**APPLICATION TO CONDUCT RESEARCH AT NJH WHEN AN**

**EXTERNAL IRB IS THE IRB OF RECORD NJH IRB**

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| --- | --- | --- | --- |
| HS#: | CTRC# (if applicable): | | DATE: |
| PROTOCOL TITLE: | | | |
| PRINCIPAL INVESTIGATOR: | | PHONE/(DIRECT) EXTENSION: | |
| IRB CONTACT: | | PHONE/EXTENSION: | |

**CHECKLIST SHOULD BE THE COVER PAGE FOR ALL NEW SUBMISSIONS**

For facilitated Secondary IRB review, submit this original signed application form and 1 complete copy of all materials listed below, as appropriate.

The following documents must be included in all applications:

External IRB approval letter(s)

All documents reviewed and stamped by the External IRB in the original approval notice

Grant proposal if National Jewish Health is a grant recipient. (This requirement does not apply when

NJH only serves as a sub-contractor or there is no grant.)

The following documents must be included when collecting health information from subjects seen at National Jewish Health or from National Jewish Health records. (Note: Compliance with the Privacy Rule is specific to each institution. External IRB-approved HIPAA forms cannot be used at National Jewish Heath.)

HIPAA Research Authorization (HIP 004)

Waiver of HIPAA Authorization / Partial Waiver of HIPAA Authorization (HIP-020)

The following document must be submitted if accessing the National Jewish Health Research Database, Biobank, or ILD repository.

Supplemental Access to NJH Repositories form

Note: To post a recruitment notice on the National Jewish Health website, submit the NJH Clinical Trials Listing form to the external IRB for review.

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**NJH IRB**

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| **PART 1: ADMINISTRATIVE REQUIREMENTS** | | |
| **1.1 PROTOCOL INFORMATION:** | | |
| **HS#:** |  | **Date:** |
| **Protocol Title:** | | |
|  | | |
| **Proposed Project Dates: From IRB Approval Date to / (Month/Year, e.g., 12/2011)** | | |

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| **1.2.1 PRINCIPAL INVESTIGATOR:** (Only NJH faculty may serve as Principal Investigator.) | | |
| **Principal Investigator:** | **Department:** | **Campus Mailing Address:** |
| **Phone Number/(Direct) Ext:** | **Fax Number:** | **E-mail Address:** |

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| **1.2.2 IRB CONTACT PERSON:** (The person with whom the IRB should correspond) | | |
| **IRB Contact:** | **Department:** | **Campus Mailing Address:** |
| **Phone Number/Ext:** | **Fax Number:** | **E-mail Address:** |

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| **1.2.3 CO-INVESTIGATORS:** Any individual member of the research team designated and supervised by the investigator at a trial site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows) and/or make direct and significant contributions to the data. Significant contributions also include the study, interpretation, or analysis of identifiable data, *including publication credit*. Note: OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. | | |
| **Co-Investigator 1:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Co-Investigator 2:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Co-Investigator 3:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Co-Investigator 4:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Attach additional sheets, as necessary. Click here if you are attaching additional sheets:** | | |

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| **1.2.4 RESEARCH PERSONNEL:** (Non-investigator staff) | | |
| **Research Staff 1:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Research Staff 2:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Research Staff 3:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Research Staff 4:** | **Primary Institutional Affiliation:** | **E-mail Address:** |
| **Attach additional sheets, as necessary. Click here if you are attaching additional sheets:** | | |

**1.3 SOURCE OF RESEARCH AND FUNDING**

**1.3.1 The research protocol and/or study materials were created by or provided by:**

**Industry sponsor:**

**Consortium of institutions/organizations: Investigator-initiated:**

**Other:**

**1.3.2 Source of funding (*Check all that apply*):**

**Industry sponsor:**

**Federal grant #: Submit Grant Proposal if NJH is an awardee. State or Local Government**:

**PI’s Academic Enrichment Funds National Jewish Departmental Funds**

**CCTSI (CTRC) None**

**Other source of funding:**

**1.3.3 Who is your contact in the Research Administration department for this study?**

**1.4 LOCATION OF RESEARCH**

**1.4.1 List the sites where researchers will have direct contact with subjects or identifiable data**

**(not including recruitment).**

**1.4.2 List the sites where recruitment will be conducted.**

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| **1.5 IRB AND INSTITUTIONAL JURISDICTION** | |
| **1.5.1 Is this a multi-center study?** |    **If YES, list total number of sites including NJH:** |
| **1.5.2 To the best of your knowledge, has this study been disapproved or withdrawn by another IRB?** |    **If YES, attached a detailed explanation of what occurred.** |
| **1.5.3 Describe the research activities to be conducted at NJH:** | |
| **1.5.4 Provide a justification for using an external IRB as the IRB for this study:** | |
| **PRINCIPAL INVESTIGATOR’S STATEMENT** | |
| **As Principal Investigator of this study, I certify that:**  • I will fulfill my responsibilities as Principal Investigator as defined by the applicable federal, state and local laws, as well as any additional responsibilities imposed by National Jewish Health;  • I am aware that the National Jewish Health IRB retains the option not to accept the external IRB’s review and can choose to conduct its own review. If the NJH IRB accepts the external IRB’s review, the external IRB becomes the IRB of record for this particular study and performs all future continuing reviews, amendment reviews and reviews of unanticipated problems for the life of the study.  • I am aware that compliance with HIPAA is specific to each institution. Subjects participating at National Jewish  Health must sign the National Jewish Health HIPAA Research Authorization. Any privacy breaches must be reported to the NJH Privacy Officer. | |

• I will not begin my research at National Jewish Health until I have received written notification that the NJH IRB has permitted the research to commence at this institution.

**I verify that I have reviewed all responses provided in this application form and that all responses are true and accurate. If these conditions are not met, I understand that approval of this research could be suspended or terminated.**

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Principal Investigator’s Signature Date