

**Miami Children's Hospital / WIRB
Initial Review Checklist**

Date sent to ORA: _____ Lawson Activity No. (LAN): _____

Date Rec'd in ORA: _____ Study Coordinator: _____

Principal Investigator: _____ Contact Person: _____

Protocol No., Sponsor: _____

Study Title: _____

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

****please send both paper and electronic copies, if available, of all documents****

WIRB REQUIREMENTS

- [WIRB Initial Submission Form](#)
- WIRB Exempt Submission
- Protocol (date: _____) (Note: If protocol has previously been reviewed by WIRB, you may submit 1 copy of the protocol title page and signature page only)
- Complete grant application, if submitted to a Federal agency.
- DEA License (if applicable) and Medical Licenses for Principal Investigator
- Medical Licenses for all Sub-Investigators (if applicable)
- Amendments (dates for those included: _____)
- Investigator's Brochure, if applicable (Note: If IB has previously been reviewed by WIRB, you may submit 1 copy of the IB title page only) (dates for those included: _____)
- IF A DEVICE study, a copy of the signed Investigator Agreement for protocols with an IDE, and ONE of the following: (circle) FDA IDE approval letter OR 510(k) clearance OR Sponsor letter stating significant or non-significant risk
- Other documents/materials (for example, patient diaries, surveys, questionnaires, etc.)
- Curriculum Vitae for Principal Investigator and all Sub-Investigators (if not on file with WIRB)
- Signed FDA Form 1572, if applicable, with WIRB listed as the IRB
- [Informed Consent Form](#)
- Radiation Safety Committee Approval (if applicable)
- Advertisements, if applicable (How many? _____)

MIAMI CHILDREN'S HOSPITAL REQUIREMENTS:

- Completed [MCH Application for Research](#) (typed & signed)
- Draft Contract, Subcontract, or Grant Documents (if sponsored by a company, govt. agency, or non-profit)
- Budget (if sponsored by a company, govt. agency, or non-profit)
- Human Subjects Training Certificates (if not on file with ORA) CitiTraining Expiration Date _____
- [MCH Financial Conflict of Interest Declaration](#) for each investigator (if sponsored by a company; submit both MCH form & sponsor's form if sponsor requires you to sign their form)
- This Cover Letter/Checklist

Reviewed and approved for mailing to WIRB by:

Signature of Office of Research Administration Staff

Date

Date sent to WIRB: _____