



Everything you need to know about the
Revised Common Rule -OR-

Much Ado about Nothing

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Subject & Timing

“Common Rule”

Main federal regulation for the protection of human subjects in research

Most provisions of the “New Common Rule” go into effect on or before **January 21, 2019**



Main Changes affecting Cornell Research

1. Eliminating continuing review for minimal risk research
2. New exemption categories and process
3. Improvements to informed consent
4. A broader definition of “Clinical Trial” and related requirements
5. Single IRB review for federally-funded cooperative research
(**effective January 2020**)



Eliminating continuing review for minimal risk research

“Good Riddance”

Troilus and Cressida
Act II, Scene 1



Eliminating continuing review for minimal risk research

Protocol Type	What to expect
MOST exempt & expedited studies	<ul style="list-style-type: none">• Annual renewal not needed• No action needed from PI• If your approval letter has an expiration date -- Prior to the expiration, the IRB office will send a new approval letter and stamped consent• Expect and pay attention to the new annual reminder email
Full board studies	<ul style="list-style-type: none">• Annual renewal <u>still required</u>, unless only analyzing identifiable data• Annual reminder email



New exemption categories and process

“It’s High Time”

Comedy of Errors
Act III, Scene 2



New exemption categories and process

Significant changes to exemption categories

- Intended to reduce administrative burden
- Some new categories are impractical and will not be implemented

Cornell IRB is streamlining the application process to take full advantage of increased opportunities for exemption

- A single, fillable application for all new studies
- You no longer need to guess what level of review your study needs

The IRB – not the PI - will continue to make determination about whether research is exempt



New exemption categories and process

- **New studies:** If it's eligible for exemption, IRB staff will grant an exemption
- **Existing studies:** If any action is needed, we will be in touch



Changes to Informed Consent

“Tis meate and drinke to me”

As You Like It
Act V, Scene 1



Changes to Informed Consent

1. Additional required consent elements (if applicable)
2. New consent form posting requirement (if applicable)



Changes to Informed Consent

Additional required consent elements

- De-identified data/specimens may be shared for future research
- Biospecimens may be used for commercial profit
- If clinically relevant results produced, are results shared with participants
- Research will involve whole genome sequencing

Consent templates have been modified to prompt addition of these elements, when required



Changes to Informed Consent

A “short statement”

Most Cornell consents are brief and would not benefit



Changes to Informed Consent

Takeaways:

New study: Use the new consent templates

Previously-approved study: Don't call us, we'll call you.

**The IRB office will contact you in the unlikely event that
your consent needs to be modified**



A Broader Definition of “Clinical Trial”

“Screw your courage to the sticking-place”

Macbeth
Act I, Scene 7



A Broader Definition of “Clinical Trial”

Key Take-away:

YOUR study might be one



Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?

YES

NO

Are participants prospectively assigned to an intervention?

YES

NO

Is the study designed to evaluate the effect of the intervention on the participants?

YES

NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?

YES

NO

This study is a clinical trial.

The study is NOT a clinical trial.



A Broader Definition of “clinical trial” - New Requirements

The IRB can help you determine if your study is a Clinical Trial

NIH-funded CTs

- Good Clinical Practice (GCP) training
- Register and provide updates on ClinicalTrials.gov

ALL federally-funded CTs

- Post consent to ClinicalTrials.gov after closed to recruitment/within 60 days of end of data collection



Single IRB review for federally-funded cooperative research

“O, that way madness lies”

King Lear
Act III, Scene IV



Single IRB review for federally-funded cooperative research

CURRENTLY, the sIRB mandate
ONLY applies to NIH PROPOSALS/STUDIES



Single IRB review for federally-funded cooperative research

- **sIRB:**
 - Conducts & coordinates ethical review for all participating sites: recruitment, consent, incident reports, data and privacy, etc.
- **Participating sites:**
 - Rely on sIRB to carry out review functions; report to sIRB any unanticipated problems, information on local context

If policy applies, NIH proposal **must include an sIRB Plan** identifying an sIRB and confirming agreement of participating sites



Single IRB review for federally-funded cooperative research

Can Cornell act as the sIRB?



Single IRB review for federally-funded cooperative research

**TO QUOTE
HAMLET
ACT III, SCENE III
LINE 87,
“NO”**



Single IRB review for federally-funded cooperative research

**...but, unless you are seeking NIH funding,
you don't need to worry about sIRB
(for now)**



Single IRB review for federally-funded cooperative research

Beginning in January 2020

Most federally-funded collaborative research in the U.S. will need to use a Single IRB



Any questions?

The IRB staff is here to help!

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