



# Revised Common Rule: Updates to Federal Regulations

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# Changes to the Federal Regulations

- The U.S. Department of Health and Human Services (HHS) and 18 other Federal Agencies are signatories to the Federal Policy for the Protection of Human Subjects (the “[Common Rule](#)”). All research supported by any of the Common Rule agencies is subject to the regulations
- Revised Common Rule regulations were set to take effect on Jan. 19, 2018. Six-month delays were announced in Jan. 2018 & Jul. 2018. The effective date is now Jan. 21, 2019
- Existing non-exempt studies that are eligible will transition to the new regulations at the time of renewal

# There is little to no change to policy on research involving:

- Greater than minimal risk to subjects
- Drugs/biologics/devices (FDA-regulated)
- Collection of biospecimens
- Prisoners
- Children
- General process for conducting IRB review/exemption

# “Common Rule” Updates and Related Policy Updates

1. Revisions to the definition of “human subjects research”
2. Continuing review (annual renewal) will no longer be required for **minimal risk** research
3. Changes to categories of Exempt research
4. New informed consent requirements/templates
5. Review by a single IRB is required for co-operative research (in 2020) & for NIH-sponsored multisite studies (as of 2018)

Update #1:

Revisions to the definition of  
“Human Subjects Research”

# HHS Definition: human subjects

Living individuals about whom an investigator conducting research obtains either:

1. information or biospecimens through intervention or interaction with the individual, or;
2. identifiable private information or identifiable biospecimens

("Data" replaced with "information or biospecimens")

# Definition: research

- HHS: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge\*
- Four types of activities considered not “research” as defined in the Rule:
  - Certain scholarly and journalistic activities
  - Certain public health surveillance activities
  - Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes
  - Certain authorized operational activities for national security purposes

# “Scholarly and Journalistic Activities”

- e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- ... including the collection and use of information that focus directly on the specific individuals about whom the information is collected



# Definition: generalizable\*

“Generalizable” means that conclusions, facts, or principles derived from particulars (individuals, medical records, etc.) that are applicable to or affect a whole category and enhance scientific or academic understanding

- The information is broadly applicable or useful outside of the institution

# Definition of “human subjects research”

- Publication or intent to publish is not part of the definition of “human subjects research”
  - Intent to publish may signify that generalizable results are anticipated
- Activities that do not otherwise meet the regulatory definition of research will not be considered subject to IRB oversight even if published or intended for publication
- When in doubt – [contact Research Integrity](#) and we can provide you with a written determination as to whether or not your activity constitutes HSR

## Update #2:

Continuing review (annual renewal) will no longer be required for most **minimal risk** research

# Continuing review (annual renewal) is currently no longer required for **minimal risk**, ***unfunded*** research

- Beginning in early 2018, new **minimal risk**, ***unfunded*** studies approved by expedited review have been approved without an expiration date
  - Existing, open minimal risk, unfunded studies have approved without an expiration date at their next renewal
- Why only *unfunded* minimal risk research?:
  - Current federal regulations require continuing review for federally sponsored research. This change allowed us to introduce flexibility prior to the implementation date of the revised Common Rule

# Continuing review (annual renewal) is no longer required for most minimal risk research\*

- After 1/21/19, CR will no longer be automatically required for most minimal risk research initiated or renewed after this date
- Researchers are still required to submit all Amendments and Unanticipated Problems Reports (UPRs) to the IRB
- When the researcher is not required to submit a continuing review, the Research Integrity office will initiate a check-in at one year and ask:
  - Is the study still open?
  - Have any amendments not yet submitted?
  - Have any UPRs not yet reported?

Update #3:

Revised and new Exempt  
review categories

# Revised and new exempt review categories

- There are three different [levels of IRB review](#): exempt, expedited, and full committee.
- The existing exempt categories have been revised and a brand new exempt category for ‘benign behavioral interventions’ has been added.
- The full text of the new exempt categories and requirements are available on the [IRB website](#).

# Exempt Research: Category 1

Research conducted in established or commonly accepted educational settings...

