Columbia University
Medical Center

# New Rule Information Session

## Monthly IRB-Investigator Meeting

## Human Research Protection Office

## January 24, 2019

Human Research Protection Office
Institutional Review Boards

# Agenda

- Regulatory Changes General Compliance: January 21, 2019
  - What you need to know
  - **All new submissions now subject to the new requirements**
- Pre-2018 Regulations (Pre-2018 Requirements)
- Regulatory Changes (2018 Requirements)
- Rascal Changes in place January 21, 2019 for new protocols
- Resources for more information

# Pre-2018 Human Subjects Regulations

- HHS Protection of Human Subjects (45 CFR 46, Subpart A)
  - As written, apply to federally funded research
  - "Common Rule" – adopted by multiple federal agencies
  - Initially promulgated in 1991 and amended in 2005
    - Notice of impending revisions was announced in 2017
    - Amended twice to delay compliance date
    - "Pre-2018 Rule"
  - Currently, Columbia applies these regulations to all research, as per commitments in our federalwide assurance of compliance (FWA)
  - Regulations of other federal agencies followed as applicable

# Regulatory Changes
# General Compliance: Jan. 21, 2019

- "Revised Common Rule", "2018 Requirements", "2018 Rule"
- HHS and 15 other federal departments and agencies
- Significant changes include:
  - Definitions (e.g., *research, human subject, identifiable biospecimens, identifiable private information*
  - New requirements for the content of informed consent documents
  - Establishes new exempt categories
  - Revises IRB review criteria
  - Removes the requirement for continuing review of ongoing research for certain studies
  - Allows the use of *broad consent*


