**Instructions for Completing the Allegheny College**

**Institutional Review Board (IRB) Proposal**

**1 July 2020**

This document provides practical reminders and definitions, as well as a metric to determine the type of review that you are requesting. For fuller details, especially if you are new to the IRB process, please see the Allegheny College IRB website:

(<https://sites.allegheny.edu/committees/guidelines-allegheny-college-institution-review-board-ac-irb/#5>).

Additionally, you may contact the chair of IRB.

**Responsibilities of Faculty/Staff Research Supervisors**

Allegheny’s IRB is a standing committee of the faculty, and oversees research proposals conducted using human subjects. As such, Allegheny College faculty members or staff are the official submitters of proposals, and have ultimate responsibility for proposal content. Many research projects are conducted primarily by students, and as part of the learning process, students may assist in completing the application. It is the responsibility of the Allegheny employee PI or supervisor to ensure that the student’s proposal is complete and follows the guidelines. This prevents delays and frustration in the review process.

**Completing the Application**

**Investigators and CITI Certification**

**Principal Investigators**

Include the name(s) of the person(s) primarily responsible for the research. An Allegheny College employee must be included as a Principal Investigator, with ultimate responsibility for the proposal and for the study.

**Additional Investigators**

If relevant, then include the name(s) of additional person(s) participating in this research.

Students, faculty, or staff proposing or participating in this research must complete the appropriate Collaborative Institutional Training Initiative (CITI) course before the application can be submitted. Upon successful completion of a CITI course, you will receive notification of your completion. In addition, Allegheny College receives notification of your completion.

Investigators must include the name of the CITI course completed, and the date of completion on the application.

Proposals submitted to the IRB do NOT need to include certificates of test completion; test results are sent to and recorded by the college.

Proposals submitted to the Carnegie IRB subcommittee must have certificates submitted to the Psychology Department Shared IRB Drive.

**Type of Review Requested**

**Exempt Review**

Research that involves no more than minimal risk and meets criteria specified by federal regulations may qualify for exemption. Exemption means that studies in this category do not need to conform to the guidelines set forth in the Health and Human Services and Office of Human Research Protection (HHS/OHRP) Regulation document 45 CFR 46. Exempt proposals are reviewed by the IRB, but do not need the rigor involved in expedited or full reviews.

Informed consent is not required, but is recommended unless there is a reason to waive it.

Research results are not required to be made available to participants, but sharing a summary of the results is highly recommended.

These proposals are reviewed by one member of the IRB or Carnegie Subcommittee.

**Expedited Review**

Expedited reviews meet the categories adopted by the Department of Health and Human Services (HHS) that involve no greater than minimal risk. These proposals are reviewed by two members of the IRB, or by two members of the Carnegie Subcommittee.

Documented Informed Consent is required.

A plan for sharing research results is required.

**Full Review**

Research that does not meet the criteria for Exempt or Expedited review must be submitted for Full Review. These applications are reviewed by all members of the IRB.

Documented Informed Consent is required.

A plan for sharing research results is required.

**Determining the Type of Review Being Requested**

Complete the following box(es) to determine the appropriate level of review to request

|  |  |  |
| --- | --- | --- |
| **Box 1** | Yes | No |
| Does the research involve individuals under the age of 18, where the research is conducted in educational settings involving normal education practices: research on instructional strategies; research comparing different educational strategies; AND the researchers are not directly interacting with participants of this research? | ☐ | ☐ |

 If you answered yes to the question in Box 1, and this is the only component of your research protocol, your proposal can be reviewed as Exempt. If you answered Yes to Box 1 but there are other components to your research or if you answered No to the question in Box 1, answer the questions in Box 2.

|  |  |  |
| --- | --- | --- |
| **Box 2**  | Yes | No |
| Does the research involve individuals 18 years and under? (If you answered Yes to the question in Box 1, and that is the only involvement of individuals 18 years and younger, answer No). | ☐ | ☐ |
| Does the research involve individuals with impaired cognitive ability? | ☐ | ☐ |
| Does the research involve pregnant females where they will be the only individuals participating in the study? | ☐ | ☐ |
| Does the research involve deception or incomplete disclosure? | ☐ | ☐ |
| If the research protocol involves collection of identifiable information from participants, could the information collected put participants at risk of civil or criminal liability or be damaging to the respondent’s financial standing, employability, or reputation? Check No if the only participants are elected or appointed public officials or candidates for public office. | ☐ | ☐ |

If you answered YES to ANY of the questions in Box 2, your proposal will require an Expedited or Full Review by the IRB, please go to Box 4 and answer the questions. If you answered NO to ALL of the questions in Box 2 please answer the questions in Box 3.

|  |  |  |
| --- | --- | --- |
| **Box 3** | Yes | No |
| Does the research protocol involve ONLY the use of educational tests, survey procedures, interview procedures, or observation of public behavior? | ☐ | ☐ |
| Does the research protocol involve ONLY the collection or study of existing information in public databases? | ☐ | ☐ |
| Does the research protocol involve ONLY the collection or study of existing information in non-public databases where all identifying information is removed? | ☐ | ☐ |

If you answered YES to ANY of the questions in Box 3, your protocol can be reviewed as Exempt. If you answered NO to ALL of the questions in Box 3, your proposal will require an Expedited or Full Review.

