



Common Rule 2018 Exemption Changes

University of Vermont/University of Vermont Medical Center



Exemption Changes

Changes include:

Exempt 1 - new considerations

Exempt 2 - changes to collection and review

Exempt 3 - new category

Exempt 4 - replaces health records review

Exempt 5 & 6 – minor changes to 5, no changes to 6, neither used here at UVM very often

Exempt 7 & 8 - UVM will not be using these two exemptions

Given the number of changes, the IRB has developed a new submission form for each Exemption Category. The forms are specific to the category and will streamline review and exempt determinations going forward.



Exemption Changes – Related Definitions

Limited IRB Review = new category of review that requires a Committee member review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable bio-specimens in the proposed research. Limited IRB review will be required for exempt level projects in categories 2iii and 3ic. These categories will require that investigators complete a Data Security and Management Plan for review.

Benign Behavioral Interventions = new category of exemption described as behavioral (not biomedical) interventions in conjunction with collecting information from an adult subject through oral or written responses. The new exemption is for research activities with adult participants that pose little risk to subjects.

Secondary Research Uses = is not defined in the regulations, but the Final Rule's preamble states that it is "re-using [for research purposes] identifiable and non-identifiable information and bio-specimens that are collected for some other 'primary' or 'initial' activity" (such as, from research studies other than the proposed research study). There is no requirement that the information and bio-specimens must be pre-existing at the time the investigator begins a research study.

Broad Consent = new concept which addresses elements of consent for storage, maintenance, and secondary research use of private information or identifiable bio-specimens. UVM/UVMMC does not currently have a hospital-level repository of private information, therefore this new concept will not be used.

Exemption 1 – Educational Exemption

What's new?

- The PI and the review IRB now must consider “adverse affects” on student learning of required educational content or on assessment of educators





Exemption 2 – Surveys/Interviews/Educational Tests/Public Observation ONLY

What's new?

- “Limited IRB Review” required for projects collecting sensitive and identifiable data = Data Security Plan form
- Clarifies that the exemption **does not apply** to projects involving:
 - Interventions
 - Collection of biospecimens
 - Linking to additional personally-identifiable data
 - Children (except for educational tests or some public observations)

Exemption 3 – Benign Behavioral Interventions

What's new?

- This exemption is completely new
- Limited to research with adults

What is a benign behavioral intervention?

- Brief in duration
- Harmless and painless
- Not physically invasive
- Not likely to have a significant adverse impact on subjects
- Not offensive or embarrassing





Exemption 3 – Benign Behavioral Interventions

- Information is collected via
 - Verbal or written responses (surveys/interviews)
 - Data entry
 - Observation of subject (including audiovisual recording)
- Does not permit data collection via physical procedures
 - Physical sensors (e.g. blood pressure monitors, EEG, FitBits)
 - Minimally invasive procedures (e.g. blood draw or saliva collection)




Exemption 3 – Benign Behavioral Interventions

- Must obtain “prospective agreement to the intervention and information collection”
- **No deception**, except where the subject is told that they will be unaware or misled about the nature or purposes of the research and they agree
 - Debriefing still required
- “Limited IRB Review” required for projects collecting sensitive and identifiable data = Data Security Plan form

Examples

- Solving puzzles under various noise conditions
- Playing an economic game
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks





Exemption 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens = New Health Record Review

What's new?

- No longer limited to retrospective data review
- Maintenance of identifiers, if all study data is protected health information (PHI) requires a "HIPAA Review" to address specific HIPAA privacy issues = Data Security Plan form



Exemption 5 – Public Benefit/Service Program Research (Federal Demonstration Projects)

What's new?

- A new eligibility criterion for this interaction/intervention exemption will be that the project must be published on a federal website.



Exemption 6 – Taste/Food Quality Evaluation & Consumer Acceptance

What's new?

- No change to this category



Exemptions 7 & 8 – Storage and Secondary Use of Data/Biospecimens under Broad Consent

- These two new exemptions require that the hospital have a repository of data and biospecimens, that allow for participants to opt in and opt as they wish.

Since UVMMC does not have a data/biospecimen repository, these two exemptions do not apply to our institution.



New Forms and Process

- The forms will be available on our forms website on January 21, 2019 for use going forward.
- The forms will be attachments to the UVMClick – IRB submission, until smart forms can be developed.
- Contact your research analyst with questions.