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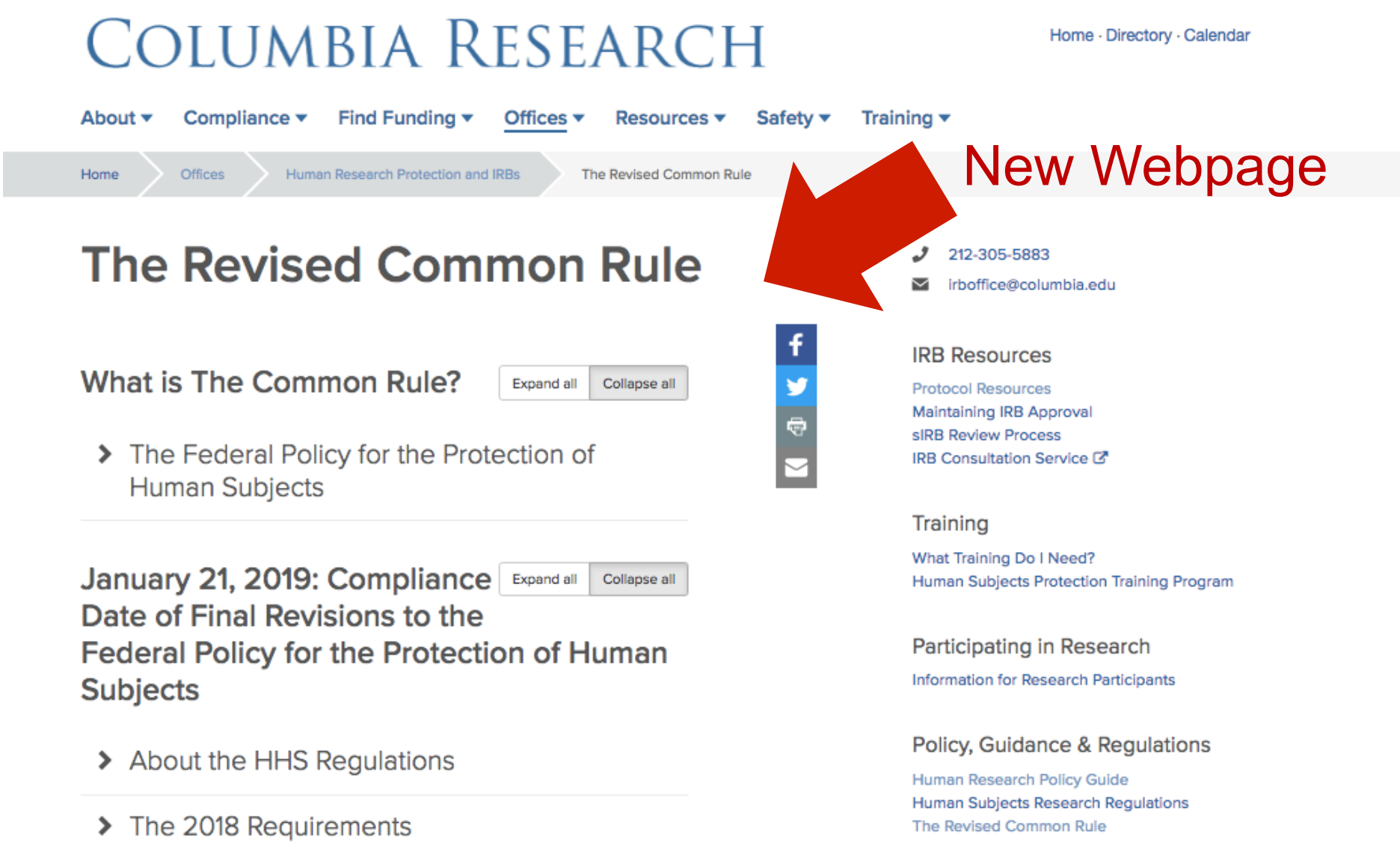
New Webpage
Human Research Policy Guide
Policy overviews and guidelines relevant to human research. In addition, the Clinical Research Handbook provides a comprehensive overview of all policies and
The Revised Common Rule
NEW! Find out about the new regulations for IRB review of research and how they affect you
Human Subjects Research Regulations & Ethical Principles
Listing of federal and state human subjects research regulations and guidance and ethical principles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The Revised Common Rule
New Webpage
The Revised Common Rule
What is The Common Rule?
Expand all
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The Federal Policy for the Protection of Human Subjects
January 21, 2019: Compliance Date of Final Revisions to the Federal Policy for the Protection of Human Subjects
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About the HHS Regulations
The 2018 Requirements
212-305-5883
irboffice@columbia.edu
IRB Resources
Protocol Resources
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IRB Consultation Service
Training
What Training Do I Need?
Human Subjects Protection Training Program
Participating in Research
Information for Research Participants
Policy, Guidance & Regulations
Human Research Policy Guide
Human Subjects Research Regulations
The Revised Common Rule

# Definition of *research*

Pre-2018

> Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Revised Common Rule adds:

> The following activities are deemed not to be research: scholarly and journalistic activities; public health surveillance activities; collection and analysis of information/biospecimens/records for certain legal activities; certain activities in support of matters of national importance

# Definition of *human subject*

Pre-2018

