HUMAN RESEARCH PROTECTIONS PROGRAM AT UT SOUTHWESTERN

eIRB Help Text Document

EFFECTIVE DATE: SEPTEMBER 27, 2023

C | E | H | I | N | S

C

Compensation is payment for participation in research and should be the same for each subject as opposed to Reimbursement which may be different for each subject if for example reimbursement is based on verification of travel expenses, etc. Note: Compensation could also be considered payment or medical care for study-related injury in certain circumstances.

Competitive Enrollment indicates that the local site may enroll more subjects than originally planned by the study sponsor. In this situation, the total number of subjects enrolled study-wide does not change.

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E

eConsent Attestation:
Please confirm that the planned eConsent process meets regulatory requirements for obtaining documented informed consent by answering YES to all that apply (If NO to any, an explanation must be provided):

- The electronic informed consent form (ICF)(s) will be a complete and exact copy of the current, IRB approved study consent document(s) and will be updated to match IRB-approved revisions.
- Consent/authorization signatures will comply with applicable law, and the consent process will include a method to confirm the identity of the signer(s).
- Web-linked materials, graphics, videos, etc. (if applicable) will only include materials approved by the IRB (reviewed with initial protocol, or eConsent or Recruitment/Subject-facing material MOD).
- The stored electronic ICF(s) identify the subject, study staff (if applicable), and date (and time, if applicable) that the consent(s) were signed; and signed electronic ICFs are stored with appropriate access, with all consent versions easily retrievable.
- The electronic consent process/ electronic ICF will present subjects with the entire contents of the IRB-approved consent. There is/will be no function available to allow a subject to navigate directly to the signature field(s) or skip any section of the IRB approved consent contents.
- The subject will receive a copy of the consent.
- Parent/Guardian credentials are/will be used to set up, verify, and document assent from minors, and assent is captured electronically as a separate field. (Note: can be recorded under Parent/Guardian's eConsent credentials).

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H

An **honest broker** is an entity that keeps sets of private information but distributes parts of those sets to other entities who should not have access to the entire set. Honest brokers often work in clinical research with biological specimens; in that case, donors of specimens allow researchers to do research on those specimens, but typically want their specimen de-identified by having protected health information separated from it. The honest broker would keep both the specimen and associated protected health information, but only allow researchers to have access to the specimen without the protected health information.[1]

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I

Inducements are offers that get people to do things they may not otherwise do. **Inducements or incentives, rewards or payments** may be acceptable depending on the population, level and type but they may also be considered Undue Influence if the reward/payment is so large as to persuade the person to take undue risks or volunteer against their better judgment. Another concern about undue influence (unacceptable inducements) is they can result in a subject lying or concealing information that may otherwise exclude them from the research. As a result, if the study involves no risk or minimal risk, the concern over undue influence is reduced. The IRB should consider ways to reduce the influence of payments or rewards that undermine a person's capacity to exercise free choice and could invalidate consent. The IRB should balance the need to reduce undue influence with the need to avoid Exploitation of populations.

IRB of record is the Institutional Review Board that is conducting the regulatory review of the study. When speaking of multi-site, collaborative research conducted by one IRB instead of multiple IRBs, the IRB of record is also referred to as the single IRB (sIRB) or the Reviewing IRB.

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Non-Research, Treatment Protocols do not collect data for research purposes but are regulated by the FDA and require IRB review and approval.

- **Emergency Use Treatment using an unapproved drug/device/biologic** is for "a situation that requires a patient to be treated before a written submission can be made" (FDA, 2017a). It is the use of an investigational drug, biologic, or medical device to treat a patient with a serious disease or condition when there is no comparable or satisfactory alternative treatment available to treat the patient. The purpose of the use is to treat a patient, and the intent is to provide direct benefit to the patient.[2]
- **Single Patient Treatment using an unapproved drug/device/biologic** is used to treat a single patient for which the FDA issues an IND or compassionate use IDE.

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[1] https://en.wikipedia.org/wiki/Honest_broker

[2] Public Responsibility in Medicine & Research (PRIM&R),; Bankert, Elizabeth A.; Gordon, Bruce G.; Hurley, Elisa A.. Institutional Review Board: Management and Function (p. 806). Jones & Bartlett Learning. Kindle Edition.

- **Humanitarian Use Device (HUD) Protocol**: An HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (21st Century Cures Act, 2016, Section 3052).[3]
- **Small or Large Group Treatment using an unapproved drug/device/biologic (Compassionate Use)** is a potential pathway for a small or large group of patients with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

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S

Secondary Research refers to the research use of biospecimens and/or data that are collected for purposes other than the proposed research, such as other distinctly separate research studies, or biospecimens or data that are collected for non-research purposes, such as biospecimens that are left over from routine clinical care[4] or data collected from the electronic medical record.

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[3] Public Responsibility in Medicine & Research (PRIM&R),; Bankert, Elizabeth A.; Gordon, Bruce G.; Hurley, Elisa A.. Institutional Review Board: Management and Function (p. 815). Jones & Bartlett Learning. Kindle Edition.
[4] Public Responsibility in Medicine & Research (PRIM&R),; Bankert, Elizabeth A.; Gordon, Bruce G.; Hurley, Elisa A.. Institutional Review Board: Management and Function (p. 695). Jones & Bartlett Learning. Kindle Edition.