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1. Overview

Purpose

Drexel University fosters a research environment that promotes respect for the rights and welfare of human participants. In support of this, Drexel University has established a Human Research Protection Program (HRPP). The Drexel University HRPP, in partnership with its research community, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under Drexel University's auspices. The purpose of this document is to describe the Drexel University's HRPP. These procedures apply to all human subject research conducted under its auspices or as reviewed by the Drexel University IRB, regardless of funding or support. These procedures establish the Drexel University's HRPP mission, organizational authority, ethical principles, regulatory compliance, purview, engagement, structure, and responsibilities.

2. Drexel University HRPP

2.1 Mission

The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- Provide timely and high-quality education, review and monitoring of human research projects; and
- Facilitate best practices and excellence in the conduct of human subjects research.

The HRPP includes mechanisms to:

- Monitor, evaluate and continually improve the protection of human research participants;
- Exercise responsible oversight of research protection;
- Educate IRB members, investigators and research staff about their ethical responsibility to protect research participants; and
- When appropriate, intervene in research and respond directly to concerns of research participants.

2.2 Organizational Authority

Drexel University's HRPP operates under the authority of the "Human Research Protection Program (HRPP)", accredited on June 14, 2013. As stated in that document, the operating procedures in this document "…serve as the governing procedures for the conduct and review of all human research conducted under the auspices of Drexel University. The Drexel University's HRPP procedures are made available to all Drexel University staff, faculty, students, IRB members, and members of the public and are posted on the Office of Research & Innovation (ORI) website.

These procedures and guidelines also cover research involving human participants conducted under the auspices of the Academy of Natural Sciences, and other institutions and entities where Drexel University's HRPP or ORI has executed a reliance agreement, memo of understanding or

other agreement, respectively, that requires the use of Drexel University's procedures and guidelines.

3. Ethical Principles

Drexel University is committed to conducting research with the highest regard for the welfare of human subjects. With the exception of transnational research, where consideration of alternative ethical principles may apply (see additional Drexel HRP procedures), Drexel University upholds and adheres to the principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). These principles are:

1) Respect for Persons, which involves the acknowledgement and support of autonomy, and protection of those with diminished autonomy.
   a) This includes obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations
2) Beneficence, which involves ensuring that possible benefits are maximized and possible harms are minimized to all human subjects.
3) Justice, which involves the fair distribution of the benefits and burdens of research through the equitable selection of subjects.

4. Regulatory Compliance

The HRPP facilitates compliance with federal regulations, state and local law, and organizational policies. Human subjects research at Drexel University is conducted in accordance with applicable regulations and requirements including, but not limited to, the following:

1. Human subject research conducted, supported, or otherwise subject to regulation by any federal department or agency which adopts the Common Rule is reviewed and conducted in accordance with the Common Rule. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in 45 CFR 46 Subpart A. For the purposes of this document and all other HRPP SOP's and guidelines, references to the Common Rule will cite the DHHS regulations (45 CFR 46).
2. Research subject to FDA regulations is reviewed and conducted in accordance with applicable regulations including, but not limited to, 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.
3. Research conducted or supported by the Department of Justice (DOJ) is subject to the pre-2018 Common Rule with regulations published at 28 CFR 46. The DOJ has established additional requirements for research conducted with the federal Bureau of Prisons (28 CFR 512) and research involving the National Institution of Justice (29 CFR 22). Investigators should consult these regulations and resources provided by NIJ when developing their research protocol. The IRB evaluates the research in accordance with these regulations when applicable (see additional Drexel HRP procedures).
4. When human subjects research is not subject to the Common Rule, FDA, or DoJ regulations, Drexel University ensures that human research subjects benefit from equivalent protections by applying the Common Rule standards, with purposeful deviations that do not meaningfully diminish protections as noted within the HRPP policies and procedures.

5. Research involving the use of Protected Health Information is reviewed and conducted in accordance with the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Part 160, 162, and 164 (see additional Drexel HRP procedures).

Several other U.S. federal departments and agencies have additional rules that apply to human subjects research that is supported by, conducted for or with, or involving the personnel or facilities of the department or agency. The IRB will evaluate such research in accordance with the applicable rules and requirements. Additional information regarding department/agency specific rules is available in the designated SOP's such as U.S. Department of Defense (DoD), U.S. Department of Education (DoE), U.S. Environmental Protection Agency (EPA), and the Family Educational Rights and Privacy Act (FERPA).

