***Allegheny College Institutional Review Board (IRB)***

***REQUEST FOR IRB REVIEW***

**Submission of IRB application**

* IRB requests must be submitted by a member of the Allegheny faculty or staff
* Students cannot submit requests directly
* Applications should be submitted as a SINGLE PDF file (excluding documentation of CITI course completion, these can be separate files)
* Naming Files must follow the protocol below:
	+ FACULTYLASTNAME\_IRBPROPOSAL\_ACADEMICYEAR\_TWO-WORDDESCRIPTOR
	+ (e.g. JONES\_IRBPROPOSAL\_2017\_FOOD-SURVEY)

Completed applications should be submitted to aconnell@allegheny.edu as pdf documents. The only exception to this is in cases where the application is for a senior project or independent study human participant research study supervised by a faculty member in Psychology. In this case the application should be submitted to jheucher@allegheny.edu.

**IRB Approval**

Approval to conduct research is based on the information/materials submitted with this application.  Using the information in the boxes below, you will identify the level of review. However, based upon the information included, a different level of review may be determined by the IRB. If so, the original proposal will be returned to you for revision. A change in procedure, materials, or information after initial approval by the IRB requires that you file an addendum for review.

**Note: In cases where you see “Click here to enter text” after you click on the active box you can either type in information or copy from another document and paste into the box.**

**Contact Persons**

If the principal investigator is a student, then information for the primary faculty supervisor must also be include in the table below

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator name(s)** | **Email**  | **Telephone**  | **Address/Office**  |
|   |  |  |  |
|  |  |  |  |

**Project Description**

|  |  |
| --- | --- |
| **Date Submitted** |  |
| **Title of Project** |  |
| **Brief (25-word limit) Description of****the Project** |  |

[**Researcher Ethics Certification**](http://sites.allegheny.edu/committees/institutional-review-board/irb-citi-training/)

Complete the following information on all persons involved in the research including the PI, faculty supervisor, and any research collaborators/assistants.

* For status, indicate whether the person is faculty, student, administration, staff, or community partner.
* Before any project can be approved, all persons involved in the design, data collection, and/or analysis must have completed the appropriate Collaborative Institutional Training Initiative (CITI) Course.  Faculty, administrators, staff and students who are originators of the research design, or advisors of a student project, must complete the Social and Behavioral Research CITI (SBR) Course; the Responsible Conduct of Research Course may not be substituted. Students who are not originators of the research design, but who are involved in the project, must complete the Students Conducting No More than Minimal Risk Research (SCMRR) Course. Below please include the completion date and the abbreviation of the course. Also, please submit the certification of completion when submitting the completed proposal.

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| --- | --- | --- |
| Name | Status | CITI Course Completion: Date and Course |
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**Type of Research** (Please check all that apply)

☐ faculty research

☐ senior project research Department \_\_\_\_\_\_\_\_\_\_

☐ course research Course Number \_\_\_\_\_\_\_\_\_\_

☐ administration research

☐ other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_

**Research History and Funding**

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

☐Yes ☐ No

Is the research funded by either external or Allegheny College research grants?

 ☐ Yes ☐ No

If yes, please indicate the type of grant received and its source. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Descriptions of Review Requests:**

**Exemption:** Research that involves no more than minimal risk and meets criteria specified by federal regulations may qualify for exemption. In this case, 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. Thus, for “Exempt” research, it is not necessary to have documented consent. See below for more guidance on what to include in proposals for research protocols that are Exempt. These proposals are reviewed by one member of the IRB.

**Expedited Request:** The Institutional Review Board (IRB) uses an Expedited review process to review studies that meet the categories adopted by the Department of Health and Human Services (HHS) that involve no greater than “minimal risk.” Expedited review procedures allow the IRB to review and approve studies that meet the criteria without a Full Committee Review. In this research, documented Informed Consent is required. These proposals are reviewed by the Chair and one other member of the IRB.

**Full Review:** Research that cannot meet the criteria for Exempt or Expedited review must be submitted for Full Review. For this research, documented Informed Consent is required. These applications are reviewed by all members of the IRB

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

To determine the level of review for your research protocol, please answer the questions in the boxes in the order they appear. Follow the directions carefully to most efficiently determine what level of review is required for your protocol.

|  |  |  |
| --- | --- | --- |
| **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. Please go to page 6 and complete the remainder of the information. Do not complete the remainder of the boxes. 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 here). | ☐ | ☐ |
| 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, please go to page 6 and provide the requested information.

If you answered NO to ALL of the questions in Box 3, your proposal will require an Expedited or Full Review by the IRB. Please answers the questions in Box 4.

|  |  |  |
| --- | --- | --- |
| **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. Please proceed to page 8 of the Application Form.

