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1. Overview

Purpose

All research using human subjects must be approved by Drexel University. Some human subjects research that presents no more than minimal risk to subjects and falls into one or more exempt categories of human subjects research are considered exempt from Institutional Review Board (IRB) approval. Exempt research is subject to review by the Drexel Human Research Protection (HRP) Office for determination of exemption status.

For research that that is IRB-approved, or determined exempt, on or after January 21, 2019, the Drexel University Human Research Protection Program (HRPP)/IRB and investigators will adhere to the revised Common Rule.

At Drexel University, exemptions are reviewed by IRB Staff and granted by an IRB Chair or their designee. Individuals involved in making the determination of an IRB exempt status of a proposed research project cannot be involved in the proposed research. Reviewers must not have any apparent conflict of interest. Identification of individuals designated to conduct exempt determinations will be made in writing.

The reviewer evaluates exempt research to ensure it fulfills the organization's ethical standards, such as:

- The research holds out no more than minimal risk to subjects;
- Selection of subjects is equitable;
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data; and
- There are adequate provisions to maintain the privacy interests of subjects.

2. Procedure

2.1 Exemption Determinations

In order to obtain an exemption determination, investigators must submit:

1. An electronic application with the completed review type determination questions;
2. All recruitment materials (e.g., letter of invitation, recruitment script, flyer);
3. Consent form/disclosure/information sheet (when appropriate);
4. All surveys, questionnaires, instruments, etc.;
5. As applicable, confirmation that permission will be obtained from non-Drexel University site(s) of performance; and
6. Verification of current human research protection training for all members of the research team, including, when applicable, the faculty advisor.

Requests for exemptions are reviewed by IRB Staff and granted by an IRB Chair, or designee. The reviewer verifies the information as presented in the IRB application and request for exemption submission meets the definition of human subject research. If the request meets the definition of human subject research, the reviewer then determines whether the research is

eligible for exemption. Although exempt research is not subject to the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report.

The individual making the determination of exemption will determine whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report. In particular, the reviewer will consider whether the research involves no more than minimal risk to participants, that selection of participants is equitable, and that there are adequate provisions to maintain the privacy of participants and confidentiality of the data.

If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose such information as:

- The study title and IRB number;
- A statement that the activity involves research;
- A statement regarding the study purpose;
- A description of the procedures;
- A statement that participation is voluntary and not participating will not affect your relationship with Drexel University;
- Name and contact information for the researcher;
- Provisions to maintain privacy interests of participants and confidentiality of the data; and
- A statement "If you have questions or concerns about your rights as a research subject you may contact the Drexel University Institutional Review Board at hrpp@drexel.edu."

The reviewer indicates whether the request for exemption was approved or denied, and if approved, the category/s under which it was permitted. The exempt application and determination letter are recorded and maintained in in the electronic system.

Once exemption review is completed, notification of the result of the review is provided to the investigator.

Exempt determinations have an administrative review date of 3 years from the date of approval. Failure to submit a 3-year administrative review will result in administrative closure of the project. Investigators should complete a closure submission in the electronic IRB system in order to notify the IRB Office when an exempt research project is complete so that the organization can maintain an accurate database of active research.

2.2 Modifications to Studies Granted Exemption

Proposed changes that may render exempt research no longer exempt must be reviewed and approved by the IRB prior to implementation. Please note that failure to comply with the exemption as granted, or incomplete disclosure of study procedures that may affect the rights and welfare of participants may require submission of a reportable new information (RNI) report.

2.3 Exempt Determinations and Limited IRB Review

When the research requires limited IRB review, the review will be conducted by the IRB Chair or a Chair-designated member of the IRB. When conducting limited review as required by exempt Categories 2 and 3, IRB members must ensure that there are adequate protections to ensure privacy of participants and confidentiality of identifiable data. Continuing review is not required for studies that qualify for a limited review. IRB members conducting limited review, when such review is required, may not disapprove research. Only the convened IRB can disapprove

research. The institution retains the authority to suspend or terminate IRB approval of research approved with a limited review.

2.4 Limitations on Exemptions

The following limitations on exemptions apply to research conducted or supported by the Department of Health and Human Services:

Children

- Exempt categories 1, 4, 5, and 6 (Drexel University does not utilize categories 7 and 8) may be applied to research involving children if the conditions of the exemption are met.
- Exempt categories 2(i) and (ii) may only be applied to research involving children involving educational tests or the observation of public behavior when the investigators do not participate in the activities being observed.
- Category 2(iii) may NOT be applied to research involving children.
- Exemption #3 does NOT apply to research involving children. [§ .104(b)(3)]
- Exemption category 4(iii) is not utilized at Drexel University due to its hybrid HIPAA status.

Prisoners

- Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. [§ .104(b)(2)]

2.5 Categories of Exempt Research

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also Food and Drug Administration (FDA)-regulated.

1. Research conducted in established or commonly accepted educational settings and that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §45 CFR 46.111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

3.

i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers
   B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. Not eligible for research conducted under the auspices of Drexel University; or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
   i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
   i. If wholesome foods without additives are consumed; or
   ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: *Exempt categories 7 & 8 require limited IRB review and are only available when broad consent will be (or has been) obtained. Drexel University will NOT implement broad consent at this time.*

3. Responsibilities

3.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, training, and monitoring. HRP staff, as designated, are responsible for making exemption determinations. For inquiries regarding these

procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

3.2 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate approvals and oversight, and submitting the applicable documentation or exceptions to the HRPP/IRB and study sponsor.

4. Revision

*Please note that this document corresponds to former HRP-423 WORKSHEET Exemptions.

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