4.1 Applications of Federal Regulations

The revised Common Rule (2018) is applied to human research that is IRB-approved, or determined exempt, on or after January 21, 2019. Additionally, the revised Common Rule is applied to any studies subject to the pre-2018 version of the Common Rule that Drexel University decides to transition.

Planned emergency research with exception from informed consent, as outlined in 21 CFR 50.24 and 45 CFR 46.101(i) is typically not conducted at Drexel University with the exception of a public health emergency. Special permission must be obtained by the HRP, ORI and University leadership prior to engagement in planned emergency research.

4.2 International Conference on Harmonization-Good Clinical Practice (ICH-GCP)

Drexel University applies the International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Guidelines (sometimes referred to as "ICH-GCP" or "E6") to clinical research conducted under its auspices. In accordance with ICH-GCP guidance (E6), clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with ICH-GCP and the applicable regulatory requirements.

5. Federalwide Assurance (FWA)

Federal regulations require that federally-funded human subject research only be conducted at facilities covered by a Federalwide Assurance (FWA) approved by the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). An FWA is an organization's assurance to the federal government that human subject research conducted at that site is in compliance with federal regulations pertaining to the protection of human subjects. The FWA designates the IRB that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research.

Drexel University has an OHRP-approved Federalwide Assurance (FWA00005917) and has designated 2 IRB(s).

In its FWA, Drexel University has opted to limit the application of the FWA to non-exempt human subject research conducted or supported by DHHS or federal agencies that have adopted the Common Rule.

6. Research Under the Auspices of the University

Research under the auspices of Drexel University includes research conducted at Drexel University, conducted by or under the direction of any employee or agent of Drexel University (including students) in connection with their institutional responsibilities, conducted by or under the direction of any employee or agent of Drexel University using any property or facility of Drexel University, or involving the use of Drexel University's non-public information to identify, contact, or study human subjects.

Engagement

DHHS regulations [45 CFR 46.101 and 45 CFR 46.103[a]] require that an institution "engaged" in human subject research conducted or supported by a federal department or agency provide the OHRP with a satisfactory assurance of compliance with the DHHS regulations, unless the research is exempt under 45 CFR 46.104.

In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

1) data about the subjects of the research through intervention or interaction;
2) identifiable private information about the subjects of the research; or
3) the informed consent of human subjects for the research.

In general, institutions that receive an award through a grant, contract, or cooperative agreement directly from DHHS for the non-exempt human subjects research (i.e., prime awardee institutions), are also considered engaged in research even where all activities involving human subjects are carried out by employees or agents of another institution.

FDA regulations are oriented to the responsibilities of IRBs, investigators, and sponsors as opposed to institutions. In general, FDA-regulated research conducted in Drexel University facilities or by Drexel University Principal or Sub-Investigators (as defined on the FDA 1572 or delegation of responsibilities log) requires review by a Drexel University-designated IRB. Exceptions to this requirement may be granted on a case-by-case basis (e.g., when Drexel University's involvement in the research is limited to the provision of a common diagnostic procedure and associated reading or analysis).

The HRP personnel, with the assistance of the HRP Director and staff as needed, will determine whether Drexel University is engaged in a particular research study. Investigators and other institutions may not independently determine Drexel University's engagement.

When Drexel University is engaged in research, the research must be reviewed and approved by the Drexel University IRB or another designated IRB prior to the initiation of the research. See additional Drexel HRP procedures for details on ceding review to another IRB.

For additional information on determining engagement please refer to the OHRP's *Guidance on Engagement on Institutions in Human Subjects Research*.

7. Written Policies and Procedures

The Drexel University Standard Operating Procedures for Human Research Protection detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the Drexel University IRB. The policies and procedures are reviewed and revised by the HRP Director or their designee. The HRP Director will approve all revisions of the procedures.

The HRP Director will keep the Drexel University research community apprised of new information that may affect the HRPP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through campus electronic mailing lists and newsletters. The procedures are available on the Drexel University Office of Research & Innovation (ORI) website and printed/electronic copies are available upon request. Changes to the policies and procedures are communicated to investigators and research staff, and IRB members and IRB staff by way of the ORI website, town hall meetings, email, newsletters, and other methods as appropriate.

