



Understanding the common rule

Exempt Overview

See Exempt Categories 1-6 and Exempt and Vulnerable Populations for Additional Details

Exempt Revisions (to be effective January 21, 2019)	<p>The New Rule makes a lot of changes to the exempt categories. This document discusses the overall changes.</p> <p>What are the key changes?</p> <ul style="list-style-type: none">• More studies can be exempt under the New Rule. Some examples are studies with brief benign behavioral interventions with adults, and some prospective chart reviews.• Exempt does not always mean exempt from all of the requirements of the Common Rule. Under the New Rule, some exempt studies will have a new “limited” IRB review to make sure the study complies with the applicable parts of the new Rule. As an example, sometimes the only concern with a study is a possible loss of confidentiality. This limited review will provide a mechanism for the IRB to focus on this concern, and still allow a study to be exempt.
Implications for Researchers:	<p>New Studies:</p> <p>Just like the current practice, when you submit a New Protocol Submission, you will be asked to indicate which level of review you think your study requires. ETSU will also continue the current practice of the IRB Chair or Vice Chair making the actual exempt determinations.</p> <p>For some studies that require the new limited IRB review, you may be asked to provide more detailed information about confidentiality.</p> <p>Two new categories of exempt, categories 7 and 8 which provide for establishment and use of repositories, will not be available at this time at ETSU. The reason is that these categories use a new concept called “broad consent”, and the regulations require very strenuous record keeping related to broad consent. In the coming months, ETSU will monitor the development of best practices regarding these new categories and re-assess their use. Repositories can still be established under expedited or convened board review.</p> <p>Existing Studies:</p> <p>Studies already determined to be exempt under the current rules will remain under the current rules. ETSU does not anticipate that the New Rule will result in any changes to existing exempt studies.</p>

Both new and existing exempt studies:

- Do NOT require continuing review.
- DO require that modifications be submitted and IRB- approved before the change is implemented.
- DO have to fulfill ETSU ethical standards.
- MAY be subject to HIPAA standards