specific parts of the research as they are not required to complete all parts if unwanted.



What Do I Even Put In A Consent?

Consent documents are the outline of the research for the participant so it should be easy to read and understand.

State that participants do not have to answer any questions they are uncomfortable with.

If there are no incentives explain that there are no direct benefits to the participants.



Where Do I Submit?

Now you will need to upload your required documents in IRBNet!

What Do I Upload?

Here are the documents you will need prepared before you submit in IRBNet. These are subject to change depending on the research you are conducting.

At a Minimum

1. Human Subejcts Application
2. Informed/Implied Consent(s)

Based on Your Research

- Surveys/ Interview Materials
- Recruitment Scripts and Material
- Letter of Permission/ Cooperation from the entity you are recruting from

Example: I am recruting my participants from a pool of teachers at a high school, I will need to obtain a letter or email from the principal of their awarness and approval for me to conduct research there.

- Budget if you are receiving internal or external funding

What Documents Do I Need?

Dr. Hilltop is conducting a research study with teachers at high schools in two counties in Kentucky. The research will include survey questions on what teaching resources are helpful for our community teachers. Recruitment will include an email with a QR code. What documents does Dr. Hilltop need to upload into IRBNet?

A. An application, an implied consent, recruitment email script, survey questions, and letters or emails from the superintendent of each county stating permission to recruit teachers in those counties.

B. An application, an implied consent, and survey questions.

C. An application, an informed consent, recruitment email script, survey questions, and a letter or email from the principle at one of the schools.

D. An application, and implied consent, and a letter or email from the superintendent of the two counties.



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B. An application, an implied consent, and survey questions.

C. An application, an informed consent, recruitment email script, survey questions, and a letter or email from the principle at one of the schools.

D. An application, and implied consent, and a letter or email from the superintendent of the two counties.

Dr. Hilltop will need all of these for IRB review and approval. All materials should be uploaded into IRBNet upon submission or there could be delays in approval.



Uploading in IRBNet

Our website now has specific instructions for how to submit in IRBNet. This is under Preparing and Submitting an IRB Application

- ➔ **Create your Project and Upload Materials**
- ➔ **Share Project with students, Co-PIs and others listed on the application**
- ➔ **Sign the Package**
- ➔ **Submit the Package**
- ➔ **If Revisions are Requested, make sure to Lock the Package back for Review!**

Who Needs to Sign?

Dr. Western is the faculty advisor for a graduate student. The student is conducting a research project which required IRB review. The student has submitted their project in IRBNet. Who needs to sign the package?

A. Just the student
B. Just Dr. Western
C. No one, the submission is enough
D. Both the student and Dr. Western



Who Needs to Sign?

Dr. Western is the faculty advisor for a graduate student. The student is conducting a research project which required IRB review. The student has submitted their project in IRBNet. Who needs to sign the package?

A. Just the student
B. Just Dr. Western
C. No one, the submission is enough
D. Both the student and Dr. Western

Dr. Western and the student need to sign. The student should share the package with their advisor for review and signature.

Reminder: Everyone listed on the project will need to sign the package.



What Do I Do Now?

Once approved you may now begin research. Don't forget these other important forms!

Continuing Review Form- Submit this to extend your study once it is about to expire. These should be completed within 30 days of expiration. If your project is expired no research activity, including data analysis may occur.

Amendment Form- Need to change something? Submit an Amendment Form to alter parts of the study that were not originally approved including but not limited to recruitment materials, adding personnel, changing survey questions, or altering participant incentives.

Closeout Form- All research completed? This includes data collection and data analysis. Once your project is completed please submit a Closeout Form to officially conclude the study and we will close your project out in IRBNet.

Please be sure to only complete forms directly downloaded from IRBNet or our Website as these are the most accurate and updated versions.



Questions?

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