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

# *Much Ado about Nothing*

January 17, 2019

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Office of Research Integrity & Assurance

# 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 | • **Annual renewal not needed**<br>• **No action needed from PI**<br>• If your approval letter has an expiration date -- Prior to the expiration, the IRB office will send a new approval letter and stamped consent<br>• Expect and pay attention to the new annual reminder email |
| Full board studies | • **Annual renewal <u>still</u> <u>required</u>,** unless only analyzing identifiable data<br>• 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”

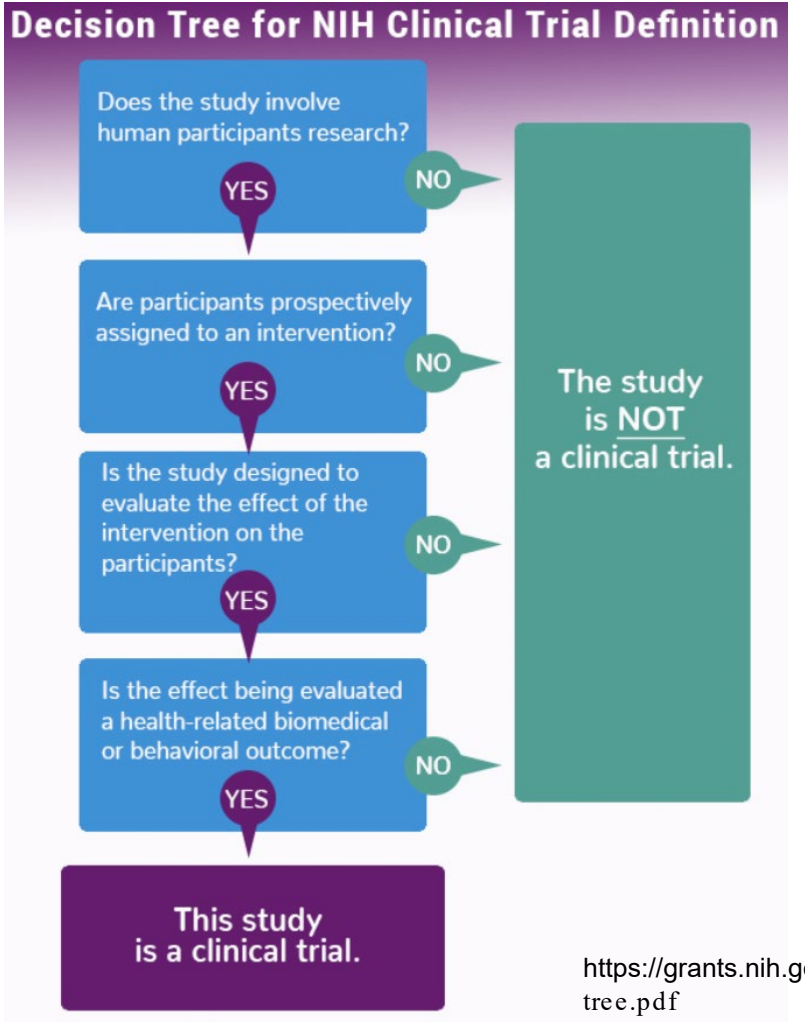
“Screw your courage to the sticking-place”

Macbeth
Act I, Scene 7

# A Broader Definition of "Clinical Trial"

## Key Take-away:

*YOUR study might be one*




https://grants.nih.gov/policy/clinical -trials/CT-decision-tree.pdf

# 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

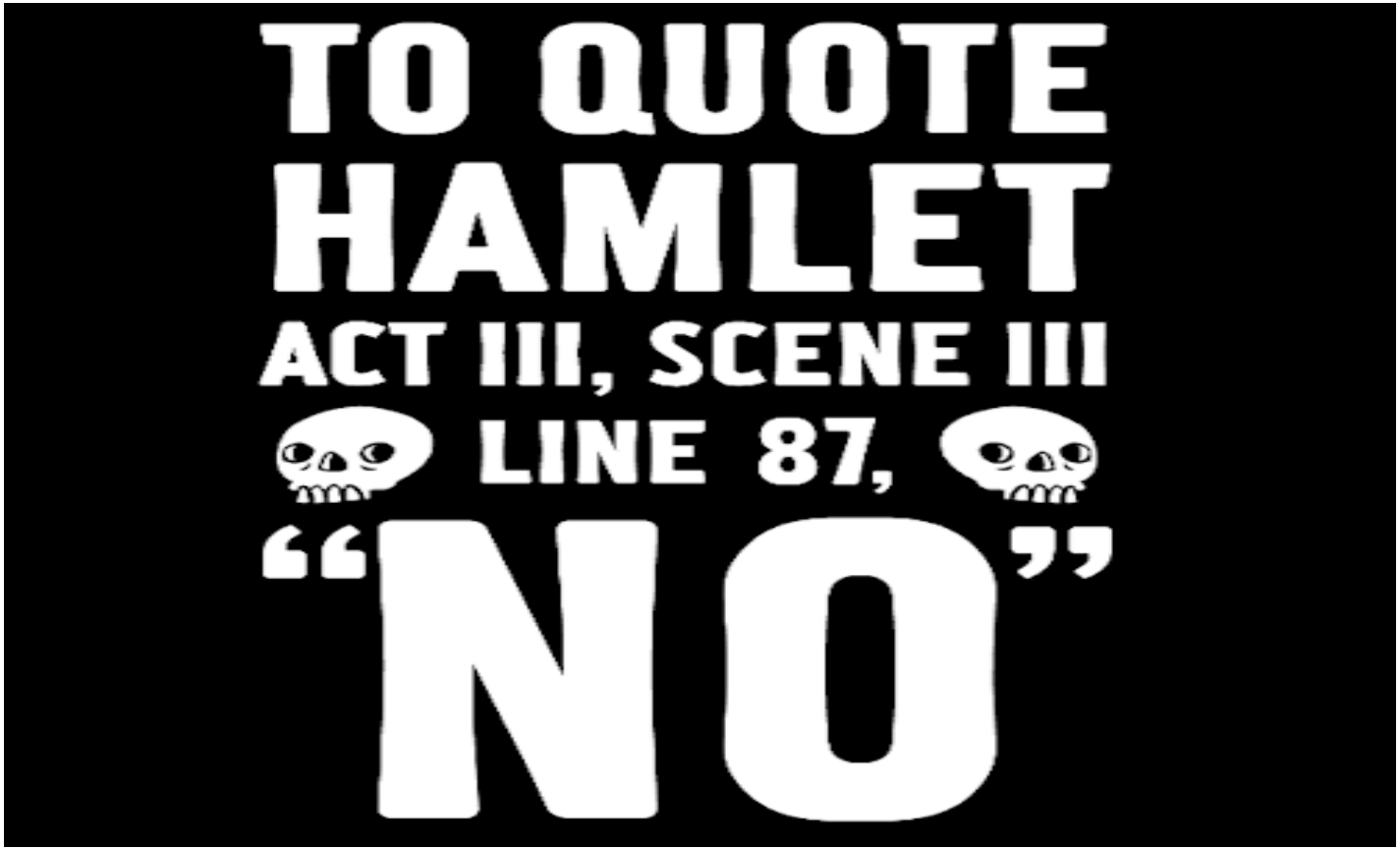
- **sIRB:**
  - Conducts & coordinates ethical review for all participating sites: recruitment, consent, incident reports, data and privacy, etc.
- **Participating sites:**
  - Rely on sIRB to carry out review functions; report to sIRB any unanticipated problems, information on local context

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



# 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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