Statement of Purpose, Authority, and Responsibility

Updated July 19, 2018

INTRODUCTION

1. Purpose

The Purdue Human Research Protection Program (HRPP) implements Purdue's commitment to protect human research participants through application of Belmont Report principles (Respect for Persons, Beneficence, and Justice).

The HRPP organizational structure exists as an extension of the Office of Research and Partnerships. As a component of HRPP, the Purdue University Institutional Review Boards (IRBs) are charged with ethical review of proposed research with human subjects.

2. Authority

HRPP and associated IRBs have the support of the Purdue University administration under Purdue University Policy B-45. Purdue University requires that all research projects involving humans as subjects, human material, or personally identifiable data be reviewed and approved by the IRB(s) prior to initiation of any research related activities, including recruitment and screening activities.

IRBs have been established to review biomedical and behavioral research involving human subjects regardless of the source of funding and location of the study. Each IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically, when Purdue University investigators are involved:

- The IRB may disapprove, modify, or approve studies based upon consideration of human subject protections;
- The IRB reviews, and has the authority to approve, require modification, or disapprove, all research activities that fall within its jurisdiction;
- The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators and auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
- The IRB may require third party observation of any human subjects research (including, but not limited to recruitment, consent, data collection, or analyses);
- The IRB may suspend or terminate approval of a study; and
- The IRB may place restrictions on a study or disallow use of collected data from human subjects.

The IRB functions independently of, but in coordination with, other institutional research review committees appropriate for consultation and guidance on issues related to protection of human subjects (e.g., exposure to radiation). Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials or other committees or Purdue University's Office of Legal Counsel. However, those officials or committees may not approve research if it has been disapproved by an IRB.

Failure to submit a research project for IRB review will be treated as noncompliance with university and federal regulations, and is subject to consequences determined by the IRB and, as deemed necessary, by Purdue University. Results from such studies may not be shared or published unless IRB approval had been obtained prior to collecting the data.

3. Responsibility

Purdue University IRBs subscribe to the same underlying principles and authorities. All research involving human subjects conducted by Purdue employees or affiliates must be reviewed and approved by at least one of Purdue IRBs. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of “research” or “human subjects,” and their implications for the jurisdiction of the IRB under Institutional policy are determined by the IRB.

The IRB's sole responsibility is to protect the rights and welfare of human subjects. The IRB reviews and oversees such research to ensure that it meets well established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines.

Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46, all research involving human subjects, and all other activities, regardless of sponsorship, are subject to IRB review and approval if the activity meets the definitions of Human Subjects Research as outlined in the federal regulations and Standard Operating Procedures (SOP) detailed herein.

The Purdue University Human Research Protection Program Standard Operating Procedures (SOPs) are acceptable and current in the versions represented in this compiled document.

SOP #	**SOP Name**	**Date of Approved Version**
201	IRB Membership	08/21/2020
202	IRB Meeting Administration	07/01/2019
203	Documentation and Records Management	08/21/2020
204	Protocol Closure	07/01/2019
300	Determination of Human Subjects Research	07/01/2019
301	Exemption Determinations	08/21/2020
302	Initial Review	08/21/2020
303	Expedited Review	08/21/2020
304	Continuing Review	08/21/2020
305	Amendment Requests	08/21/2020
306	Post-Approval Monitoring	08/21/2020
320	Informed Consent Requirements	07/01/2019
321	Waiver or Alteration of Informed Consent	07/01/2019
408	Noncompliance	08/21/2020
409	Unanticipated Problem & Adverse Event Reporting	08/21/2020
410	Suspension or Termination of Research	07/01/2019
501	Research Involving Pregnant Women, Fetuses, and Neonates	07/01/2019
502	Research Involving Children	07/01/2019
503	Research Involving Prisoners	07/01/2019
600	Additional Protections Beyond The Common Rule	08/21/2020

DocuSigned by:
Stephen Elliott
832A337B022E421...

8/18/2020

Stephen Elliott, Ph.D. — Date
IRB Chair

DocuSigned by:
Christopher R. Agnew
10B088AFA9744AE...

8/18/2020

Christopher R. Agnew, Ph.D. — Date
Institutional Official