> (f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Revised Common Rule

> Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

# Elimination of continuing review

- Eligible studies are those that:
  - Were reviewed by an expedited review process, unless the reviewer justifies why CR would enhance protection of subjects
  - Have progressed to the point that they involve only data analysis or "accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care".
- A brief progress report that will be reviewed administratively will be required. Reasons for this include the need to:
  - Account for active research
  - Track recruitment
  - Update personnel

# Elimination of requirement for grant

- The requirement for the IRB to review the complete grant for a federally funded project has been eliminated
- The IRB will no longer require a copy of the complete grant
- The IRB may require a copy of some sections of a grant if additional information is needed for the IRB review (e.g., Methodology, Human Subjects section)

# Exempt Criteria – What's New?

- New Process for review (limited IRB Review)
  - For projects that collect sensitive, identifiable data, the IRB must review privacy/confidentiality protections (IRB criterion for review)
- Subpart C: Research that only incidentally includes prisoners may qualify for exemption
- **Exemption #1:** Now must consider "adverse effects" on student learning of required educational content or on assessment of educators
- **Exemption #2:** Expanded criterion for projects collecting sensitive and identifiable data which requires "limited IRB review" (for privacy/confidentiality protections). Does not apply to:
  - Interventions
  - Collection of biospecimens
  - Linking to additional personally-identifiable data
  - Children (except for educational tests or some public observation, i.e. (i) and (ii)

