

Nonmedical Institutional Review Board Full Review Application Checklist

No. of Copies for Each Applicable Form	
11	Section 1: Core Application [Forms A & B]
11	Section 2: Informed Consent/Assent Process [Forms C-H]
11	Section 3: HIPAA Materials [Forms I-K]
11	Section 4: Additional Study Material [Forms L-S]
11	Section 5: Vulnerable Populations [Forms T-W]
2 or 3 (see Section 6 for Details)	Section 6: Materials for Primary Reviewer and Detailed Protocol/Grant Application Review [Forms X-DD]

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	
<input type="checkbox"/>	A. General Information Sheet
<input type="checkbox"/>	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 <i>applicable</i> item for the entire IRB. If Form G and/or H apply, include 11 copies for the entire IRB.	
FORM	
<input type="checkbox"/>	C. Proposed Informed Consent Form(s) (English and if applicable, Spanish or other translation)
<input type="checkbox"/>	D. Proposed Assent Form(s) (English and if applicable, Spanish)
<input type="checkbox"/>	E. Request for Waiver of Informed Consent Process
<input type="checkbox"/>	F. Request for Waiver of Documentation of Informed Consent Process If applicable, Cover Letter Template.
<input type="checkbox"/>	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))
- N.** **For Off-site Research**

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

<input type="checkbox"/>	X.	Research Financial Interest Disclosure Statement (RFIDS) (for externally-funded research) If "yes" to Q.'s on the DFIF (Form X) - 2 copies of DFIF & management plan
<input type="checkbox"/>	Y.	Research Financial Interest Disclosure Statement (RFIDS) (for non-externally funded research) 2 copies of DFIF (Form Y)
<input type="checkbox"/>	Z.	1 Original Signature Assurance Sheet and 2 copies
<input type="checkbox"/>	AA.	2 copies of the grant application