Revised Common Rule: Summary of Changes

At 4:15 PM on January 17, 2018 HHS delayed the effective and implementation date of the revised HHS IRB regulations (the Common Rule) from January 19, 2018 to July 19, 2018. As a result, as of January 18, 2018, we are implementing only the following changes at this time:

- **Consent forms** have a variety of minor changes that are still being implemented. The concise summary requirement, however, will not be implemented until July.
- The new and revised **Exempt Categories** will not be implemented until July.
- Changes to **continuing review** requirements:
  - Expedited (minimal risk) studies are no longer required to submit annual subject counts. However, Expedited studies are still required to submit abbreviated annual progress reports.
  - New Exempt research is being given a 3 year approval period and will be required to submit brief progress reports at that time.
- For **federally funded research**, the IRB requires the submission of both the grant application and a working protocol. The IRB requires that the protocol meet all the requirements in the protocol elements checklist.

If you have questions regarding the delay in implementation of the revised regulations, please contact irb@einstein.yu.edu.

To the Einstein-Montefiore Research Community:

On January 19, 2018 a new version of the HHS IRB regulations (the Common Rule) will go into effect. This is the first update to the regulations since they were published in 1991. There are four categories of changes that will directly affect the research community: (1) additional consent language requirements, (2) new and revised Exempt Categories of research, (3) revised continuing review requirements, and (4) removal of the requirement for the IRB to review grant applications or proposals. The Einstein IRB has revised its application materials and consent templates to reflect these changes.

Here is a more detailed summary of the changes:

- **Consent forms** will now require a concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document. Information about the concise summary requirement and other new consent language requirements is available here. Concise summary examples are available here. *Existing studies are not required to meet the new consent language requirements.*
- There are major updates to the six **Exempt Categories**. The changes are:
  - (1) Research, conducted in established or commonly accepted educational settings
    - **NEW**: A new ineligibility criterion will be added to this interaction/intervention exemption for research that involves possible "adverse effects" on student learning of the required education content and/or on the assessment of educators.
    - Note: Some research under this category may require the submission of consent documents and scripts. Consent documentation may include short oral scripts, cover letters, introductory paragraphs on surveys/research instruments and e-mails introducing potential research subjects to the study. Signed documentation of consent is not necessarily required for this category (but may be required under HIPAA). Exempt consent template language is available in the iRIS help menu.
  - (2) Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) of adults.
NEW: The scope will be expanded to include the collection of sensitive and identifiable data. However, the following is not allowed:
- Interventions
- The collection of biospecimens

Note: Einstein requires submission of consent documents and scripts for this category. Consent documentation may include short oral scripts, cover letters, introductory paragraphs on surveys/research instruments and e-mails introducing potential research subjects to the study. Signed documentation of consent is not necessarily required for this category (but may be required under HIPAA). Exempt consent template language is available in the iRIS help menu.

NEW CATEGORY: (3) Research involving benign behavioral interventions with adult subjects if the subjects prospectively agrees to the intervention and information collection.
- 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.
- The research may not involve deception (unless subjects are prospectively informed that they will be misled).
- Note: Einstein requires submission of consent documents and scripts for this category. Consent documentation may include short oral scripts, cover letters, introductory paragraphs on surveys/research instruments and e-mails introducing potential research subjects to the study. Signed documentation of consent is not necessarily required for this category (but may be required under HIPAA). Exempt consent template language is available in the iRIS help menu.

(4) Secondary research uses of identifiable private information or identifiable biospecimens
- NEW: Prospective data review

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency
- NEW: A new eligibility criterion for this interaction/intervention exemption will be that the project must be published on a federal website.

(6) Taste and food quality evaluation and consumer acceptance studies
- NO CHANGES

Changes to continuing review requirements:
- Expedited (minimal risk) studies will no longer be required to submit annual subject counts. However, Expedited studies will still be required to submit abbreviated annual progress reports.
- New Exempt research will be given a 3 year approval period

The IRB will no longer review grant applications or proposals:
- The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. The Einstein IRB thus no longer accepts the submission of the grant application instead of a protocol. The IRB instead requires that a working protocol be submitted that meets all the requirements in the protocol elements checklist.

To accommodate the changes to the Exempt regulations, all Exempt studies submitted after January 1st will be reviewed under the new regulations and will be held for approval until January 19th. If you need a new Exempt study approved under the existing regulations during that time period, please contact us at irb@einstein.yu.edu. The new Exempt section of the IRB application will be released at the end of 2017.

HHS has also proposed a one-year delay of the “general Implementation date while allowing the use of three burden-reducing provisions during the delay year.” (The three provisions were not named in the announcement.) This proposal has not yet been approved, and rumors are that it will be
approved a few days before the January 19th deadline. As a result, some (or perhaps all) of the new regulations may be delayed. In order to allow the research community to make plans, the IRB has decided to release the new Exempt categories and include the new consent requirements in our newest consent template and to strongly encourage researchers to include the new language in submissions that will be approved after January 19th.

The Einstein IRB will begin offering educational sessions and provide guidance on the new requirements once HHS clarifies the implementation date for the revised Common Rule.

Please reach out to irb@einstein.yu.edu if you have any questions or concerns.

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