# Exemption #3: Benign Behavioral Intervention

- Completely New! *Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection*
- 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: Benign Behavioral Intervention

- 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)
- Must obtain "prospective agreement to the intervention and information collection," i.e. **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
- "Limited IRB Review" required for projects collecting sensitive and identifiable data

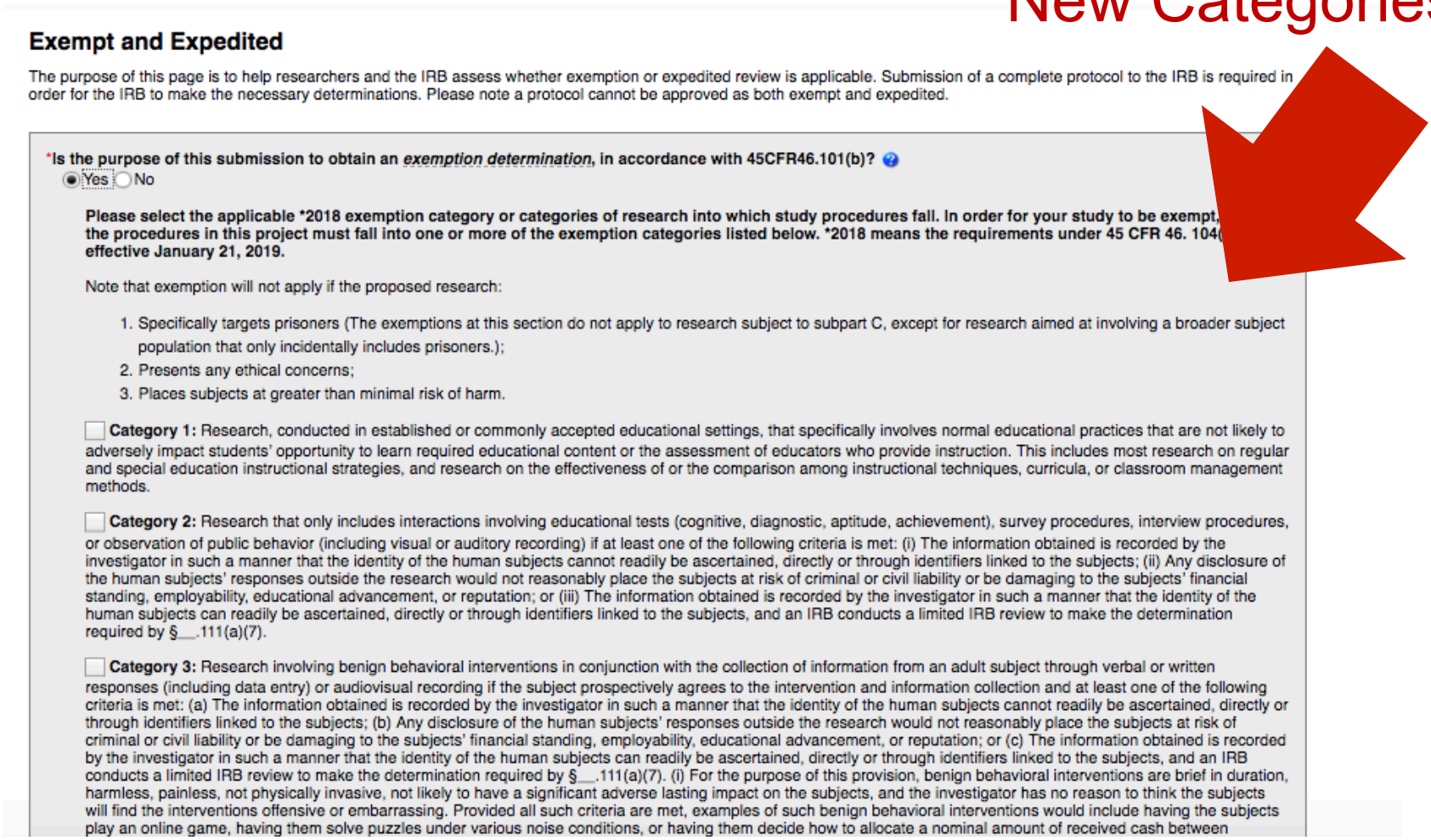
# Exempt Criteria – What's New? Continued

