

March 31, 2021

Re: EG Guideline for Good Clinical Practices: 1 May 1996 (ICH/GCP), Section 3 To Whom It May Concern:

The University of Pennsylvania Institutional Review Board (IRB) operates in compliance with the guidance issued by the International Conference on Harmonization (ICH), ICH harmonized tripartite guidelines: EG Guideline for Good Clinical Practices: 1 May 1996 (ICH/GCP), Section 3 **with the exception of the following.**

3.1.2 The IRB/IEC should obtain the following documents:

- Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, **the investigator's current curriculum vitae** and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfill its responsibilities.
 - The University of Pennsylvania IRB does not require submission of CVs of investigators at the time of IRB submission; however, Penn has a policy that no investigator is permitted to conduct research unless they are considered to be adequately trained to conduct such research. This assessment is incorporated into the IRB review process.

3.4 Records:

- The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority (ies). The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and **membership lists.**
 - The University of Pennsylvania IRB does not disclose the names of its membership to sponsors for confidentiality purposes and to preclude the perception that sponsors have the potential to influence the review processes. Of note all IRB members sign a conflict of interest disclosure memo as part of their membership.
 - IRB membership is comprised of:

- physician scientists of different disciplines and backgrounds (the exception is the social/behavioral sciences IRB, which does not require a physician scientist member)
- other scientists of different disciplines and backgrounds
- non-scientists (persons without scientific background either through education or experience)
- non-affiliates (persons who are not associated with Penn)

Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and applicable regulatory requirements.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website:

<https://irb.upenn.edu/directory>.

Sincerely,

Jessica L. Yoos, MA, M.Phil., CIP
Director, Human Research Protections