Human Subjects Review for Student Research

Undergraduate, Credential, and Master's level student investigators are required to submit their applications to the College Research Review Committee for Human Subjects Review.

Some applications will be approved by the College Committee while other applications will need to be reviewed and approved by the University Institutional Review Board (IRB).

Whether or not an application requires University review is based on the risk level assigned by the College Committee. Students should work with their advisors to identify the most likely risk level assignment before submitting their application, and plan their timeline to accommodate the College or University reviews.

Review of human subject research applications is regulated by federal regulations from the Office of Human Research Protection (OHRP) and university policy. For more information and details about the <u>University Institutional Review Board (IRB) Human Subjects Research</u>.

Risk Levels

Exempt

Some research categories have been identified as exempt by the federal regulations. The research must still be reviewed by the committee to determine whether it truly fits into these categories. Examples include research in established courses on instructional techniques, observational research on adults (not children), surveys with adults where data are recorded in a way that participants cannot be identified, analysis of existing data where participants are anonymous, etc. See the **Exempt Decision Trees** for more information on determining whether your research might fit into an exempt category.

Research classified as exempt risk level by the College Committee does not need secondary review by the University IRB.

Minimal Risk

Research that is categorized as minimal risk is research in which the probability and magnitude of harm or discomfort anticipated for participants are no greater than what might be encountered in daily life or during the performance of routine physical or psychological examination or tests.

Research classified as minimal risk must go to the University IRB. Minimal risk applications can be reviewed by the University IRB as expedited review – for expedited review applications can be submitted at any time and feedback from the review is returned within 2 weeks.

Greater Than Minimal Risk

Research classified as greater than minimal risk is research where the probability of harm or discomfort or magnitude of possible harm (physical, psychological, social, or economic) from participation in the research study are more than what might be encountered in daily life.

Greater than minimal risk requires review by the University IRB and will require review by the convened full board. The University IRB board meets once a month, the due dates and meeting dates are listed on the <u>Office of Research Affairs' Review Categories and Timelines</u>.

Vulnerable Populations: Note that working with certain populations, like children, can increase your risk level under certain circumstances because these groups are designated as vulnerable populations by the federal government and provided additional protections. For example, when working with children you will need both the child's assent and the parent's consent to for their participation, and will need to be sure that they are free from pressure to participate from adults in a position in authority. This can make research with your own students or children tricky to meet these protections. Per

University Policy, any research or project involving undocumented individuals will need to be reviewed by the University IRB.

Not Reviewable Research

Some research projects do not meet the federal definition of research reviewable by the human subjects committee. Research projects that do NOT involve:

(a) **interaction** or **intervention** with people, AND (b) obtaining private, individually identifiable information about living individuals are not required to be reviewed. If this is the case, fill out the cover page of the online application below that your research is not reviewable (the application will terminate upon your indicating you are not using human subjects and your responses will be sent to the committee for reference). Please note that many research projects involve interaction or intervention while collecting data; these projects must be submitted and approved by CRRC.

How to Apply

Step 1

After you finalize your methodology, click on the following link and completely fill out the **Human Subjects Research Application**. This online submission form must be completed in one sitting. The application needs to be completely filled out, even if it means repeating yourself. Answer all parts of each question, but do not provide information not asked for. Do not cut and paste big sections from your petition or chapters and do not say "see attached" or "see below". Provide all of the relevant information in the form.

Step 2

Your advisor's signature must be uploaded to the application, so be certain your advisor has approved your research or project and all of the areas of the Human Subjects Application before uploading. Note: You cannot save and return to the application, so you must have your advisor's approval and signature before submitting your final application. Have all attachments ready to upload upon completion of the application.

Note: There is information and examples on the University IRB website on how to prepare consent forms, online surveys, etc.

Within 24 hours of submission you will receive an email confirming that your application has been received by the College Committee.

Due Dates

The <u>College Research Review Committee</u> generally meets 1:30-3:00pm on the third Thursday of each month (except December and May when we meet the second Thursday). Submission due dates are listed below. Feedback from the meeting is generally returned to PI's within 4-5 business days following the meeting.

Fall 2020 Application Deadlines for Student Submissions

Application due September 7, 2020 by 5pm for review on September 17, 2020. Application due October 5, 2020 by 5pm for review on October 15, 2020. Application due November 9, 2020 by 5pm for review on November 19, 2020. Application due November 30, 2020 by 5pm for review on December 10, 2020.

Spring 2021 Application Deadlines for Student Submissions

Application due February 8, 2021 by 5pm for review on February 18 2021. Application due March 8, 2021 by 5pm for review on March 18, 2021. Application due April 5, 2021 by 5pm for review on April 15, 2021. Application due May 3, 2021 by 5pm for review on May 13, 2021.

Training

Starting in Fall 2018, everyone who submits a human subjects application needs to have

completed the appropriate training and education to meet the university requirements.

Student researchers need to complete a Human Subjects tutorial provided by CITI and

provide a copy of their completion certificate with their human subjects application. The

link to the tutorial is below with instructions for registration:

CITI Training Guidance

1. CITI Registration Guidelines

This course is FREE. Use the Guide above to ensure you correctly register.

2. Complete the courses

3. Attach a copy of the certificate to the application (either department application and university

application)

Please note that many research courses include EDGR 260 and many 250 courses

require the completion of this tutorial as part of their course. If you completed it in a

course you should be able to log back in to the system and re-print your completion

certificate.

Questions

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