What type of review are you requesting? (please place an X on the appropriate line)

 \_\_\_ Exempt

 \_\_\_ Expedited

 \_\_\_ Full

**Participant Information** (Participants are those from whom information is being collected.)

|  |  |  |
| --- | --- | --- |
| **Participants will be:** | **Yes** | **No** |
| Allegheny College students | ☐ | ☐ |
| Allegheny College employees | ☐ | ☐ |
| Adults NOT belonging to vulnerable group | ☐ | ☐ |
| Adults belonging to an identified vulnerable group (e.g., prisoners, nursing home residents, patients, cognitively impaired, etc.) | ☐ | ☐ |
| Individuals who are 18 years and under | ☐ | ☐ |

**Participant Compensation**

Will participants receive any form of compensation for their participation? Yes ☐ No ☐

**If yes,** indicate the compensation provided.

Description and Rationale of Project (250 word limit) Information can be pasted into box below

Methods/Procedures (Describe the methods/procedures to be used to collect data.) Please include whether you will be collecting the data in an anonymous, confidential manner, or neither. Also, include how you will report the information gathered. It is important here to consider demographic questions, and why you are asking them, since, while we might not like to acknowledge this, certain answers to certain questions may put an individual at risk of civil or criminal liability or be damaging to respondent’s financial standing, employability, or reputation. Information can be pasted into the box below.

**Survey or Focus Group Questions:** In an appendix or appendices (for protocols using more than one instrument) include the list of questions to be asked or administered to your research participants. Since members of the IRB may not be familiar with certain instruments, we ask that even in cases where the questionnaires or surveys have been published, we ask they be included (this allows the IRB to review the submissions more efficiently).

**Signed Approval Forms:** If your research involves using specific courses, groups, or organizations, we ask that you provide a signed document from the appropriate individual. It is necessary to have a signed document, an email approval is not sufficient. It is customary for individuals who are asking for approval to provide this authority with a document that details what is being requested, and a place for their signature, date, their title, and their printed name.

**Information provided for participants (EXEMPT protocols):** While the federal guidelines for EXEMPT protocols do not require documenting informed consent, it is encouraged that researchers provide information, either in writing or verbally, to the participants about the purpose of the research, their time commitment, that participation is voluntary, and that they can choose to decline to answer any question or leave the study at any time. This is a component of ethics for even those studies that pose no or no more than minimal risk to participants. If there is potential that your target audience for the research will include individuals who are under the age of 18, please indicate how you will exclude them from the study.

 In addition, while these protocols are not required to include a debriefing statement, it is encouraged that participants be thanked for their time after completion of the study, and be provided an opportunity to receive the outcome of the research.

 We also strongly encourage that, if you have utilized and Allegheny College or off campus organization or group, the person who wrote the approval letter for the organization or group, be provided a summary or full report of the results of this research. Please include a description of the information provided for the participants prior to beginning study as well as information you will provide following the completion of the study. These can be attached as appendices. Also, if specific individuals will be identified in your final report, please include the script you will use to ask for permission, AND, it is recommended that in these instances, you obtain a signed document that provides a record of this consent.

**If you are completing an application for an EXEMPT Protocol, you may stop here.** Please submit all information as one pdf document, including, as appendices, survey instruments to be used, the letters for approval (if applicable), information provided for participants prior to and after participation, and forms for obtaining signatures if names of individuals will be used in your final report.

**Informed Consent Documentation (EXPEDITED or FULL REVIEW) - please fill out table on next pg**

The table below identifies the major elements of informed consent, and, this document is required for protocols that fall under the Expedited or Full review categories. Please review them carefully and then indicate whether the element will be included or if a modification or exclusion is being requested for that element. Please include the Informed Consent document with this application.

**Requests for Modification or Exclusion of Elements of Informed Consent**

IRB applicants are allowed to **modify or exclude elements** of in the informed consent document above if all of the following conditions are met:

1. The research involves no more than minimal risk.
2. Participant rights are not altered by a waiver/modification.
3. The research could not be practicably conducted without the modification.
4. The participants are fully debriefed, including an explanation for the modification, following participation whenever possible.

