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Post Approval Monitoring Program for the Protection of Human Subjects in Research

PI Self-Assessment: Exempt Studies

Purpose:

The goal of Post-Approval Monitoring (PAM) of studies involving human subject research is to confirm by observation and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with an Institutional Review Board (IRB)-approved protocol. An additional goal of the program is to provide education to the investigators on best practices for conducting their human subject research study in compliance with their IRB-approved protocol, Texas A&M University-San Antonio (TAMUSA) IRB policies and guidance, and Federal regulations. The program is also designed to help investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

Preparation:

Perhaps the most effective way to prepare for a Post-Approval Monitoring visit is to carefully and objectively review your approved protocol and make sure that you and your staff are performing the research activities as presented in the IRB application. Exempt status is granted for research that is low risk, with all procedures falling within explicitly defined by Federal regulations. Changes in research procedures, content, or scope of information collected may result in loss of exempt status, therefore requiring additional IRB oversight.

Many variables can play into the need for adjustment in the design, procedures, etc., of your protocol. A change may seem trivial to a researcher, but it may be of great concern to the IRB, federal regulators, or auditors. While some modifications to exempt research can be implemented without review by IRB, certain changes do require prior review by the IRB to confirm that the change does not alter the original exempt determination.

Additionally, *the IRB Administrator is always willing to assist in answering questions, or to help facilitate modifications to your protocol. They can be reached at 210-784-2317 or irb@tamusa.edu.*

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Suggested areas to examine when assessing your study:

- Are key personnel performing duties as described and approved? Are modifications needed?
- Have there been early withdrawals from the study? Participant complaints?
- Have there been any adverse events? Were they reported?
- Who is responsible for conducting study procedures?
- Are procedures being conducted in accordance with the IRB protocol?
- Who is responsible for training study personnel on IRB-protocol specific procedures?
- Are records of training maintained?
- Are all research team members that have contact with participants or the participants' identified data listed as personnel on the study? Is a personnel modification needed?
- Are all personnel (i.e., PIs, Co-PIs, Research Staff) aware of all IRB-approved modifications?
- Are study documents (i.e., applications for approval, approval letters, informed consent) maintained for 3 years after the close of the study?
- Are documents, records, and data stored as outlined in the IRB-approved protocol?

A note about informed consent for Exempt Studies:

Exempt research is not subject to the regulatory requirements of human subject's research. However, all researchers are responsible for ensuring their research is conducted ethically. Important ethical considerations such as voluntary participation, informed consent, protection of confidentiality apply. Although the IRB does not review or approve consent processes and/or documents for exempt projects, the Texas A&M University-San Antonio's IRB expects investigators to provide, at minimum, the following information to prospective participants (and their parent/legal guardian) prior to their enrollment in the study:

- A statement that the project involves research;
- A general description of the study procedures and time commitment;
- A description of any plans to video or audio record participants;
- A description of any discomfort or risk (such as discomfort responding to sensitive or personal questions);
- A statement that participation is voluntary;
- A statement that the participant may skip any questions they do not feel comfortable answering in an interview or survey; and
- The measures that will be used to ensure confidentiality of data collected in the research, including how audio or video recordings will be used.

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Exemption 3 under the 2018 Common Rule requires "prospective agreement" from subjects and, when applicable "authorized deception". Thus, research involving benign behavioral interventions may be exempt only when:

- Prospective subjects are given an opportunity to agree to participate prior to inclusion in the study (i.e., there is some type of informed consent process).
- If deception about the purpose of nature of the study is planned, prospective subjects are informed that they will be unaware of or misled about the nature or purposes of the research, and agree to proceed.

Common Findings:

Below are examples of common findings from post-approval monitoring visits for exempt studies:

- New inclusion of participants from a vulnerable population (e.g., children, prisoners, pregnant women, cognitively impaired persons, persons who are institutionalized, etc.);
- A change in study procedures or methods of data collection, including but not limited to:
    - substantive changes to the nature or scope of data to be collected (e.g., a change in topic or content of survey or interview questions, etc.);
    - changes in confidentiality measures or how identifiers will be collected or recorded;
    - the addition of any physical interventions;
    - the addition of usability testing procedures;
    - any changes that, in your opinion, increase the risk or discomfort to the participants.
- Changes such that the revised procedures are not all included in the exemption categories defined by federal regulations. *[Note: The specific category or categories for which your research was granted exemption can be found in the approval letter you received when the study was last reviewed.]*
- Study Records
    - Confidentiality is not maintained as indicated (i.e., identifiers remain connected to data, or identifiers were collected contrary to the IRB protocol).
    - Persons reviewing study records that are not approved or trained to do so.

If you have identified discrepancies between your current practices and those outlined in the approved protocol and these questions, please make the appropriate corrections. This may require submitting a modification to your protocol, or simply implementing better documentation practices.

Remember, the goal of Post-Approval Monitoring is not to "catch" researchers. Rather, it is designed to facilitate research by making sure it is conducted in a manner where the conditions of Federal Regulations and University Policy are met, and by assisting researchers to identify and correct any deficiencies.

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