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