Nonmedical Institutional Review Board
Full Review Application Checklist

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<th>No. of Copies for Each Applicable Form</th>
<th>Description</th>
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<td>11</td>
<td>Section 1: Core Application [Forms A &amp; B]</td>
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<td>Section 2: Informed Consent/Assent Process [Forms C-H]</td>
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<td>Section 5: Vulnerable Populations [Forms T-W]</td>
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<td>2 or 3 (see Section 6 for Details)</td>
<td>Section 6: Materials for Primary Reviewer and Detailed Protocol/Grant Application Review [Forms Z-AA]</td>
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Each component of the application has been assigned a letter of the alphabet (as shown under the left-hand "Form" column). When preparing your application, be sure to collate all applicable materials in the assigned alphabetical order. Note there may be some letters of the alphabet missing due to changes in IRB application requirements or forms applicable to Medical IRB only.

**Section 1**
Core Application - completion of A & B is required
Include 11 copies of each for the entire IRB.

**FORM**

- **A.** General Information Sheet
- **B.** Research Description with Appendices

**Section 2**
Informed Consent/Assent Process
You must select applicable item(s) from Form C - F and include 11 copies of each applicable item for the entire IRB. If Form G and/or H apply, include 11 copies for the entire IRB.

**FORM**

- **C.** Proposed Informed Consent Form(s) (English and if applicable, Spanish or other translation)
- **D.** Proposed Assent Form(s) (English and if applicable, Spanish)
- **E.** Request for Waiver of Informed Consent Process
- **F.** Request for Waiver of Documentation of Informed Consent Process
  If applicable, Cover Letter Template.
- **H.** For recruitment of Non-English speaking subjects, attach translated consent document
### Section 3
**HIPAA (Health Insurance Portability and Accountability Act)**
If HIPAA applies to your research, attach 11 copies of each applicable item for the entire IRB. [visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.]

**FORM**
- I. If you plan to de-identify the data, complete the **HIPAA De-identification Certification Form**
- J. Proposed HIPAA Authorization Form
- K. Request for Waiver of HIPAA Authorization Form

### Section 4
**Additional Study Materials**
Complete/attach all of the below items that apply to your research; include 11 copies for the entire IRB.

**FORM**
- L. Proposed advertisement(s) of any type for recruiting subjects
- M. Proposed data collection instrument(s) (i.e., survey(s), questionnaire(s))

### Section 5
**Vulnerable Populations**
Complete all of the forms below that apply to your research; include 11 copies of each applicable form for the entire IRB.

**FORM**
- T. Research Involving Adults with Impaired Consent Capacity
- U. Research Involving Pregnant Women, Fetuses, &/or Neonates
- V. Research Involving Prisoners
- W. Research Involving Children

### Section 6
**Materials for Primary Reviewer and Detailed Protocol/Grant Application Review**
Attach the indicated number of copies.

**FORM**
- Z. 1 Original Signature Assurance Sheet and 2 copies
- AA. 2 copies of the grant application