8. The Drexel University HRPP Structure

The Drexel University HRPP consists of various individuals and committees such as: the IO, the Executive Director of the HRP, the HRP/IRB personnel, the IRB(s), the Institutional Biosafety Committee (e.g., for gene transfer research), Radiation Safety Committee, Office of Sponsored Programs (OSP), Office of General Counsel, investigators, research staff, and health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer). The objective of this system is to assist Drexel University in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

9. Relationship Among Components

The Drexel University Compliance Committee, University Research Council, Board of Trustees through the Audit Committee and ORI's Research Compliance and Regulatory Affairs representatives meet distinctly and regularly to ensure a dialogue is maintained between the various compliance entities at Drexel University. Membership at these meetings is comprised of Directors, Institutional Senior Leadership, and other members from the following:

- Office of Sponsored Programs (OSP)
- Human Research Protections (HRP) Office
- Conflicts of Interest (COI)
- Office of General Counsel (OGC)
- Environment, Health and Radiation Safety (EHRS)
- Radiation Safety Committee
- Institutional Animal Care and Use Committee (IACUC)
- Compliance Program Services and Privacy Program Services
- Drexel Applied Innovation
- Stem Cell Review, e.g., ESCRO
- Human Resources
- Information Technology
- Research Quality Assurance Program
- Institutional Biosafety Committee (IBC)

10. Responsibilities

10.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections (HRP) Office are responsible for maintaining these procedures, applicable tools, training, granting exceptions, and monitoring. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

The HRP is responsible for ethical and regulatory oversight of research at Drexel University that involves human subjects. The HRP administers, supports, and guides the work of the IRBs and all related activities.

10.2 HRPP Responsibilities

The HRPP, in partnership with its research community, including researchers and research staff; Institutional Review Board (IRB) members and chairs; IRB staff; the Institutional Official (IO); and employees and students, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices.

The HRPP is responsible for ensuring compliance with federal regulations, state law and Drexel University policies.

10.3 Institutional Official Responsibilities

The ultimate responsibility of the HRPP resides with the IO. The IO is legally authorized to represent Drexel University. At Drexel University, the Executive Vice Provost for Research is the IO.

The IO is the signatory of the FWA and assumes the obligations of the FWA. The IO is responsible for ensuring that the Drexel University HRPP and IRB(s) have the resources and support necessary to comply with all laws, regulations, and policies that govern human subject research. Such resources include, but are not limited to:

- Staffing commensurate with the size and complexity of the research program;
- Appropriate office space, equipment, materials, and technology;
- Resources for the production, maintenance, and secure storage of HRPP and IRB records;
- Resources for auditing and other compliance activities and investigation of non-compliance;
- Access to legal counsel; and
- Supporting educational opportunities related to human research protections for IRB members, relevant administrative staff, and all members of the research team;
- Support for evaluation of COI; and
- Support for Community Outreach.

The IO maintains continuous oversight and conducts reviews of the HRPP and IRB through reviews of the annual AAHRPP report, check-ins, receipts of adverse events, meetings with leadership, and involvement in meetings.

The IO is also responsible for:

- Fostering, supporting and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and the adherence to regulations and policies;
- Ensuring that the IRB functions independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and members if they experience undue influence or if they have concerns about the function of the IRB;
- Oversight of the IRB;
- Oversight over the conduct of research conducted by all Drexel University investigators;
- Assuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- Assuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations; and
- Oversight of the development and implementation of an educational plan for IRB members, staff and investigators.

The IO must complete appropriate training on human research protections and has expertise in human research protections. The HRP Office will provide ongoing continuing education for the IO concerning human research protections.

The designated IO is made known to Drexel University employees and is accessible by phone, email, in person, or other methods of communication. The IRB Chairs and HRP Director have access to the IO for any concerns or issues related to the HRPP.

In the performance of these duties, the IO has the authority to delegate such activities as may be necessary in order to effectively administer the program. However, the IO is ultimately responsible and is expected to be knowledgeable about all human subject protections responsibilities at Drexel University.