|  |  |  |
| --- | --- | --- |
| **Box 4** | Yes | No |
| Does the research protocol involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior? | ☐ | ☐ |
| Does the research protocol involve new studies of drugs already on the market where risks to participating individuals are minimal? | ☐ | ☐ |
| Does the research protocol involve collection of blood samples by finger stick from healthy, nonpregnant adults who weigh at least 110 pounds, where the amounts drawn do not exceed 550 ml in an 8-week period and collection does not occur more frequently than 2 times per week?  | ☐ | ☐ |
| Does the research protocol involve collection of biological specimens for research purposes by noninvasive means, such as (a) saliva collected without stimulation or stimulated by chewing gumbase or wax, or applying dilute citric acid to the tongue; (b) dental plaque and calculus collected in a manner consistent with routine prophylactic techniques; (c) mucosal cells collected by buccal swab or mouth washing? | ☐ | ☐ |
| Does the research protocol involve the collection of data through noninvasive procedures such as (a) physical sensors applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) testing sensory acuity; (c) weighing; (d) using electrocardiography or electroencephalography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. | ☐ | ☐ |
| Does the research protocol involve materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)? | ☐ | ☐ |
| Does the research protocol involve collection of data from voice, video, digital, or image recordings made for research purposes? | ☐ | ☐ |
| Does the protocol involve research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies? | ☐ | ☐ |

If you answered YES to ANY of the items in Box 4, your protocol can be reviewed as **Expedited.**

If you answered NO to ALL of the items in Box 4, your protocol needs to be reviewed as **Full.**

**Participant Information**

Define the participants from whom information is being collected. This helps to ensure that the correct level of review is conducted.

**Project Description**

**Date Submitted**

Self-explanatory

**Project Title, Description, and Rationale**

Provide a Title and description that can be understood by someone who is not an expert in the proposed field of study, and which explains why the study is important. Avoid jargon or technical language. Explain why the study is important.

**Is the research a continuation of a previously reviewed and approved project?**

Answering “yes” means that this study is a continuance of a previous study. A new or related study, even if it is informed by previously approved work, is not considered to be a continuation.

**Methods/Procedures**

Describe the methods to be used to conduct the study and collect data. Explain specifically how data will be protected (e.g., including how data will be handled, stored, and destroyed, who has access to the data, etc.). A step-by-step listing of methods will enable the IRB to see the rationale and plan of the methods.

**Sharing Research Results**

If the work is a senior comprehensive project, then participants can be directed toward the college D-space where the results may be found. For course projects, a written summary may be provided. For work that is published on a college website or in a professional outlet, identifying the locations of the work, if they are publicly accessible, may be acceptable. Other means of sharing may be acceptable. It is the duty of the investigator to ensure that results are shared with interested participants**.**

**Data Type**

Data are anonymous only when there is no information that can identify the participant (e.g. name, unique descriptors, etc.)

Data are confidential when the participant’s identity could be linked with their responses, but those responses will not be seen by anyone other than the PIs, and any data made public will omit identifying details. Confidential data requires a high degree of data security (e.g. locked in an employee office or on a dedicated, password-protected computer or location.)

COVID-19

Given the current COVID-19 crisis, describe how this study avoids the risk of infecting participants with COVID-19.

**Compensation**

Allegheny College does not pay participants for being in a study. Researchers are allowed to raffle off gift cards, with a limit of $23 dollars (more than that is considered taxable income). Cash cards (MC, VISA, etc.) and Amazon gift cards (considered to be cash cards) are not allowed.

**Type of Research**

Self-explanatory

**Incomplete Disclosure or Deception:** In some cases, it is necessary to withhold information from participants in the description of the research, and in the Informed Consent document. Because of this, research that involves either Incomplete Disclosure or Deception is mandated to provide a complete debriefing with participants following the completion of the study. Thus, these research protocols need either Expedited or Full Review.

**Informed Consent Documentation**

Select the appropriate categories (ME1-13) if you seek to modify or exclude various elements of informed consent

**Research that requires Incomplete Disclosure or Deception**

If your study requires incomplete disclosure or deception, then complete the table, identifying for which element(s) (IDD1-9) you seek a waiver.

**Appendices**

Attach all relevant appendices to the end of the application. They must be included in the single PDF document that you submit. Do not submit as separate attachments.

**Proposal Submission Checklist**

Complete the checklist to ensure that your application is complete

**Single PDF**

**Proposals must be submitted as a SINGLE PDF file. If there are permission letters, those must be scanned and appended to the end of the proposal.**

**Proposal File Title for Submission**

Must follow this format:

For Faculty Principle Investigator:

LASTNAME\_IRBPROPOSAL\_YEAR\_TwoWordDescriptor

Example: BAGGINS\_IRBPROPOSAL\_2020\_POWER RINGS.PDF

For Student PI (for example, a senior comp):

FACULTYSUPERVISORLASTNAME\_STUDENTLASTNAME\_IRBPROPOSAL\_YEAR\_TwoWordDescriptor

Example: SOCRATES\_PLATO\_IRBPROPOSAL\_2020\_HemlockEfficiency

All proposals must be submitted as PDF files; Word or other text files will not be accepted (this ensures that work submitted by proposers cannot be altered intentionally or unintentionally by anyone other than the submitter.

**Site for Submission**

Completed proposals must be submitted via e-mail to the current chair of the IRB, except for student research with human subjects that is supervised by a faculty member in Psychology. In this case the application should be submitted to the current chair of the Carnegie Subcommittee. Committee chairs are listed on the IRB website.

**Review**

Review typically takes two weeks. If the committee hasn’t responded by then, the faculty PI or supervisor may wish to send a brief email to the committee chair to whom the proposal was sent and make sure there isn’t a problem. Most proposals require at least some editing or modification, requiring a submission of an edited version, and then a re-review by the committee. It is important, therefore, that investigators plan accordingly so that proposed work can be conducted in a timely manner. It is not the responsibility of the IRB to ensure that research is conducted at the convenience or efficacy of the proposer.