Columbia University Medical Center

Monthly IRB-Investigator Meeting (MIM)

HRPO Updates on Select Research Policies and Guidance Documents

March 18, 2021

Agenda

- Appendix A: when is it required?
- DUA/MTA webpage and intake process
- e-Consent follow-up

EH&S Safety Matters Newsletter Spring 2021

- Clarification of when IBC review is required concurrent with IRB review for COVID-19 research
  - As importantly, when IBC review is NOT required
- Review is solicited by attaching a hazardous materials Appendix A to the IRB protocol
- IRB will not approve the protocol until the Appendix is approved
- Newsletters: https://research.columbia.edu/safetymatters-newsletter

IBC review is required, for COVID-19 research:

- Only for research employing subjects that have active COVID-19 infection. Research on subjects who are convalescent and have tested negative by PCR is not subject to IBC review. Nonetheless, strict adherence to universal precautions should be exercised in handling any clinical specimens.
- Only for research where COVID-19 specimens are processed in Columbia University laboratories, or for studies where COVID-19 specimens are packed and shipped to another facility for testing. Studies where COVID-19 specimens are processed solely in hospital labs, which are CLIA/CLEP-regulated, are exempt from IBC review. Investigators processing COVID-19 specimens must take Rascal training TC5500.

IBC review is required: (continued)

- For all types of specimens from subjects that have active COVID-19 infection (e.g., nasopharyngeal swab, saliva, blood).
- For studies where potentially infectious material is received from the University's COVID-19 Biobank, as well as directly from the study subjects.

IBC review is NOT required:

- for studies that employ materials from subjects with COVID-19 disease that has been inactivated immediately following collection (i.e., at the bedside), inactivated in the University's COVID-19 Biobank, or inactivated by a collaborator.
- However, the Biosafety Office reviews all such research. Therefore, please email biosafety@columbia.edu to confirm that the inactivation procedure employs an approved method.

IBC review continues to be required:

- When recombinant DNA (e.g. COVID-19 mRNA vaccine) is administered to research subjects (Appendix M required).
- When infectious agents other than SARS-CoV-2 are cultured from research subject specimens in a Columbia University laboratory.
- When recombinant or non-recombinant infectious agents (e.g. live vaccines) are administered to research subjects.

Helpful resources include:

- Guidance on attaching Appendix A to an IRB protocol https://research.columbia.edu/sites/ d e f a u l t / f i l e s / c o n t e n t / E H S / B i o S a f e t y / R a s c a l % 2 0A p pe n d i c e s / AppendicesandAttachtoIRBprotocol.pdf
- The EVPR clinical research handbook https://research.columbia.edu/sites/default/files/ content/EVPR/Handbooks/Clinical%20Research%20Handbook% 202020%20FINAL_0.pdf
- The biosafety office, who can be contacted at biosafety@columbia.edu

SPA DUA/MTA Webpage

- IRB review may identify the need for a MTA or DUA
  - Referral to SPA
- Request a DUA or MTA for Research Purposes webpage: https://research.columbia.edu/mta-dua
- MTA or DUA likely needed if you are:
  - Exchanging (either sending or receiving) materials or data from/to a non-Columbia party for research purposes
- To request an MTA and/or a DUA, complete the online MTA/DUA Intake Form: https://cumc.co1.qualtrics.com/jfe/form/SV_29rqFAm9Dh4xX6Z
- General information and FAQs

Update from e-Consent MIM

- Workgroup to develop guidance
- Guidance is in final draft for review by group
- Answers to outstanding questions:
  - DocuSign – acceptable for most uses; exceptions are explained in the Electronic Signature-DocuSign information https://cuit.columbia.edu/electronic-signature
  - REDCap dual signature process: first signature with “incomplete” status then sent to potential participant for second signature; or vice versa.
    - Research records should describe consent process and dates of actions taken.

Questions?

Contact the HRPO

If you have a question about a submitted protocol:

- Identify the IRB to which it is assigned
- Contact the designated HRPO staff:
  - https://research.columbia.edu/sites/default/files/content/HRPO/Directories/HRPOStaffDirectory%2011.30.2020.pdf

General questions only:

– irboffice@columbia.edu

– 212-305-5883