10.4 Director of the HRP Responsibilities

The Director of the HRP is selected by and reports to the IO through the Associate Vice Provost for Research Compliance and Regulatory Affairs and is responsible for:

1. Developing, managing, and evaluating policies and procedures that ensure compliance with all state and federal regulations governing human subject research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing the administration of the IRB.
2. Advising the IO on key matters regarding research at Drexel University.
3. Implementing Drexel University's HRPP policies and procedures.
4. Submitting, implementing, and maintaining an approved FWA through the IO and the OHRP.
5. Assisting investigators in their efforts to carry out Drexel University's research mission.
6. Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.
7. Developing training requirements as required and as appropriate for investigators, IRB members and staff, and research staff, and ensuring that training is completed on a timely basis.
8. Serving as the primary contact at Drexel University for the OHRP of DHHS, the FDA, and other federal regulatory agencies.
9. Day-to-day responsibility for the operation of the HRP, including supervision of HRP staff.

10. Responding to questions regarding the protection of human subjects.
11. Working closely with the Chairs of the IRBs on the development of policy and procedures, as well as organizing and documenting the review process.

10.5 HRP Staff Responsibilities

In addition to the leadership structure described above, other support staff members for the HRP and IRB may include depending upon experience and expertise, IRB Coordinators and IRB Analysts. The Drexel University HRP and IRB staff must comply with all ethical standards and practices. The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis or as required by the University. The Drexel University HRP staff reports to the HRP Executive Director, who has day-to-day responsibilities for its operations.

10.6 Institutional Review Board (IRB) Responsibilities

Drexel University has two IRBs, appointed by the IO. The IRBs prospectively review and make decisions concerning all human research conducted at Drexel University facilities, by its employees or agents, or under its auspices unless another IRB has been designated to do so. The IRBs are responsible for the protection of rights and welfare of human research subjects at Drexel University through review and oversight of safe and ethical research. The IRBs discharge this duty by complying with the requirements of federal and state regulations, the FWA, and Drexel University policies. (See additional Drexel HRP procedures for a detailed description of the Drexel University IRB and external IRBs.)

The IRB functions independently of, but in coordination with, other Drexel University committees and officials. However, the IRB makes its independent determination whether to approve or disapprove a research plan based upon whether or not human subjects are adequately protected.

Research that has been reviewed and approved by an IRB may be subject to review and disapproval by Drexel University officials. However, those officials may not approve human research that has not been approved or has been disapproved by an IRB.

10.7 The Office of General Counsel Responsibilities

The Drexel University HRPP relies on the Office of General Counsel for the interpretations and applications of state law and the laws of any other jurisdiction where research is conducted as they apply to human subjects research. The Office of General Counsel will also advise the IRB about other legal issues such as who is a minor, and who can serve as a legally authorized representative or guardian based on applicable laws as requested. When there are any conflicts between federal or national law and other applicable laws, the Office of General Counsel will be consulted for guidance and to identify an appropriate resolution.

10.8 Department Chairs and/or Organizational Leaders Responsibilities

Department Chairs and organizational leaders are responsible for ensuring that the investigator is qualified by training and experience to conduct the proposed research. For each human subjects research study submitted to the Drexel University IRB for approval, the department chair or leader must certify that the department chair/leader accepts responsibility for supporting adherence to the federal and state regulations and Drexel University policies governing the

protection of human subjects of research, including applicable Drexel University credentialing requirements. Department chairs/leaders are responsible for assuring that investigators have the resources required to conduct the research in a way that will protect the rights and welfare of participants. Such resources include but are not necessarily limited to personnel, space, equipment and time.

Department chairs/leaders are required to review all proposals before they are submitted to the IRB for review. The attestation of the Department chair or leader when approving the routing of submissions to the IRB confirms that:

1. the investigator is qualified and has the necessary resources to safely conduct the study, and
2. attests to the scientific merit of this study, which means:
    - The research uses procedures consistent with sound research design; and
    - The research design is sound enough to reasonably expect the research to answer its proposed question.

Refer to Drexel procedures for Principal Investigators (ORI-002) and Research Agents (ORI-004) for additional details on departmental responsibilities.

