

Medical Institutional Review Board Full Review Application Checklist

No. of Copies for Each Applicable Form	
20	Section 1: Core Application [Forms A & B]
20	Section 2: Informed Consent/Assent Process [Forms C-H]
20	Section 3: HIPAA Materials [Forms I-K]
20	Section 4: Additional Study Material [Forms L-S]
20	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]
2	Section 7: Other Committee/ Review Approval [Forms EE-II]

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.

Section 1	
Core Application - completion of A & B is required	
Include 20 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 20 copies of each <i>applicable</i> item for the entire IRB. If Form G and/or H apply, include 20 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"/>	If Department of Health and Human Services (DHHS)-approved protocol (such as NIH-sponsored Cooperative Group Clinical Trial), attach the DHHS-approved Sample Informed Consent Form
<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 20 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

- | | | |
|--------------------------|----|---|
| <input type="checkbox"/> | I. | If you plan to de-identify the data, complete the HIPAA De-identification Certification Form |
| <input type="checkbox"/> | J. | Proposed HIPAA Authorization Form |
| <input type="checkbox"/> | 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 20 copies for the entire IRB.

FORM

- | | | |
|--------------------------|----|---|
| <input type="checkbox"/> | L. | Proposed advertisement(s) of any type for recruiting subjects |
| <input type="checkbox"/> | M. | Proposed data collection instrument(s) (i.e., survey(s), questionnaire(s)) |
| <input type="checkbox"/> | N. | For Off-site Research |
| <input type="checkbox"/> | O. | Use of Any Drug* Being Tested in Research - Form <i>*May include dietary supplements, or substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease</i> |
| <input type="checkbox"/> | P. | Use of Any Device Being Tested in Research - Form |
| <input type="checkbox"/> | Q. | Use of Radioactive Materials (Radiation Safety Form) |
| <input type="checkbox"/> | S. | Copy of the package insert or FDA approved label (PDR reference) for drug or device studies using the FDA approved medication/device for approved medical indication. |

Section 5

Vulnerable Populations

Complete all of the forms below that apply to your research; include 20 copies of each applicable form for the entire IRB.

FORM

- | | | |
|--------------------------|----|--|
| <input type="checkbox"/> | T. | Research Involving Adults with Impaired Consent Capacity |
| <input type="checkbox"/> | 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

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

Y. **Research Financial Interest Disclosure Statement (RFIDS) (for non-externally funded research)**
2 copies of DFIF (Form Y)

Z. **1 Original Signature Assurance Sheet** and 2 copies

AA. 2 copies of the grant/contract application

BB. Attach 3 copies of the sponsor's detailed drug protocol *and/or* the complete Department of Health and Human Services (DHHS)-approved protocol (such as NIH-sponsored Cooperative Group Clinical Trial)

CC. For research involving administration of drug(s), attach 3 copies of the Investigator Brochure

DD. For research involving the use of a device(s), attach 2 copies of the device/detail protocol proposal

Section 7

Other Required Committee/Review Approvals

For research falling under the purview of any of the below committees or offices, attach 2 copies of the review or final approval materials (1 for IRB records and 1 for the IRB Primary Reviewer).

FORM

EE. **Institutional Biosafety Committee (IBC)**

FF. **Radioactive Drug Research Committee (RDRC)**

II. **Medical Center/College of Medicine** (for involvement of Medical Center students and/or College of Medicine students as research subjects)