- **Exemption #4:** No longer limited to retrospective data review; Permits secondary use of identifiable protected health information (PHI) (with HIPAA privacy board review)
- **Exemption #5:** No Substantive Changes
- **Exemption #6:** No Change
- **Exemption #7: Completely New!** Storage and maintenance of identifiable data and/or biospecimens for future research collected under broad consent (i.e. creation of a repository); Limited IRB Review required
- **Exemption #8: Completely New!** Use of data or biospecimens collected under broad consent; Limited IRB Review required

No plans to review under Exemption Categories #7 & #8

# Rascal Changes – Exempt/Expedited Page

New Categories



**Exempt and Expedited**

The purpose of this page is to help researchers and the IRB assess whether exemption or expedited review is applicable. Submission of a complete protocol to the IRB is required in order for the IRB to make the necessary determinations. Please note a protocol cannot be approved as both exempt and expedited.

*Is the purpose of this submission to obtain an ***exemption determination*****, in accordance with 45CFR46.101(b)?**

(•) Yes ( ) No

**Please select the applicable *2018 exemption category or categories of research into which study procedures fall. In order for your study to be exempt, the procedures in this project must fall into one or more of the exemption categories listed below. *2018 means the requirements under 45 CFR 46. 104( effective January 21, 2019.**

Note that exemption will not apply if the proposed research:

1. Specifically targets prisoners (The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.);
2. Presents any ethical concerns;
3. Places subjects at greater than minimal risk of harm.

☐ **Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).

☐ **Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7). (i) For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between

# Informed Consent Changes: Broad Consent

- One time consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
- Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) *is permitted as an alternative to the informed consent requirements.
- Specific consent elements required.
- Refusal of broad consent **eliminates future waiver by IRB.**
- *No plans to implement broad consent at this time*

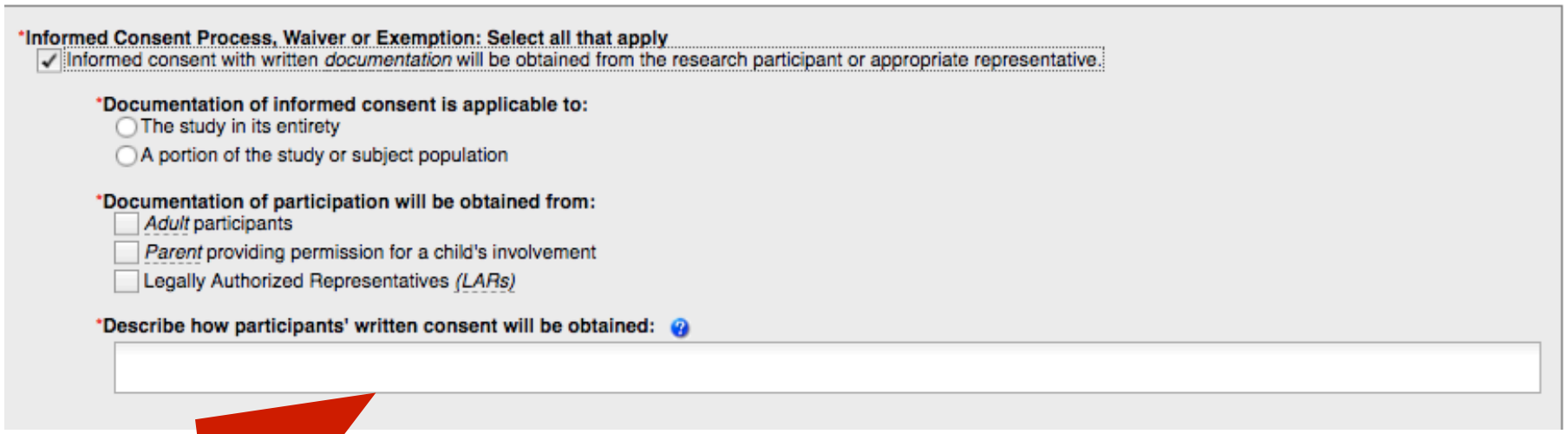
# Informed Consent Changes: Key Information