Exemption excludes research involving possible "adverse effects" on student learning of the required education content and/or on the assessment of educators



# Exempt Research: Category 2

Research that only includes interactions involving educational tests, surveys, interviews, or observation of public behavior (including visual or auditory recording) of adults

Exemption excludes: interventions;  
collection of biospecimens

# Exempt Research: Category 3

(New Category) Research involving “benign behavioral interventions” with adult subjects if the subjects prospectively agrees to the intervention and information collection

Allows for some minimal risk interventions to qualify for Exempt determinations

# Category 3: Benign Behavioral Interventions

“... are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”

# Category 3

- Children are not permitted as subjects
- Deception not permitted unless the participant prospectively agrees
- Ex: statement in consent form
  - “... specific details about this study may be withheld from you at the outset. However, the full details of your participation will be provided upon the conclusion of your participation.”

# Limited IRB Review (Categories 2 & 3)

Categories 2 & 3 now allow for the collection of sensitive, identifiable information provided that the IRB conducts a “limited IRB review” to evaluate whether there are adequate privacy and confidentiality protections in the study protocol

# Exempt Research: Category 4

Secondary research uses of identifiable  
private information or identifiable  
biospecimens

(Note: publicly available *deidentified*  
information is not considered HSR per the  
regulations, and thus does not require IRB  
review)

# Revised Exemptions

- What do you have to do now?
  - Revised application forms that include the new exempt categories have been posted.
  - The IRB is able to apply new exemptions on January 21, 2019 – meaning that if your exempt application is reviewed on or after that date, we will apply the new rules.
  - Exempt research approved prior to January 21, 2019 is subject to the current rules.
  - The new exempt rules only effect new studies – existing [minimal risk](#) studies that were approved via expedited review will not be converted to exempt.

Update #4:

New Informed Consent  
requirements and templates



# New Informed Consent Requirements

Final consent forms that are over 4 pages long now require a concise summary of study activities, risks, and benefits presented first in the consent form.

*Informed consent documents that are longer than 4 pages are required to begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate. Skip the Key Information section for now. If once you complete modifying this template, the final consent form is less than four pages long, delete this section. If the final consent form is longer than four pages, enter the following information, and delete this instructional text:*

**Key Information**

Study Purpose:

Major Requirements of the Study:

Significant Risks:

Potential Benefits:

Duration of Participation:

# New Elements of Informed Consent

- Required: disclosure that de-identified data or biospecimens may be shared for future research (or not)
- As applicable:
  - Biospecimens will be used for commercial profit and whether subjects will share in profit.
  - Clinically relevant results will be returned.
  - Research will involve whole genome sequencing.

Researchers may still request a waiver or alteration of the required elements of informed consent with their IRB application (process does not change)

# New Requirement for Waiving/Altering Informed Consent

- To approve a waiver or alteration of informed consent for research involving **identifiable data** or biospecimens, the IRB must find that it is impracticable for the research to be conducted with de-identified data or biospecimens.
- IRB application forms and approval criteria worksheets have been revised to include this requirement and will begin applying it Jan. 21, 2019.

# **New Requirement for Waiving/Altering Requirement to Document Informed Consent**

- The IRB may approve a request to waive or alter the requirement to document informed consent (i.e. a signed consent form) for minimal risk research in communities or with cultural groups where signing documents is not the norm.
  - There must be an appropriate alternative mechanism or documenting that consent was obtained.
- IRB application forms and approval criteria worksheets have been revised to include this requirement and will begin applying it Jan. 21, 2019

## Update #5:

Review by a single IRB is required for some federally-funded multisite studies

# Review by a single IRB is required for some federally-funded multisite studies

- [Common Rule agency](#)-sponsored research with multi-institutional collaborators must be reviewed by only one IRB, which will serve as the IRB of record for all collaborators.
- Required January 25, 2018 for NIH; January 2020 for all other [Common Rule agencies](#).
- LU already has a single IRB review process in place (IRB Authorization Agreements for Human Subjects Research under “[IRB Guidance](#)”)
  - There will be no change, other than to require an IAA when necessary.

# Questions?

## Contact:

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