



Streamlining IRB Exempt Research Review

- IRB Exempt Self-Determination
- Updated IRB Exempt Protocol Narrative

As part of our initiative to streamline the IRB review process, two new updates will be available on April 2, 2018:

1. An Exempt Self-Determination Tool, and
2. An updated Exempt Protocol Narrative for research that requires IRB review

IRB Exempt Self-Determination

Lead Researchers can determine whether their exempt research qualifies for IRB Exempt Self-Determination (i.e., no IRB review required).

Permissible Exempt Research Categories for Self-Determination:

- Category #1: Established or commonly accepted educational settings that specifically involves normal educational practices
- Category #2: Interactions involving educational tests, survey, interview procedures, or observation of public behavior (including visual or auditory recording)
- Category #3: Interactions involving educational tests, survey, interview procedures, or observation of public behavior (including auditory recording) and the participants are public officials

Exceptions to Exempt Self-Determination (i.e., IRB review required) includes research that involves:

- The following target population:
 - Children (under the age of 18)
 - Prisoners
 - Adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
 - Students or employees of the study team
 - American Indian/Alaska Native Tribes
- Access to, or the collection of, Protected Health Information (PHI)
- Access to, or the collection of student education records
- Collecting participant identifiers *where* participants disclose sensitive information that could place them at risk for criminal or civil liability, or might be damage their financial standing, employability or reputation
- Disclosure of participant identifiers in presentations and/or publications
- Use of deception
- Engagement of non-UCI researchers
- International research
- Financial Conflict of Interest

Guidance and Form

Additional [Guidance](#) for this new process and the [Exempt Self-Determination Tool](#) will become available on April 2, 2018.

Important notes regarding Exempt Self-Determination

- Maintain a copy of your *completed Exempt Self-Determination Tool* with your research records
- Any modifications to your Exempt research activity that would substantially change the risk level or place the research activity into another [IRB review category](#) (Expedited Category Research and/or Full-Committee) will require the submission of an [IRB application](#).
- DHHS retains final authority as to whether a particular human subjects research study *conducted or supported by DHHS* is exempt from the DHHS regulations [[45 CFR 46.101\(c\)](#)]
- Lead Researchers may request that Human Research Protections (HRP) staff review and confirm the *completed Exempt Self-Determination Tool*, should the Lead Researcher prefer or the study sponsor require.

Updated Exempt Protocol Narrative

Biomedical Exempt research and Social Behavioral Educational Exempt research that require IRB review will now be able to use one Exempt Protocol Narrative. The Exempt Protocol Narrative is succinct and simplified to reduce ambiguity and to ensure Exempt Category applicability.

The updated [Biomedical/SBE Exempt Protocol Narrative](#) will be available on April 2, 2018.