IRB APPLICATION CHECKLIST

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

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