

IRB Review – Exempt Research

“Exempt” human subjects research is a sub-set of research involving human subjects that *does not require* comprehensive IRB review and approval because the **only** research activity involving the human subjects falls into one or more specific exemption categories as defined by the Common Rule.

- Exempt projects are not subject to continuing review
- Amendments are required only if changes to the project could alter the exempt determination
- An exempt determination does not lessen the investigator’s ethical obligations, including the completion of human subjects protections training
- Review the Common Rule on exempt research: [45 CFR 46.104](#)

#1 – EDUCATIONAL EXEMPTION – [Guidance Documents – Exempt Category 1](#)

What’s New: A new *ineligibility* criterion will be added to this interaction/intervention exemption for research that involves possible “adverse effects” on student learning of the required education content and/or on the assessment of educators.

#2 – SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR – [Guidance Document – Exempt Category 2](#)

What’s New: This category is expanded to include the collection of sensitive and identifiable data. However, the following is not allowed:

- Interventions
- The collection of biospecimens
- Linking to additional personally-identifiable data
- Research with children (*except* for educational tests or some public observation)

Limited IRB Review is required if the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. The Limited Review (by a designated member of the IRB) serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

3 – BENIGN BEHAVIORAL INTERVENTION (NEW) – [Guidance Document – Exempt Category 3](#)

A “benign intervention” is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact.

What’s New: This new exemption permits data collection via an interaction (e.g., survey, interview, audio/visual recording) from adult subjects with prospective agreement. However, the following is **not allowed**:

- Research with children
- Deception, unless prior agreement obtained
- Physiological data collection methods (e.g., EEG; wearable devices, such as FitBit™; blood pressure monitors)
- Linking to additional personally-identifiable data

Limited IRB Review is required if the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. The Limited Review (by a designated member of the IRB) serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

#4 – SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS)

What's New: The scope of this exemption is expanded to allow:

- Prospective data review
- Maintenance of identifiers, if **all** study data is protected health information (PHI)
- Research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities

#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.

#6 – TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE

What's New: Unchanged

#7 – STORAGE / MAINTENANCE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH “BROAD CONSENT” (NEW)

What's New: This new exemption 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.

NOTE: Currently, the USA IRB will **not mandate nor implement the institutional use of Broad Consent**, as the tracking requirements may be burdensome. Exempt categories 7 and 8, which rely on Broad Consent, **will not be available**. The IRB will continue to support study teams seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:

- Study-specific consent and IRB review
- MCI Biobanking Protocol
- IRB waiver of consent (as eligible) and IRB review
- Exemption #4

For studies designed to collect identifiable data and/or biospecimens **solely** for the purpose of maintaining a repository, the study team may find it useful to employ a specialty informed consent template (e.g., [biorepository template](#))

#8 – USE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH “BROAD CONSENT” (NEW)

What’s New: This new exemption allows for secondary research use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with “Broad Consent”.

NOTE: Currently, the USA IRB will **not mandate nor implement the institutional use of Broad Consent**, as the tracking requirements may be burdensome. Same applies for Exemption #7 as noted in detail above.

Annual Check-In Report

Exempt research studies do not require continued IRB review (i.e. there will be no expiration date for approval). However, the IRB will require an annual check-in to monitor ongoing research where continuing review is not required.

In support of the periodic monitoring (i.e., reporting) requirement where continuing review is not required, IRBNet provides a "Next Report Due" date. This new field provides a mechanism to record reporting requirements when continuing review and Project Expiration Dates are typically not applicable.

This new feature "Next Report Due" date also drives automated alerts to notify the Project Team of the next annual check-in date. The "Next Report Due" is displayed on the following page: My Projects and Project Overview. You will see when the next scheduled annual check-in (i.e., report due) is due for each project.