THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

IRB NEWSLETTER

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THIS ISSUE

ANNOUNCEMENTS

EFFECTIVE: JANUARY 21, 2019
Federal regulations that safeguard individuals who participate in research studies have changed. The new federal policies mandating the protection of human subjects are known as the "Common Rule," and on January 21, 2019, a substantial revision to the Common Rule will take effect. These changes are designed to ease researcher burden while enhancing the protection of human subjects. This Newsletter highlights some of the more relevant changes that may affect your research project.

Common Rule changes that may impact you:

Of particular interest to clinical researchers are changes in three areas: expanded exemption categories, continuing review changes, and consent form changes.

1) Modified Exempt Categories

The new Common Rule broadens the types of research that may be determined to be exempt from IRB review. Noted below are some of the modifications to existing exempt categories:

- Educational research conducted in established educational settings (Category 1) should not adversely affect classroom instruction time or students' performance.
- Research involving the use of educational tests (Category 2) allows for collection of potentially sensitive or harmful identifiable information from adults if the IRB makes a determination that adequate provisions for protecting privacy and maintaining confidentiality are in place.
- Secondary data (Category 4) **is not restricted to information/specimens pre-existing** at the time the investigator begins the research study.

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It remains UT GSM's IRB policy that researchers must submit, through iMedRIS, a determination that applicable human subjects research activities are exempt from IRB review.

2) Continuing Review Changes

Some minimal risk studies previously reviewed under expedited review will no longer be required to renew their IRB approval on an annual basis (continuing review). Unless the IRB determines otherwise, continuing review of research is not required if the research:

- Is eligible for expedited review;
- Is reviewed by the IRB in accordance with the limited IRB review (new IRB regulatory category) procedure; or
- Only involves data analysis (including analysis of identifiable information or identifiable biospecimens) or access to follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Investigators conducting eligible studies will be informed of post-approval requirements at the time of initial approval.

3) Consent Form Changes

Consent forms will need to include a brief summary that explains the research to potential participants in an easy-to-understand and clear manner. Consent forms must be concise while also giving the full context of a study, including its risks and benefits, so potential participants have all the information they need to make an informed decision. Consent forms will additionally need to include information regarding the potential for future use of de-identified data and biospecimens. Consent form template examples for these revised requirements will be added to the UTGSM IRB website.

iMedRIS ASSISTANCE

Let us help you! Visit us in the IRB office (3rd floor GSM) and we will walk you through your submission. Use our computer or bring your own. We are happy to help!

CONTACTS

For questions or information related to the new Common Rule changes, including the new iMedRIS application process, contact UT GSM's IRB office or visit our website at: http://gsm.utmck.edu/irb/main.cfm **as updates become available.**

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