10.9 Principal Investigator and Faculty Mentor Responsibilities

The principal investigator (and Faculty Mentor, as applicable) is ultimately responsible for the protection of the human subjects who participate in research. The investigator is expected to abide by the highest ethical standards when developing a research plan that incorporates the principles of *The Belmont Report*. The investigator is expected to conduct research in accordance with the IRB approved research plan and to oversee all aspects of the research by providing training and supervision of support staff, including oversight of the informed consent process. All subjects must give informed consent unless the requirement has specifically been waived by the IRB. Investigators must establish and maintain an open line of communication with research subjects within their responsibility. In addition to complying with all applicable policies and standards of regulatory bodies, investigators must comply with Drexel University requirements for conducting research. The investigator is responsible for ensuring that all research staff complete all required training as well as training for their responsibilities in any given specific research study. When investigational drugs or devices are used, the investigator is responsible for providing a plan for their storage, security, dispensing, accounting, and disposal. As a reminder, faculty mentors have the same responsibilities as the principal investigator.

Study-Specific Coordination

In addition to IRB approval, the Investigator must obtain and document the approval, support, or permission of other individuals and departments or entities impacted by the research as well as approval by other oversight committees or offices as applicable, including, but not limited to:

- St. Christopher's Hospital for Children
- Stem Cell Use (ESCRO Review)
- Affiliated Hospital(s)/Institutions
- Confirmation that permission to enter classrooms or hospital units will be obtained
- Confirmation that permission from external research locations (sites) will be obtained
- Privacy

- Registrar of the applicable institution for FERPA-covered student data
- Drexel University Minors Program
- Risk (i.e., insurance coverage)
- Third Party Risk Management (use of software or applications not managed by Drexel)
- Information Technology
- Departmental approvals
- Data or material access and use permissions (e.g., Medical, Educational Records, execution of a data use agreement or material transfer agreement)
- Institutional Biosafety Committee
- Radiation Safety Committee
- Conflict of Interest Program

For any that are indicated, a letter of support, collaboration, permission, or approval from the designated authority, may be requested at any time by the IRB or HRP Office. Final IRB approval may not be given until all necessary letters or documentations requests are received. The IRB may request review or consultation with any of the above listed or other Drexel University committees or components even when such review or consultation is not technically required by policy.

Other committees and officials may not approve research involving human subjects to commence that has not been approved or has been disapproved by the IRB.

10.10 Office of Sponsored Programs Responsibilities

The OSP staff review all research agreements with all sponsors including federal, foundation, and non-profit sponsors. Only designated individuals within ORI have the authority to approve research proposals and to execute research agreements on behalf of Drexel University.

The OSP ensures that required Association for the Accreditation of Human Research Protection Programs (AAHRPP) language is included in contracts.

OSP, the study team, and the IRB office coordinate efforts to ensure that all applicable individuals have filed appropriate COI disclosures to meet applicable COI policies and confirm that the contract and the consent documents are consistent in terms of costs to subjects and who pays in case of injury.

When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of Drexel University, a subcontract is executed between the Drexel University and the collaborating institution, unless an independent investigator agreement or other mechanism is executed to establish agency with Drexel University. The subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval. The collaborating institution must also ensure that key personnel involved in human subject research are in compliance with the U.S. National Institutes of Health's Required Education in the Protection of Human Research Participants Policy and provide documentation of education of key personnel to the Drexel University, when required.

11. Resources

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.
- World Medical Association - *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*
- 10 U.S. Code § 980 - Limitation on Use of Humans as Experimental Subjects
- DHHS Regulations: 45 CFR 46 - Protection of Human Subjects
- FDA Regulations: 21 CFR 50 - Protection of Human Subjects and 21 CFR 56 - Institutional Review Boards
- 32 CFR 219 - Protection of Human Subjects
- 21 CFR 312 - Investigational New Drug Application
- 21 CFR 600 - Biological Products: General
- 21 CFR 812 - Investigational Device Exemptions
- DoD Instruction 3216.02 - Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research
- DoD Directive 3210.07 - Research Integrity and Misconduct
- Health Insurance Portability and Accountability Act (HIPAA), 45 CFR 160, 162, and 164
- Family Educational Rights and Privacy Act (FERPA), 34 CFR 99
- International Conference on Harmonization ("ICH") Good Clinical Practices ("GCP") Guidelines
- U.S. Department of Health and Human Services, Office for Human Research Protections - Guidance on Engagement on Institutions in Human Subjects Research
- U.S. National Institutes of Health - Required Education in the Protection of Human Research Participants Policy

12. Revision

*Please note that this document corresponds with former procedures HRP-010, Human Research Protection Program. Changes and revision dates for these procedures were not previously formally documented.

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