- "Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."
- Key information:
  - Voluntary participation
  - Summary of research procedures
  - Risks
  - Benefits

- Duration of participation
- Alternatives

- Brief social/behavioral consent documents may already meet this requirement
- Template guidaance now available on the HRPO Website

# Consent Process Information




Update to confirm key summary will be presented

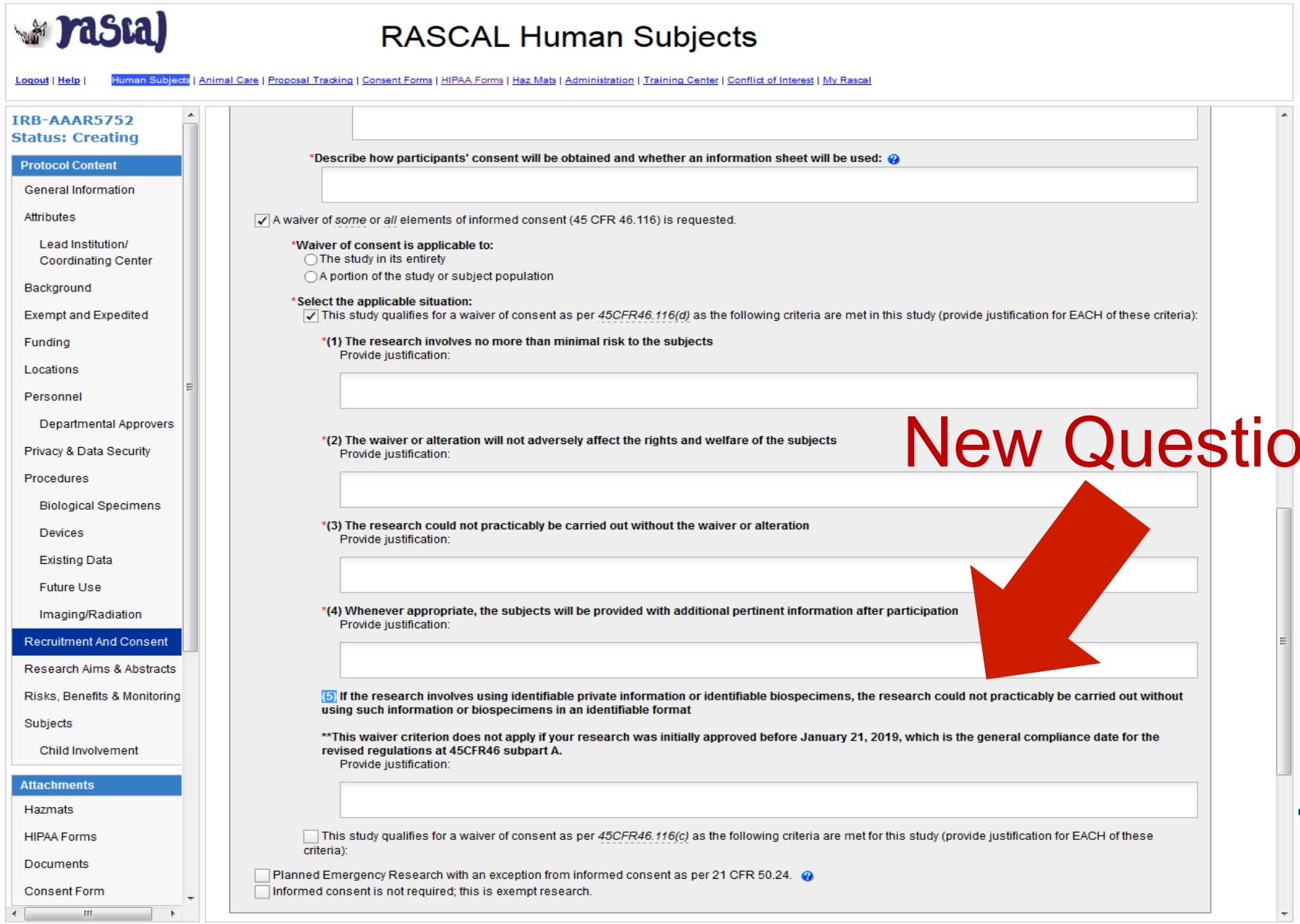
# Informed Consent Changes: Elements

- New required consent element:
  - De-identified data or biospecimens may be shared for future research (or not)
- New additional 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

# Informed Consent Changes: Waivers

- Waiver of informed consent: What's New
  - Added criterion that the use of identifiable private information or identifiable biospecimens could not be practicably carried out without using such information/specimens in the identifiable form.
- Waiver of documentation of consent: What's New
  - Electronic Consent included
  - Key Information must be presented and documented as being presented first during the oral consent process
  - Added criterion that allows waiver of documentation of consent if subjects are members of a distinct cultural group or community in which signing forms is not the norm (provided there is an appropriate alternative mechanism for documenting consent was obtained and the study presents no more than minimal risk.

# Waiver of Consent (46.116)



# Waiver of Documentation of Consent (46.117)

**Informed Consent Process:**

*Informed Consent Process, Waiver or Exemption: Select all that apply

- [ ] Informed consent with written *documentation* will be obtained from the research participant or appropriate representative.
- [x] Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.

If applicable, remember to attach the Information Sheet that will be provided/mailed to those subjects who agree to participate. If permission will be obtained over the phone, attach the Verbal Consent Script to be used to introduce the study to potential participants

*Waiver of written documentation of consent is applicable to:

- ○ The study in its entirety
- ○ A portion of the study or subject population

*Waiver of documentation of consent applies to:

- [ ] *Adult* participants
- [ ] *Parent* providing permission for a child's involvement
- [ ] Legally Authorized Representatives *(LARs)*

New Question

*Select the applicable basis for the waiver request: This study qualifies for a waiver of Written Documentation o… …s per 45CFR46.117(c) as the following criteria are met in this study

- ○ The only record linking the subject and the research would be the consent document and the principal risk wo… …l harm resulting from a breach of confidentiality. Each subject, or parent/LAR if applicable, will be asked whether the subject wants documentation … …ubject with the research, and the subject's wishes will govern
- ○ The research presents no more than minimal risk of harm to subjects and involves no procedures for which wri… …consent is normally required outside of the research context.
- ○ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. ****This waiver criterion does not apply if your research was initially approved before January 21, 2019, which is the general compliance date for the revised regulations at 45CFR46 subpart A.**

# Informed Consent Changes: Posting ICF

- 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."
- At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

