45 CFR 46

Code of Federal Regulations
Title 45. Public Welfare
Part 46. Protection of Human Subjects

2018 Requirements

Major Regulation Changes

Exemptions - New categories and clarification of existing categories.

Informed Consent - rearrangement of content is designed to facilitate a potential subject's decision to participate or not.

Continuing Review - No longer required for minimal risk research.

Single IRB-of-Record (sIRB) - IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB.

Exemptions

1 - Educational exemption. 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
The scope will be expanded to include the collection of sensitive and identifiable data. However, the following is not allowed:

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

Exemptions

3 - Benign behavioral intervention (NEW). 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.

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 (FitBit); blood pressure monitors)
- Linking to additional personally-identifiable data
- Undisclosed deception required full IRB review

Exemptions

4 - Secondary research (identifiable private information/biospecimens)

- 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

Exemptions

5 - Public benefit/service program research (federal demonstration projects)

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

6 - Taste/food quality evaluation & consumer acceptance

Unchanged

Exemptions

7 - Storage / maintenance of identifiable data/biospecimens obtained with "broad consent" (NEW)

WU will not implement at this time

8 - Use of identifiable data/biospecimens obtained with "broad consent" (NEW)

WU will not implement at this time

Informed Consent

1. Statement that the project is research and participation is voluntary
2. A summary of the research including: purpose, duration and list of procedures
3. Reasonable, foreseeable risk or discomforts
4. Reasonable, expected benefits
5. Alternative procedures or course of treatment, if any