

## **JHHS/U of L HSPPO New Study Submission Checklist**

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

**To:** **Jewish Hospital 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 3 Copies of the complete submission**

- UL Submission Application and Checklist (UL 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 (\_\_\_\_\_)

**Has contract information been submitted to UL Office of Industry Contracts?**

YES: \_\_\_\_\_ Date Submitted: \_\_\_\_\_  
NO: \_\_\_\_\_ Explanation: \_\_\_\_\_

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**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**