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."*

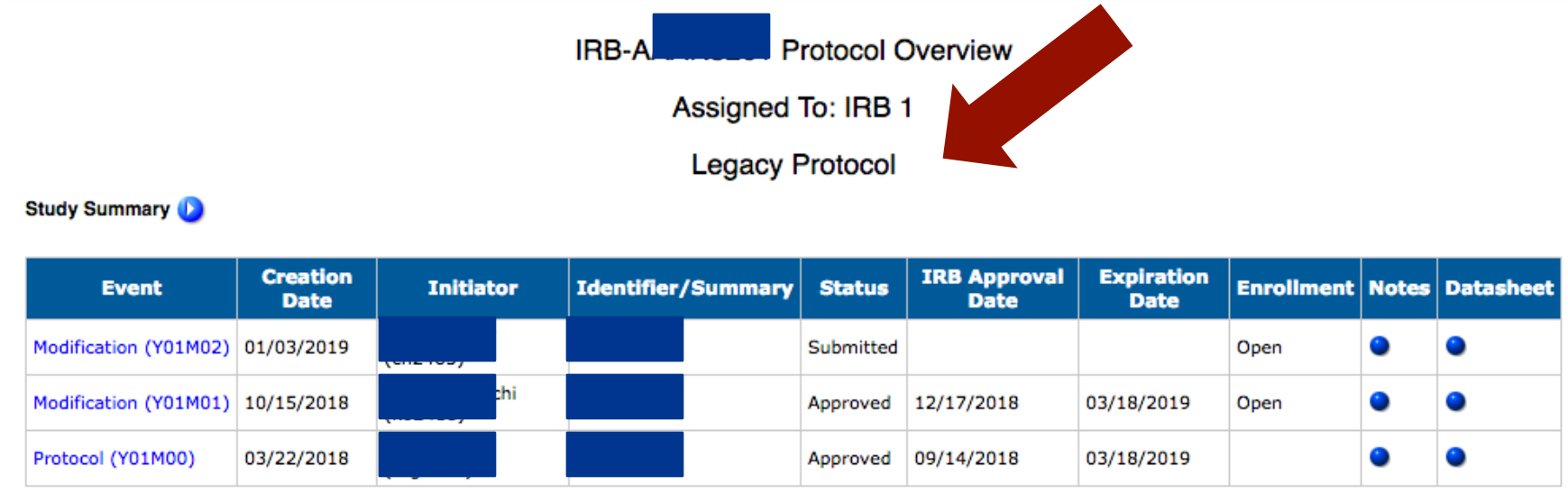
# What does this mean for Columbia?

# Implementing 2018 Requirements

- Revisions in the Rascal IRB module, released January 21
- Changes to IRB review processes
- Template/guidance for consent summary posted on website
- Multiple workshops and informational sessions to explain the new and revised requirements
- Information distributed via HRPO/IRB listserv
- Guidance posted on HRPO/IRB website

# Researchers should consider now:

- Regulations apply to research approved by an IRB **on or after** Jan. 21, 2019
- Institutions have the option of transitioning "legacy" protocols
  - **Columbia does not plan to transition**
  - **Protocols will be identified as Legacy in Rascal**



IRB-A [redacted] Protocol Overview

Assigned To: IRB 1

Legacy Protocol

Study Summary

| Event | Creation Date | Initiator | Identifier/Summary | Status | IRB Approval Date | Expiration Date | Enrollment | Notes | Datasheet |
|---|---|---|---|---|---|---|---|---|---|
| Modification (Y01M02) | 01/03/2019 | [redacted] | [redacted] | Submitted | | | Open | | |
| Modification (Y01M01) | 10/15/2018 | [redacted] | [redacted] | Approved | 12/17/2018 | 03/18/2019 | Open | | |
| Protocol (Y01M00) | 03/22/2018 | [redacted] | [redacted] | Approved | 09/14/2018 | 03/18/2019 | | | |

- Create Admin Closure Report

# Researchers should consider now (cont):

- New protocols submitted to the IRB before Jan. 21, 2019 but were not approved prior to Jan. 21, 2019 must comply with the new requirements:
  - This applies even if a convened review has been conducted
  - HRPO/IRB will facilitate compliance with new requirements

# Revised Common Rule resources

- Federal Register notice, January 19, 2017: https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf
- Council on Government Relations summary of changes: https://www.cogr.edu/sites/default/files/Summary%20of%20Changes%20to%20the%20Common%20Rule_COGR.pdf
- OHRP Revised Common Rule Educational Materials: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html

# Questions?

# Contact Us

HRPO Office: 154 Haven Avenue, First Floor

Walk-in Consultations: Tuesdays, 10-11 am

Phone: 212.305.5883

Email: irboffice@columbia.edu

IRB website: https://research.columbia.edu/IRB