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 (students and postdocs)?  
  (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)
  - 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