

# MONTHLY IRB- INVESTIGATOR MEETING

Columbia University  
Human Research Protection Office

December 12, 2019

# Agenda

Demonstration of a new Rascal feature, the Protocol Tracker

- Lists events, including summary of changes and attached documents, in one report

Explanation of Annual Report requirements and demonstration how it works in Rascal

New initiative to decrease the need for review at multiple convened meetings

Clarification about personnel on IRB protocols

Genetic Testing Policy revision

GDPR guidelines and applicability questionnaire

# When is an Annual Report Required?

- As per the revised Common Rule (45 CFR 46 2018 Requirements), continuing review requirements are eliminated for eligible studies 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”.
- Columbia requires an Annual Report
- Brief report to account for:
  - Active research
  - Track recruitment

# What can be submitted?

- Update to subjects section only
- Modifications are not accepted with Annual Reports
- May attach Cancer Center Renewal form or approval from non-CU reviewing IRB

**Changes to the research and/or submission of violations must be made via the modification module in Rascal**

- Annual Report is reviewed by HRPO staff

# VISION 2020

Columbia University  
Human Research Protection Office

Monthly Investigator Meeting  
December 12, 2019

# Strategies to Increase Efficiency & Effectiveness

- Aim to reduce number of convened IRB reviews
  - PIs or their designees asked to reserve time (no more than an hour) to be available for questions from the IRB
  - Applies to New Protocols only
- Review of New Protocol Resubmissions
  - Administrative processing with priority

**Help us Help You!**

- Ensure that submissions and resubmissions are complete

# Research Personnel

- Roles should be appropriate for research participation
- Visitors need to be registered with HR/OFA/Provost, as applicable
  - Properly cleared visitors can be added to studies
- Non-Columbia personnel should not be named in the Personnel section of the Rascal submission
- Students who are being paid or volunteering as research assistants need to be cleared by HR/OFA/Provost
- PI/department have responsibility for ensuring that personnel have the appropriate roles
- New guidelines are being developed

# GDPR

- General Data Protection Regulation
- Effective May 25, 2018
- Applies to data of individuals in the European Economic Area (EEA)
- Stringent data security/protection requirements
  - Data processors; data controllers
- Enhanced consent requirements
- Significant fines for noncompliance
- Not specific to research



# GDPR research situations

- Enrollment in EEA member state
  - Written consent
  - Additional requirements
- Data of subject in EEA
  - Consent required unless anonymized (strict standards)
  - Pseudonymization concept (coded data)
- Sponsor has global operations
  - Requests inclusion of GDPR language in consent forms even if enrollment is not in EEA

# Guidelines and Questionnaire

- Guidelines for research situations will be posted on the HRPO website
- Questionnaire may be required by HRPO, for review by OGC
- Contact us as soon as possible if GDPR is involved to avoid delays

# Revisions to the Genetic Testing Policy

- Consideration of who should have to take the informed consent training
- Reconciliation of the Policy with the training
  - *This course is required for research coordinators who will be obtaining informed consent for genetic research when results of the genetic testing may be returned to participants.*

# Revisions

Informed consent for genetic testing conducted in connection with a research study may be obtained in person by a member of the study research team so long as such person is (1) the principal investigator or co-investigator of the study, (2) a genetic counselor certified by the American Board of Genetic Counseling, Inc. or (3) a research coordinator who has been certified by the University as having completed the University's Informed Consent in Genetic Research training ~~in obtaining consent for genetic testing~~ (each, a “Qualified Consenter”), or remotely through electronic means, so long as a Qualified Consenter is available by telephone or other interactive media to answer questions of potential subjects.

# Final Text

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# Contact us (CUIMC)

HRPO staff identified in correspondence (for returned Events)

[irboffice@columbia.edu](mailto:irboffice@columbia.edu)

212.305.3553

No appointment needed consultations:

- Mondays 3-4pm, PH10
- Tuesdays 10-11am, 154 Haven Avenue, First Floor
- Wednesdays 10-11am, PH10
- Thursdays 10-11am, PH10

HRPO website: <https://research.columbia.edu/irb>

# Questions?

