

## WHAT ARE THE MAJOR CHANGES IN THE REVISED COMMON RULE?

### Changes to definitions:

- The definition of research now excludes journalistic endeavors, oral histories and data collection for professional non-research purposes (examples, criminal justice activities and data collection for national security purposes).
- The human subject definition is changed to include identifiable biological specimens.

### Changes to Continuing Review Regulations:

- As part of the new regulations, annual continuing reviews are eliminated for all new expedited studies approved on or after January 21, 2019, **unless the IRB determines that a continuing review should be required for a specific study.**
- Continuing review is also not required if the research was initially approved by a convened meeting and has progressed to the point that it involves only one or both of the following activities:
  - Data analysis (including analysis of identifiable information or identifiable biospecimens)
  - Access to follow-up clinical data from procedures that subjects would undergo as part of clinical care
- Full board studies will still need annual continuing review approval.
- Please note that even if a continuing review is not required modifications and reportable events (adverse events and/or unanticipated problems) must be submitted to the IRB for review.

### Changes to Consent Forms:

Long consent forms and/or consent forms for federally funded studies will **require a concise summary:**

- The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.
- The summary should include the following 5 elements:
  - 1) A statement that the project is research and that it is voluntary.
  - 2) A summary of the research (purpose, overview of procedures etc.)
  - 3) Any foreseeable risks or discomforts
  - 4) Any expected benefits to participants (if applicable)
  - 5) If applicable, alternative procedures to course of treatment

You will find concise summary examples on the Forms and Samples page.

### Changes to the Exempt categories:

Exempt 1 – Normal educational practices - Revised

- The following restriction was added “not likely to adversely impact student’s opportunity to learn required educational content, or assessment of educators who provide instruction”.

#### Exempt 3 Benign Behavioral Intervention – New category

- The former exempt category 3 was eliminated and replaced with a category granting exemption to studies 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.
- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
- Benign behavioral interventions are defined as: “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.”

#### Examples that would fit under Category 3:

1. having subjects play an online game
  2. having subjects solve puzzles under various noise conditions
  3. playing economic games
- If a study involves deception, it can be exempt under category 3 if the participants are told during the recruitment/consent process that there is an element of deception in the study, and they agree to participate knowing this.

#### Exempt 7 – Not implemented at the University of Maine at this time

- Allows for the storage of data and/or specimens in a repository, with identifiers maintained, that were collected under an approved IRB protocol with Broad Consent\* for future secondary use research.

#### Exempt 8 - Not implemented at the University of Maine at this time

- Allows for secondary research use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with Broad Consent\*

\* Broad consent is an alternative consent process for use only for the storage, maintenance and secondary use of identifiable private information or biospecimens for future research (yet to be determined). See [HHS Recommendations for Broad Consent Guidance](#) for more information on broad consent.

At this time the University of Maine (similar to many other institutions) will not use broad consent.

#### Changes to review of cooperative research:

- Research conducted by investigators at multiple research sites must rely on a single IRB of record (sIRB). However, implementation for this is January 20, 2020.