Prior to completing your application:

☐ 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 IRB application must include the following (where applicable):

Note: All forms can be found on the Forms & Instructions webpages

☐ The appropriate IRB Application Form 
(See the Initial Application webpage)

☐ The Assurance (must be signed by the PI and, if applicable, the Student Researcher)

☐ Recruitment materials – as they will appear to subjects (e.g., with graphics, on letter head)
  ☐ 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

☐ Translation Certifications for all translated documents

☐ 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