جامعة نيويورك أبوظبي
NYU ABU DHABI

The Revised IRB Common Rule - Summary

The proposed changes to the common rule will bring about significant changes to IRB categories and processes for reviewing human subjects research. The main purpose of these changes is to relax regulations around minimal risk research and reduce burden for researchers and administrators. Processes around more than minimal risk research will not see much change and the application of the new common rule will include introduction of post-approval monitoring and audits.

Here's an outline of what changes to expect and the effects they'll have on human subjects research at NYUAD

_____

Major regulation changes:

1. **Changes to Exemption categories (see 'New Exemption Categories Table' for detailed description)**:
    - Modification to most existing categories
    - Expansion in scope to several existing categories
    - Addition of new categories

2. **New exempt determination processes**. Exempt research will still require initial review by an IRB member (usually staff). For minimal risk research that involves aspects of identifiable information that might be sensitive or potentially harmful if disclosed, an IRB member (usually) staff will conduct a limited review, similar to that which is conducted presently, to ensure that certain informed consent, privacy and confidentiality safeguards are put in place. If these safeguards are met, then the study can still quality for Exempt status.

3. **Revisions to Informed Consent Requirements.** A new "Key Elements" section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not. This only applies to full board studies and expedited studies with consent forms 3 pages or longer.

4. **Continuing Review**. Annual review of minimal risk projects will no longer be required, however the IRB retains the right to require a continuing review for particular projects (e.g., those which may present slightly more than minimal risk). Full board studies still require annual continuation requests via a form to report on the status of the project. For Exempt and Expedited studies, notification will be sent every 2 years to the PI to inquire about status. At the end of a project, the PI will be asked to complete a closure form. Amendment requests are still required for all protocols before implementing changes. Research teams are still required to report unexpected adverse events to the IRB for <u>all</u> studies.

5. **Single IRB-of-Record (sIRB).** Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is

conducted in the United States. Research at NYUAD is not subject to this revision. However NYUAD's IRB may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. This opportunity will be explored on a case-by-case basis and will be subject to the collaborating institution's willingness to take part.

6. **Post-approval monitoring**. A post-approval monitoring program will be implemented upon recommendation of OHRP in order to counterbalance the lack of continuing annual review. Studies with more than minimal risk will be the main focus, but any approved research is subject to post-approval monitoring and will be selected at random. For more information, please see 'Post-Approval Monitoring'. While there may be punitive measures taken by the full Board for serious or continuing noncompliance, the purpose of this program (especially in the first few months) will be primarily educational and supportive.

What to Expect:

1. NYUAD IRB standard operating procedure updates;
2. Changes to IRB application and other forms;
3. Revisions to Informed consent guidelines for full board studies and expedited studies with consent forms longer than 3 pages. Other relevant guidance documents will be revised as well;
4. Post-approval monitoring process and related forms will be shared on the webpage and with projects selected;
5. Short CITI course on the revised Common Rule will be required on or after January 21, 2019, this will not be a requirement for those who attending the in-person info sessions.

The new regulations do not impact studies determined exempt prior to the proposed implementation date of January 21, 2019. Studies approved as Expedited prior to January 21, 2019 will be grandfathered into the new system at the time of annual renewal (expiration date). Upon submission of a re-approval request, these studies will be switched over to a 2-year expiration.

NYU Abu Dhabi • Abu Dhabi, UAE • P.O. Box 129188 • +971 2 628 4313 • fax: 02 659-0783 • Email Address: IRBnyuad@nyu.edu