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|  | **Please place an X in the appropriate column** | **Modification Requested** | **Element Included** |
| 1. | Statement that participation is voluntary and that there can be no consequences for either failure to participate or termination of participation.  | ☐ | ☐ |
| 2. | A place for the participant to affirm that they are over 18 | ☐ | ☐ |
| 3. | Statement that the project is research | ☐ | ☐ |
| 4. | Statement of the rationale for the research | ☐ | ☐ |
| 5. | Description of the length of participation | ☐ | ☐ |
| 6. | Description of the methods/procedures to be used | ☐ | ☐ |
| 7. | Identification of experimental procedures | ☐ | ☐ |
| 8. | Description of any foreseeable risks or discomfort | ☐ | ☐ |
| 9. | Statement of the benefits of the research to the participants or others.  Note:  Compensation is not seen as a benefit.  | ☐ | ☐ |
| 10. | Statement about the extent to which information provided by participants will be kept anonymous or confidential.  | ☐ | ☐ |
| 11, | If more than minimal risk is involved, an explanation of available treatments should injury occur and where additional information can be obtained.  | ☐ | ☐ |
| 12. | Contact information for both the researcher (and research supervisor if the researcher is a student) along with the chair of the IRB in case there is injury or a question concerning participant rights.  | ☐ | ☐ |
| 13. | A place for the participant to sign the informed consent document | ☐ | ☐ |

Please justify the rationale for exclusion of any of the elements of informed consent.

If you are doing research involving individuals who are under the age of 18, then, you should have asked for a waiver to element 2. In this case, it will be necessary to present the informed consent document to the child’s parent or guardian to obtain their signature. In addition, you are asked to indicate how you will inform the children of the specifics of the research, and obtain the assent or refusal to participate. In cases where they are able to provide a signature, it is encouraged that you do so, in other cases, indicate how you will document assent or refusal. Please include a document containing the information to be present to the child with this application.

In some cases it is appropriate to obtain verbal agreement to participate, rather than a signature. In these cases you should have asked for a waiver to item 13. In these cases indicate the rationale for obtaining verbal rather than written consent. Indicate how you will document the verbal consent. If is often advisable to request a waiver for a signed document, especially if it has potential to link the individual to the research and would thus constitute a breach of confidentiality.

In cases where the only contact the researcher has with the participant is through electronic means, then, you should also request a waiver for obtaining a signature on the informed consent document. If you are conducting an electronic survey, and will not have the ability to obtain a physical signed consent document, please indicate how you will confirm consent.

**Research that requires Incomplete Disclosure or Deception.**

In cases where the researcher chooses not to disclose all information about the research to the participants at the beginning of the study, then, you should have asked for waivers of several of the elements of informed consent. In cases where Incomplete Disclosure or Deception is used, it is required that participants be debriefed at the end of their participation. If you chose to use Incomplete Disclosure or Deception as part of your research design, please complete the table below regarding the elements to be included in the debriefing statement. We STRONGLY discourage you from waving any elements in the Debriefing statement. If you are concerned about the “leaking” of information between participants, it is encouraged that you include a statement in the debriefing statement asking them to not disclose elements of the study to others, and the reasons you are asking this. If you chose to waive elements of the Debriefing statement, it is necessary to provide a strong rationale for doing so.

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| **Components of a Complete Debriefing are given below, please place an X in the correct Column.** **Note, if you have not used either incomplete disclosure or deception, PLEASE DO NOT COMPLETE THIS TABLE** | **Modification Requested** | **Element Included** |
| Debriefing immediately following participation in the study. | ☐ | ☐ |
| An explanation of the rationale for the research and the procedures used.  | ☐ | ☐ |
| An explanation and justification of any deceptions used in the research.  | ☐ | ☐ |
| A statement of the research hypotheses.  | ☐ | ☐ |
| An offer to provide participants with a copy of the findings of the research when completed with appropriate contact information to request the results  | ☐ | ☐ |
| Contact information for the principal investigator, the research supervisor (if the PI is a student), and the chair of the IRB.  | ☐ | ☐ |
| Sources the participants might consult if they desired additional information on the topic.  | ☐ | ☐ |
| An opportunity to ask any questions and/or have concerns addressed  | ☐ | ☐ |

Please justify any waivers of the debriefing, and include the debriefing document with the remainder of the components of this application.

**Research not involving Incomplete Disclosure or Deception.**

If you have not used incomplete disclosure or deception in your research, it is not mandated that you provide a debriefing. However, it is encouraged that participants be thanked for their time after completion of the study, and be provided an opportunity to receive the outcome of the research.

 We also strongly encourage that, if you have utilized an Allegheny College or off campus organization or group, the person who wrote the approval letter for the organization or group, be provided a summary or full report of the results of this research.

In the application please include information you will provide participants following the completion of the study.

**Please include all of the information requested in one pdf document.**

For inclusion of additional pages in this application, it will be necessary compose them in a different Word document. To enter that material into this document, copy it and then paste it into the active text box below. When finished, convert the entire document to the pdf format.