

## **JHHS/WIRB New Study Submission Checklist**

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**Date:** \_\_\_\_\_

**To:** **JHHS Center for Advanced Medicine**  
**Melissa Sewell, Research Compliance Coordinator**

**From:** \_\_\_\_\_, **Principal Investigator**

**Re: Protocol No.:** \_\_\_\_\_  
**Title:** \_\_\_\_\_  
\_\_\_\_\_

As indicated by the boxes checked below, the enclosed documents are submitted for Initial Review:

***Items that must be included: Please include 2 Copies of the complete submission***

- WIRB Submission Application (WIRB Website)
- MIRA Application (UL Website)
- Protocol (date: \_\_\_\_\_, Version \_\_\_\_\_)
- Informed consent form (hard copy)  
OR
- Informed consent form (MS Word, 3.5" DISKETTE)
- Curriculum Vitae for Principal Investigator and all Sub-Investigators
- DEA and Medical Licenses for Principal Investigator
- Medical Licenses for all Sub-Investigators (if applicable)
- JHHS Clinical Research Services Agreement (JHHS Website)
- Sponsor Contract
- Budget Information
- Study Synopsis Form (JHHS Website)
- CITI (Human Subjects Protection Training) for **ALL** research personnel (JHHS Website)
- HIPAA and Research Training for **ALL** research personnel (JHHS Website)

***Optional Items if Applicable:***

- Updated and signed FDA Form 1572, if applicable, with WIRB listed as the IRB
- FDA letter granting an IDE for the proposed use, sponsor letter stating that the study is a non-significant risk device study, or letter explaining why the investigation is exempt from the IDE requirements under 21CFR 812.2(c) or otherwise exempt.
- Complete grant application, if submitted to a Federal agency.
- Other documents (\_\_\_\_\_)

\_\_\_\_\_  
***Signature of Principal Investigator or Designee***

\_\_\_\_\_  
***Date***

Send this form with all documents to:

**Melissa Sewell**  
**Jewish Hospital**  
**Center for Advanced Medicine**  
**200 Abraham Flexner Way, 6<sup>th</sup> Floor**  
**Louisville, KY 40202**  
**Phone- (502) 587-4839**