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| **Overview** |

The Human Research Protection Program (HRPP) developed the following guidelines to inform researchers of their responsibilities when conducting either exempt or non-exempt Human Subjects Research.

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| **Education** |

Researchers are responsible for completing training on the conduct of human subjects research prior to engaging in the human subjects research activities. The Principal Investigator (PI) is responsible for overseeing the training of all research team members, including those who collect or work with identifiable data, and/or those who fit under the HRPP criteria of key personnel. The principal investigator must maintain records of training for these research personnel and make such records available for inspection at the request of the HRPP and/or the Institutional Review Board (IRB).

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| **Maintaining Ethical Standards** |

Researchers are responsible for conducting research in accordance with the ethical principles outlined in the Belmont Report. These are the fundamental ethical principles upon which human subject protections are based:

• **Respect for Persons.** Ethical research honors the autonomy of individuals to make an informed choice about participation in research and provides suitable protection for vulnerable persons.

• **Beneficence.** Ethical research has scientific or scholarly value in which the potential benefits outweigh the risks that are justified and minimized.

• **Justice.** Ethical research is designed and conducted so that the burdens and benefits are fairly distributed.

More in-depth information about the Belmont Report is found at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

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| **Conduct of Research** |

Researchers are responsible for ensuring the research is conducted according to the IRB approved protocol. Students may not serve as PI. Principal Investigators must be responsible for the actions of all co-investigators and researchers, which also means being responsible for any non-compliances of the research team. PIs must ensure that students are adequately prepared to conduct human subject research as well as the IRB application process. This includes not only completing the required educational training, but also writing the IRB application. PIs are responsible for reading and approving each IRB application prior to submission. This review is documented by the PI’s signature on the application.

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| **Subject Enrollment and Informed Consent** |

Researchers must obtain formal approval from the Purdue HRPP/IRB prior to advertising, recruiting, or enrolling participants in a study. A subject is “enrolled” in the research once they have signed an informed consent document. Alternatively, if signed consent has been waived by the IRB, enrollment occurs when a person has otherwise been identified as a research subject as outlined in the approved protocol.

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| **Changes to Protocols and Renewals Requiring IRB Review** |

Researchers must submit an amendment to the IRB if revisions or changes to any aspect of the protocol are necessary. Such changes pertain to research team members, research design, procedures, number of subjects, subject population, and changes to consent documents, study instruments or recruitment materials. IRB approval must be obtained before implementing any changes, unless the change is to remove an immediate hazard to subjects in which case the IRB should be immediately informed following the change.

The expiration date of a protocol appears on the IRB approval notice. Prior to the expiration date of the protocol, researchers are required to submit a completed Continuing Review Form with any required supplementary materials per the processes documented in IRB SOP 304 “Continuing Review”. It is the researcher’s responsibility to submit the Continuing Review Form and any supplementary materials in a timely manner to ensure a lapse in IRB approval does not occur. Once the protocol’s approval expires, researchers must cease all research activities related to the protocol until the protocol is once again in approved status.

Some minor changes that do not result in increased risk or burden or decrease in benefits to participants may not require IRB review. Examples of minor changes not requiring review by IRB include:

* Rescheduling of data collections when a participant misses an appointment or data collection is incomplete due to unforeseen circumstances that do not increase risk to participants (e.g., equipment failure resulting in data collection cancellation, etc.).
* Removal of study instrument(s) so long as it does not reduce any previously found direct benefit or ocompensation to participants.
* Minor editorial changes to study instruments or recruitment material (e.g., corrections of grammar/language to increase participant understanding).
* Updating dates and times related to when research activities will occur (so long as such dates/times and number of data collection activities are within the approved protocol period).
* Changes to recruitment material to update contact information.

However, all changes to personnel or procedures must be reported. A self-reported end date must be indicated on applications by the research team.

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| **Reporting**  |

Researchers are responsible for reporting unanticipated problems and adverse events to the IRB. If the problem/adverse event is serious, or the problem/event is expected but occurs with unexpected severity or frequency, or the problem/event is unanticipated it must be reported to the IRB in accordance with the procedures outlined in IRB SOP 409 “Unanticipated Problem & Adverse Event Reporting”, posted on the Purdue IRB website. PIs may also choose to self

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| **Record Retention** |

Researchers must retain research records for at least three (3) years after the closure of the IRB approved protocol. All research records regulated by the Health Insurance Portability and Accountability Act (HIPAA), including research authorizations and waivers of authorization must be kept for at least six (6) years after closure of the protocol.

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| **Conflicts of Interest** |

Regardless of their role in a study, researchers must disclose any conflicts of interest. Scenarios constituting real or perceived conflicts of interest must be reported on the IRB application. The IRB will work with the investigator and relevant offices to evaluate any necessary steps for management and mitigation of risk to participants. Conflicts of interest include conflicts as defined by Purdue University Policy as well as any conflicts related to the conduct of the study (e.g., a faculty member wishing to recruit their own students to participate in their research study, financial conflicts of interest).

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| **Post Approval/Exemption Monitoring** |

Researchers exempted or approved by the Purdue HRPP/IRB are responsible for facilitating the periodic review associated with conduct and recordkeeping in studies. Routine review is a necessary component of an IRB protocol and contributes toward the shared goal of human subjects research protections. Monitoring is conducted in accordance with Purdue University HRPP Standard Operating Procedure 306, “Post Approval Monitoring”. In-person reviews are conducted between designated post-approval monitoring staff and research personnel to confirm that all measures are documented appropriately in an IRB approved protocol.