Massachusetts Institute of Technology

To Members of the MIT Research Community:

The Common Rule, the ethical standards governing the conduct of human subject research, has undergone significant revisions effective January 21, 2019. The changes, known as the New Rule, will help alleviate some of the administrative burden associated with the conduct of human subject research.

Existing protocols approved before January 21, 2019 will not be impacted by the New Rule and not subject to the changes outlined below.

COUHES CONNECT

COUHES is excited to introduce COUHES Connect, a new online platform that allows investigators to manage their COUHES protocols electronically. Investigators can track submissions, view and download approved documents, check exempt status, and view upcoming expiration dates – with more features coming soon!

Exempt Research

New Categories

Existing exempt categories have been modified or removed, and new categories have been added which are more inclusive of current research methodologies.

Exempt Evaluation

Investigators conducting exempt research will no longer be required to submit an exempt application to COUHES for review. Instead, investigators will submit an Exempt Evaluation through COUHES Connect. Investigators engaged in the conduct of exempt research are required to comply with the Investigator Responsibilities for Exempt Research guidance.

Continuing Review

Protocols approved under expedited review will no longer require yearly renewals unless otherwise determined by COUHES. Instead, investigators will submit an annual progress report and a Continuing Review Questionnaire every three years.

Consent Form Requirements

Informed consent requirements have undergone significant changes. These include: a mandatory key information section at the beginning of the consent form and special provisions concerning the use and storage of biospecimens. Additionally, if the planned research involves data collection from individuals in the European Union, special provisions to comply with the General Data Protection Regulations must be included. COUHES templates have been revised to include the updated requirements.

Terms and Definitions

Several terms and definitions have been added or modified for clarity, including:

Vulnerable Populations

Vulnerable populations has been clarified to include all subjects that are vulnerable to coercion or undue influence.

Research

Activities deemed **not** to meet the Federal definition of *research* have been clarified to include: scholarly or journalistic activities, public health surveillance, and research conducted by criminal justice agencies.

Clinical Trial

The New Rule now defines a *clinical trial* and introduces new regulatory requirements.

Recording Keeping

Clarification on existing policies, which allow investigators to store IRB related documents electronically, and permit electronic signatures on informed consent documents.

Single IRB Review (Effective January 2020)

Investigators engaged in multisite research will be required to rely on a single IRB for oversight and review.

For more information on the New Rule, visit https://www.hhs.gov/ohrp/.

Please visit the COUHES website for the latest updates on COUHES Connect and upcoming regulatory changes.

Leigh Firn, MD
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