

Key Changes to Human Subject Research Program at WSU

WSU Investigator Training: Revised
Common Rule - 45 CFR 46

January 2019



Instructions

To understand the changes to WSU IRB processes, please review these slides and the new Exempt Review, Expedited Review, and Informed Consent policy and templates posted on:

<http://www.wright.edu/research/compliance/policies-procedures-and-forms>

Revised Common Rule

The purpose of this presentation is to summarize the changes to WSU IRB policies and procedures that will go into effect on January 21, 2019 due to the revision of the DHHS Common Rule (45 CFR 46).

Revised Common Rule - History

- Compliance with Common Rule (a.k.a. 45 CFR 46) has been required per Wright State's Federalwide Assurance (FWA).
- An active FWA is required for institutions to receive federal funding to conduct research involving human subjects.
- All current WSU IRB policies and procedures are based on the Common Rule and FDA regulations.

Key Changes Summary

- **Eliminates continuing review** for most minimal risk research
- **Expands exemption categories** and changes the review processes
- **Reframes informed consent information** and adds required elements
- **Requires single IRB review** of research involving external collaborators

What's not changing for the IRB?

WSU IRB review of projects that involve the following will not change substantially:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners

Continuing Review Process

- Studies that qualify for **expedited review** at either initial (on or after January 21, 2019) or continuing review will be given an approval period of two years instead of one year.
- At the time of renewal, you will be required to submit a Continuing Review/Administrative Update Form (same form as current continuing review form in InfoED) which can reviewed and renewed administratively (i.e., by IRB office only)
- Submission and IRB approval of Amendments and Reportable Events is still required while the study is open.

Continuing Review Process

- This change is not applicable for FDA-regulated research.
- You will receive email reminders to submit your administrative update, however, it is your responsibility to ensure that it is received by the IRB Office at least 4 weeks before your study approval will expire.
- You must close the study once you are done using the Study Closure form. This can be done at any time during the renewal period.

Exempt Review Process

- The categories of research that qualify for exemption have been expanded and revised.
- Exemptions are granted by the WSU IRB Office after review of your initial submission
- For some types of exempt studies under the revised rule, additional IRB review will be required to determine if there are appropriate provisions to protect privacy and confidentiality (Limited IRB Review)

Exempt Review Process

- Reliance on external IRB exemption determination for WSU research is not permitted.
- Exempt research does not require continuing review, administrative renewal, or written informed consent.
- However, if research involves protected health information (PHI) written authorization is still required unless a HIPAA Waiver is granted.
- At 2019 continuing review cycle, some ongoing research may be determined to now be exempt.
- See following slides for specific category changes

Exemption 1

Educational Activities

What's new?

- 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?

- Projects collecting sensitive and identifiable data may be exempt after “limited IRB review” (for privacy/confidentiality protections)
- 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, but 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 - Continued

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 - Continued

- Investigator 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 encouraged
- “Limited IRB Review” of privacy/confidentiality plan required for projects collecting sensitive and identifiable data

Exemption 3 - 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

What's new?

- No longer limited to retrospective data review
- Permits secondary use of identifiable protected health information (PHI) with written authorization or HIPAA waiver of authorization

Exemptions 7 and 8

These two exemptions involve storage and secondary use of data/biospecimens through the use of “broad consent.”

Broad consent requires extensive tracking and resources and will not be allowable at WSU at this time.

Informed Consent Changes

- Key Information Summary required for federally-funded research initiated on or after January 21, 2019.
- Limited to first page of consent form.
- Template available under “Informed Consent” at <http://www.wright.edu/research/compliance/policies-procedures-and-forms>

Informed Consent Changes

- New required consent element
 - De-identified data or biospecimens may be shared for future research (or not)
- New consent elements (if applicable)
 - Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
 - Clinically relevant results will be returned (or not)
 - Research will involve whole genome sequencing
- New template language can be found in Consent/Authorization Template

Informed Consent Changes

- Added a fourth criteria to grant waiver of informed consent (for secondary use of data)
 - Must validate why use of identified data/biospecimens are necessary to the research
- You must provide sufficient information to the IRB for all four waiver criteria in your initial application

Informed Consent Changes

- For federally-sponsored clinical trials, a copy of the consent form must be posted on a “Federal Web site that will be established as a repository for such informed consent forms.”
- OHRP defines a clinical trial as: “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effect of the interventions on biomedical or behavioral health-related outcomes.”

Single IRB Review Requirement

- Requires that all federally-sponsored research with multi-institutional collaborators be reviewed by one designated IRB of Record
 - Not required until January 2020
- Note: NIH Single IRB (sIRB) requirement was in effect as of January 25, 2018

Federal Common Rule Resources

Videos and Q&A can be found here:

<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html>

WSU IRB Contact Information

- Jodi Blacklidge: Submissions
 - WSU IRB Staff
 - jodi.blacklidge@wright.edu
 - (937) 775-3974
- Christian LaMantia: Regulations
 - Interim WSU IRB Staff – External Consultant
 - Christian@rccounselor.com