Attachments Check List for Non-Exempt Applications

This list includes core application components as well as examples for a variety of different study designs. Upload those items that are applicable for your protocol. Specific circumstances may trigger the need for additional attachments not listed here; please consult with OPHS staff *as needed, by emailing ophs@berkeley.edu or calling 510-642-7461.*

- ❑ Applicable human subjects training curriculum completion certificates, such as HIPAA training or Good Clinical Practice (GCP) training (for requirements, see https://cphs.berkeley.edu/training.html and https://cphs.berkeley.edu/policies_procedures/ga102b.pdf). Note: While most study personnel must complete Collaborative Institutional Training Initiative (CITI) training, CITI completion reports do not need to be attached in eProtocol.

- ❑ Subject recruitment materials, such as:
  - Verbal announcements, solicitation letters, mail scripts, etc.
  - Flyers/informational letters
  - Advertisements – MTurk, Craigslist, Research Psychology Pool listing, XLab listing, etc.
  - Recruitment meeting materials – itinerary, slides, etc.

- ❑ Recruitment site permission letters do not need to be attached in eProtocol, but the protocol (part 6b) should confirm that investigators have/will obtain all necessary site permissions.

- ❑ Survey instruments– standardized and/or non-standardized

- ❑ Data collection forms (for research with secondary data)

- ❑ Interview and/or focus group guides

- ❑ Supplemental subject materials such as:
  - Home-administered test kit directions
  - In-Lab experiment instructions
  - Online experiment instructions
  - Website screen shots
  - Manuals (e.g., PhotoVoice instruction guide for participatory research study)
  - Academic course outlines/materials **only if** they constitute part of the study interventions

- ❑ General debriefing scripts. If subjects will **re-consent for the use of their data**, do not include in Attachments section. Instead, add to Informed Consent (i.e., section 15-social-behavioral; section 19-biomedical)

- ❑ Medical Research Subject's Bill of Rights (required when study interventions include medical and/or physiological procedures; e.g., blood draw by venipuncture/finger stick, MRI, saliva collection, anthropometric measurements, etc.)

- ❑ Industry-sponsored research protocol (should include the sponsor's version date)

- ❑ Investigational brochure (e.g., clinical trial of drug or device)

- ❑ EH&S Safety Evaluation of investigational devices (e.g., with electrical, mechanical, laser components).

- ❑ Product labels (i.e., for all investigational and/or commercial drugs associated with protocol)

- ❑ Other institutions' IRB approval letters/determinations of exemption

- ❑ Reliance Request Document – download the 4-page document from the UC IRB Reliance Registry (attach when another UC wishes to rely upon the UCB IRB review via the MOU)

- ❑ UCB Request to Review Research for Another Institution form, if requesting for another institution to rely on UCB's IRB review OPHS uploads the Inter-Institutional Agreement when finalized)

- ❑ UCB Request to Review Research for an Individual Investigator form, if requesting for an individual investigator to rely on UCB's IRB review; OPHS uploads the Individual Investigator Agreement when finalized)

- ❑ HIPAA authorization form (for guidance on when needed, see https://cphs.berkeley.edu/hipaa.pdf)

- ❑ References