**Revisions to the Federal Regulations Governing Human Subjects Research – effective January 21, 2019**

**At University of Maryland Baltimore, these changes are applied to all non-exempt, non-FDA regulated research, regardless of funding.**

**New regulations apply to research that is IRB approved after January 21, 2019.**

**Currently approved research will not be transitioned to new regulations ( ex. If your study currently requires continuing review (CR), then CR will be required for the length of your study).**

**If new studies are currently undergoing IRB review and would be approved after January 21, 2019, then they are subject to these new regulations.**

1. Update to what is not considered research—journalistic activities, certain public health surveillance activities.
2. Updated definition of human subject
   1. Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
3. Requirement removed for continuing review of minimal risk research and for greater-than minimal risk research that is in long-term follow-up or data analysis only. UMB IRB can require continuing review for minimal risk research in instances of non-compliance. UMB will require a progress report every two years to ascertain information on enrollment numbers.
4. Changes to basic and additional elements of informed consent to be included in informed consent document (ICD)
5. ICD - *Reasonable Person Standard*: The prospective research participant must be provided with information “that a reasonable person would want to have in order to make an informed decision,” as well as an opportunity to discuss such information.
6. Requirement for concise and focused summary of information at the beginning of ICD that a subject or legally authorized representative would want to have to make a decision about potentially participating in a study.
7. Requirement for final version of ICD used to recruit subjects to be posted by lead researcher either to Clinical trials. gov or Regulations.org. This is to promote transparency of research and improve quality of ICDs long-term. HRPO recommends not posting ICD unless sponsor/grantee or UMB directs lead researcher/awardee to do so.
8. Broadening and revision to exemption categories. (Continuing review is not required)
   1. Category 1 -Educational research: Minor changes were made, clarifying that the research must not disrupt students’ learning.
   2. Category 2 -Previously, this category only applied to anonymous or non-sensitive research. Now there is a provision for certain kinds of sensitive data to remain identifiable or coded, if sufficient protections are in place to ensure data security.
   3. Category 3- Involving only “benign behavioral interventions” with adult subjects. The data must be anonymous or non-sensitive, or have sufficient protections in place to ensure data security. Benign defined as brief, harmless, painless not physically invasive etc.
   4. Category 4 - Secondary research on existing data or specimens that are identifiable if certain conditions are met.
   5. Category 5—Research conducted by federal depts. or agencies—may be in conjunction with faculty.
   6. Category 6 –Food and taste—unchanged.

See HRPO website (<https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/> ) for new IC template (combined with HIPAA) and additional links to training on changes/revisions to Federal regulations governing human subjects research.