



COLUMBIA UNIVERSITY  
MEDICAL CENTER

# Monthly IRB-Investigator Meeting

## December 20, 2018

Human Research Protection Office  
Institutional Review Boards

*Discover. Educate. Care. Lead.*

# Agenda

- Regulatory Changes Effective January 21, 2019
  - What you need to know
  - **What you should do now for new protocols currently under review**
- Revisions to the Incidental Findings from Imaging Procedures Conducted for Research Studies Policy
- General Data Protection Regulation (GDPR)
- Update on Columbia Human Research Protection Program reaccreditation



# Current 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 Effective 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*



# 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."**



# 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

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



# Consent requirements include:

- Prospective subject must be provided with the information that a reasonable person would want to know
- Must begin with a concise and focused presentation of key information
- Information must be detailed and presented in a way that facilitates understanding of the reasons why one might participate
- If identifiable private information or identifiable biospecimens will be collected, one of two specific statements re future use
- Additional requirements for information about use of biospecimens: potential commercial use; return of results (y/n), whether whole genome sequencing



# 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





# Broad consent options

- 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*



# Plans for implementation

- Revisions in the Rascal IRB module
- Changes to IRB review processes
- Template for consent summary
- 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
- New protocols submitted to the IRB before Jan. 21, 2019 but not yet approved on 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
- ***Recommendation: Make every attempt to move new protocols under review to approval before Jan. 21, 2019.***



# 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](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>



# Changes to the IF policy (10/1/18)

- “Incidental Findings from Imaging Procedures Conducted for Research Studies Policy”
- Identify specific types of images that are excluded (XtremeCT [QCT/HRpOCT], DEXA, similar non-high density scans)
- Better organization of information
- Terminology change: “Credentialed Radiologist” to “Credentialed Reader”
- Clarification of information to be included in the protocol
- Clarification of requirements for reporting of IFs at the time of continuing review



# General Data Protection Regulation (GDPR)

- Website: [https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules\\_en](https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en)
- Notice: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0043&from=EN>
- *“The new Regulation will strengthen the protection of the individual’s right to personal data protection, reflecting the nature of data protection as a fundamental right for the European Union.”*
- Affects data about EU citizens and data from EU.
- HRPO will provide guidance on a case-by-case basis after consulting with OGC. Contact the HRPO if GDPR applies.



# What is AAHRPP?

Association for the Accreditation of Human Research Protection Programs

- Non-profit, independent, international
- Accredits public and private organizations
- 251 accredited organizations
- In the US and foreign countries
- Intensive, indepth internal review and validation of HRPP



# Why Undergo the Process? What's the Value?

- Strengthens human subjects protections
- Builds public trust and confidence
- Value of accreditation extends to research enterprise as a whole
- Gain a competitive edge with Sponsors and other funders
- Reduce the risk of noncompliance
- Common commitment to continuous quality improvement

<http://www.aahrpp.org/learn/considering-accreditation/value-of-accreditation>





# Accreditation Process



They enjoyed meeting representatives of our HRPP, who were open, vibrant, enthusiastic and described the incredible work going on at Columbia  
They were impressed with the quality of our program, from institutional leadership through the HRPO staff

# Strengths

Columbia's HRPP met or strongly met the vast majority of AAHRPP standards, and time constraints prevented them from being able to give credit to them all, but they called out the following strengths:

- Human Research Protection Office staff, for their knowledge and support to researchers
- Rascal, for providing the infrastructure for research compliance – they heard “many great things” about it
- Our IRBs, for having the expertise necessary to review the complex research that is being done at Columbia, e.g., the creation of IRB 5 to provide the expertise necessary to review next generation sequencing
- Institutional leadership, which provided support and necessary resources
- CTO, for meeting AAHRPP's contract requirements, which is not always seen at site visits
- The Irving Institute's Community Engagement Core Resource (CECR), which was singled out as especially impressive with the investment in strengthening academic-community partnership



# Observations

- Record/Documentation
- Evaluations of IRB members and Chairs
- Clarification of actions taken by the IRBs as reflected in IRB correspondence (e.g., deferred to the Chair, deferred to the convened IRB) and the terminology utilized in Rascal (e.g., Pending, Returned, Deferred)
- Additional requirements for review when research is funded by federal agencies other than FDA or HHS



# Questions?



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