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.

- ❑ Human subjects training curriculum completion certificates (for requirements, see http://cphs.berkeley.edu/training.html). 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:
  - o Verbal announcements, solicitation letters, mail scripts, etc.
  - o Flyers/informational letters
  - o Advertisements – MTurk, Craigslist, Research Psychology Pool listing, XLab listing, etc.
  - o Recruitment meeting materials – itinerary, slides, etc.

- ❑ Recruitment site permission letters (for specifics, see eProtocol instructions for part 6b)

- ❑ 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:
  - o Home-administered test kit directions
  - o In-Lab experiment instructions
  - o Online experiment instructions
  - o Website screen shots
  - o Manuals (e.g., PhotoVoice instruction guide for participatory research study)
  - o 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.)

- ❑ Data security plan and Agreement (e.g., If required by holder of a restricted use dataset prior to their release of data for your secondary analysis purposes)

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

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

- ❑ 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)
- ❑ Inter-Institutional Agreement (used when another IRB will rely upon the UCB IRB review; OPHS uploads the Agreement when finalized)
- ❑ Individual Investigator Agreement (used when an unaffiliated investigator is engaged in the research; OPHS uploads the Agreement when finalized)
- ❑ Research Aspects of HIPAA training completion certificates (needed if accessing PHI; link to training available on the CPHS web site)
- ❑ HIPAA authorization form (for guidance on when needed, see http://cphs.berkeley.edu/hipaa.pdf)
- ❑ References