

# HRPO/IRB UPDATES AND Q/A SESSION

Columbia University  
Human Research Protection Office

May 16, 2019

# Agenda

- Updates
  - GDPR
  - “Approval” letters
  - Reliance processes
  - Expanded Single IRB requirements
  - Certificates of Confidentiality
  - Informational sessions
- YOUR Questions...OUR Answers

# General Data Protection Regulation

- EU General Data Protection Regulation
- Privacy and data security law
- Effective May 25, 2018
- Scope – protections in the processing of personal data of individuals in the European Economic Area; rights of EEA individuals over their personal data
- Personal data – any information relating to an identified or identifiable natural person
- Additional consent documents may be required, e.g.,
  - Privacy notice
  - GDPR consent form
- Pseudonymisation -

# Additional defined terms include:

- Pseudonymisation
- Processing
- Profiling
- Processor
- Controller
- Recipient
- Genetic data
- Biometric data
- Data concerning health

# What you need to know/do now

- Alert the HRPO as soon as possible if you:
- Will enroll subjects in the EEA
  - The EEA consists of the following countries: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK.
- Will receive data from the EEA
- Receive a sponsor's model consent form that includes reference to GDPR or GDPR language, or a GDPR privacy notice or GDPR consent form
- Are asked to commit to GDPR requirements, procedures, etc

# IRB Determination Letters

- Currently called “IRB Approval Letter”
- Issued upon IRB or administrative approval of IRB “events”
- Posted in the Print Menu in Rascal
- May contain restrictions, requirements, conditions
- \*Important to be thoroughly reviewed
- Changes in Rascal forthcoming
  - Name change to “IRB Determination Letter”
  - Email containing notification of letter release will include link to letter
  - This email will go to PI, coordinators, initiator
  - Protocol Overview will indicate that letter is released
  - Email content has been revised

# Reliance Processes

- IRB reliance – agreement between institutions that the responsibility for IRB review will be ceded to an institution other than the one conducting the research
  - “Single IRB”, “Central IRB”, “Reviewing IRB”
  - “Relying Institution”
  - Requirement for certain NIH-funded multicenter studies
  - Requirement for certain other studies or groups of studies
  - Voluntary in other situations
  - Columbia may be a Reviewing IRB or Relying Institution
- Some reliance situations are established
  - NeuroNext, StrokeNet, TrialNet, HVTN, certain cooperative oncology studies,
  - NYSPI for most Psychiatry studies

# Reliance Requests

- New reliance situations
  - Reliance (either way) is an active Columbia decision
  - Complete a Reliance Request form
  - Contact [irboffice@columbia.edu](mailto:irboffice@columbia.edu)
  - Plan as far in advance as possible
- Considerations
  - Columbia's role
  - Status of Reviewing IRB (if Columbia will rely)
  - Reliance Agreement
  - Terms/Responsibilities of each party
  - Whether reliance is required, preferred, voluntary



# Expanded Single IRB Requirements

- January 2020 – 45 CFR 46 single IRB requirement for certain cooperative research
- §46.114 (b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
- Applies to federally funded research

# Certificates of Confidentiality

- NIH policy effective October 1, 2017
- Certificates of Confidentiality (COCs) will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016
  - At end of award project period, if data collection will continue, must apply for a CoC
  - <https://grants.nih.gov/policy/humansubjects/coc.htm>
- If not NIH funded, may still request a CoC

# HRPO/IRB Informational Sessions

- Questions for the audience:
  - What topics should be covered in upcoming HRPO/IRB informational sessions?
  - Is this time of day conducive to your attendance?
  - Are you interested in Rascal workshops?
  - Do you have suggestions for improvements to the Rascal IRB module?

# Questions?



# Columbia University Irving Medical Center:

- [irboffice@columbia.edu](mailto:irboffice@columbia.edu)
- 212-305-5883

## IRB Liaison Schedule: PH 10 (Irving Institute)

- Monday: 3-4pm
- Wednesday: 10-11am
- Thursday: 10-11am

Open Office Hours: Tuesday 10-11am (154 Haven)