Biomedical Non-Exempt eProtocol Questions

If any of the below questions apply to your research, please complete a biomedical version of the eProtocol form. Note that below questions have been included for informational purposes only. Please do not submit this document to OPHS/CPHS. All human subjects research applications must be submitted through eProtocol.

1. Does this research fall under FDA regulations?
2. Any use of human blood, body fluids, tissues, or cells (including cell lines)* by drawing samples, accepting samples already drawn, receiving samples from any source, or in any other way?
3. Will biological specimens be stored for future research projects?
4. Will specimens be sent out of UCB as part of a research agreement?
5. Will proprietary drug or device testing be done?
6. Any use of embryonic stem cells? *NOTE: If research involves embryonic stem cells, see UCB Stem Cell Policy and Committee.
7. Any use of medical devices or equipment cleared/approved for marketing?
8. Any use of any experimental or investigational devices or equipment (i.e., not cleared/approved for marketing?)
9. Any use of commercially available drugs, reagents, or other chemicals administered to subjects (even if drugs themselves are not being studied)?
10. Any use of investigational drugs, reagents, or chemicals (i.e., not cleared/approved for marketing)?
11. Do you intend to use ionizing radioactive materials or ionizing radiation-producing devices in your research (e.g., injectable, oral, x-rays, etc.)?
(CAUTION: The UCB Radioactive Materials License does not permit human research using radioactive materials or radiation from such materials.)
12. Do you intend to use any non-ionizing radiation sources (laser or magnetic sources) in your research?
13. Describe the source of ionizing radiation or non-ionizing radiation.
14. Medical Equipment: If the research involves use of medical equipment, explain whether the equipment is approved for marketing and routinely employed in clinical practice.
15. List any investigational devices.
16. List any investigational Drugs, Reagents, or Chemicals.
17. List commercial drugs, reagents, or chemicals.
18. If applicable, indicate if a particular study treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
19. If reviewing or accessing Protected Health Information (PHI) from UC Berkeley's Tang Center, Optometry Clinic, Psychology Clinic, Intercollegiate Athletics, or Human Resources for activities preparatory to research, describe the process and confirm that the health information will not be removed from the "covered entity".
20. Health Insurance Portability and Accountability Act (HIPAA)
The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. UC Berkeley's covered entities

are the University Health Services (including its health care services on behalf of Intercollegiate Athletics) and the Optometry Clinic. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without their authorization (i.e., IRB waiver of authorization). For more information, see CPHS Guidelines HIPAA and Human Subjects Research.

a. Does the study involve use of Protected Health Information (PHI) from a "covered entity" outside of UC Berkeley (i.e. another organization or institution)? For more information, see HIPAA and Human Subjects Research.

b. Does the study involve use of a "Limited Data Set" from a covered entity? For more information, see HIPAA and Human Subjects Research. Please see The Industry Alliance Office website for limited data set requirements.

If Yes, patient authorization for use of the data set is not required; however, you must have a data use agreement in place with the data holder from which the data will be obtained as required by HIPAA. Contact the Industry Alliance Office for further information at (510) 642-5766.

c. Does the study involve use of Protected Health Information (PHI) from UC Berkeley's University Health Services (including its health care services on behalf of Intercollegiate Athletics) and/or the Optometry Clinic?