Brandeis UNIVERSITY
Human Research Protection Program

INITIAL PROTOCOL CHECKLIST

Prior to completing your Initial Protocol:

- ☐ Does your project constitute Human Subjects Research?
  (See Defining Human Subjects Research)
- ☐ Is your CITI training up-to-date?
  (See the *Required Training* webpage)
- ☐ Do you have an appropriate Data Management and Protection plan?
  (See the Guide to Data Management and Protection)
- ☐ Have you checked to see if your research is Exempt?
  (See the Exempt Research Categories)
- ☐ If your research involves animals, do you have *IACUC* approval?
- ☐ If your research involves human blood, fluids, tissues, or cell lines; infectious agents; select agents; or DNA, do you have *IBC* approval?

Your completed Initial Protocol must include the following (where applicable):
Note: All forms can be found on the *Forms & Instructions* webpages

- ☐ Recruitment materials – as they will appear to subjects (e.g., with graphics, on letter head)
  (Detailed requirements for recruitment materials can be found on the Recruitment webpage)
  - ☐ Copies of ads, notices, and flyers
  - ☐ Telephone scripts
  - ☐ Solicitation letters or emails
  - ☐ Pamphlets or brochures
  - ☐ Letters of permission or agreement from outside sites (with their understanding of everyone's roles)
- ☐ Informed Consent/Assent materials – as they will appear to subjects (e.g., with graphics, on letter head)
  (See the *Informed Consent* webpage as well as the Elements of Informed Consent and Informed Consent Template)
  - ☐ Informed consent/assent forms
  - ☐ Informed consent computer screens
  - ☐ Cover letters
  - ☐ Consent to participate forms (when using deception)
  - ☐ Information sheets (most often in lieu of informed consent forms)
  - ☐ Informed consent script (most often in lieu of informed consent forms or information sheets)
  - ☐ Debriefing forms
- ☐ Study Instruments
  - ☐ Surveys/questionnaires
  - ☐ Interview questions and scripts
  - ☐ Focus group questions and scripts
  - ☐ Any other test or assessment materials
  - ☐ Equipment diagrams
- ☐ Permission Letters
  - ☐ Permission/agreement letters from external sites (with their understanding of everyone's roles)
    (Detailed requirements can be found on the Off-campus Site Permissions webpage)
  - ☐ Data use agreements (DUAs)
  - ☐ Memorandums of understanding (MOUs)
- ☐ International Research Addendum if conducting research outside the US
  - ☐ Approvals from foreign IRBs/ethics committees/countries/leaders/experts
- ☐ Be prepared to submit Translation Certifications for all translated documents (recruitment materials, informed consent documents, study instruments) once they have been approved in English