

# IRB APPLICATION CHECKLIST

**\*\*All applications & correspondence submitted to the IRB committee must be signed by the PI!\*\***

## Exempt Research Application

- IRB Exempt Application (2 copies)
- Demographic Form (2 copies)
- HIPAA Authorization (2 copies) OR Waiver for HIPAA Authorization (2 copies)
- Consent Forms, Assent Forms, Parent Permission, Site Permission Letters, etc (2 copies)
- Tools, data collection sheets, survey instruments, assessments, rater forms, etc (1 copy)
- Item Inventory List in memo form- specifically list all items being submitted (1copy)
- Conflict of Interest Form (1 copy for each participant)
  - All necessary forms indicated above can be found at the following address:
    - [lsuhsc.edu/administration/academic/ors/irb.aspx](http://lsuhsc.edu/administration/academic/ors/irb.aspx)
- Copy of CITI Training Certificate (1 copy for each participant)
  - Guide for creating a CITI account and completing training:
    - [lsuhsc.edu/administration/academic/ors/docs/CITI\\_Instructions.pdf](http://lsuhsc.edu/administration/academic/ors/docs/CITI_Instructions.pdf)
  - Collaborative Institutional Training Initiative website: [citiprogram.org/](http://citiprogram.org/)
- IBC Application or Request for IBC Exemption (submitted via email)
  - Institutional Biosafety Committee Forms can be found at the following address:
    - [lsuhsc.edu/administration/academic/ors/ibc.aspx](http://lsuhsc.edu/administration/academic/ors/ibc.aspx)

## Expedited Research Application

- IRB Expedited Application (2 copies)
- Demographic Form (2 copies)
- HIPAA Authorization (2 copies) OR Waiver for HIPAA Authorization (2 copies)
- Consent Forms, Assent Forms, Parent Permission, Site Permission Letters, etc (2 copies)
- Protocol (2 copies)
- Site Permission Letter (2 copies)
- Tools, data collection sheets, survey instruments, assessments, rater forms, etc (1 copy)
- Item Inventory List in memo form- specifically list all items being submitted, signed by PI (1copy)
- Conflict of Interest Form (1 copy for each participant)
  - All necessary forms indicated above can be found at the following address:
    - [lsuhsc.edu/administration/academic/ors/irb.aspx](http://lsuhsc.edu/administration/academic/ors/irb.aspx)
- Copy of CITI Training Certificate (1 copy for each participant)
  - Guide for creating a CITI account and completing training:
    - [lsuhsc.edu/administration/academic/ors/docs/CITI\\_Instructions.pdf](http://lsuhsc.edu/administration/academic/ors/docs/CITI_Instructions.pdf)
  - Collaborative Institutional Training Initiative website:
    - [citiprogram.org/](http://citiprogram.org/)
- IBC Application or Request for IBC Exemption (submitted via email)
  - Institutional Biosafety Committee Forms can be found at the following address:
    - [lsuhsc.edu/administration/academic/ors/ibc.aspx](http://lsuhsc.edu/administration/academic/ors/ibc.aspx)

## **Full Board Review Research Application**

- IRB Clinical Research Application (2 copies)
- Demographic Form (2 copies)
- Federal Grant Proposal (2 copies)
- Investigator's Brochures (2 copies)
- Safety Reports (2 copies)
- Subject Instruction Sheets (2 copies)
- Patient Diaries (2 copies)
- HIPAA Authorization (2 copies)
- Consent Forms, Assent Forms, Parent Permission, Site Permission Letters, etc (2 copies)
- Protocol (2 copies)
- Advertisements (2 copies)
- Scripts (2 copies)
- Site Permission Letter (2 copies)
- Tools, data collection sheets, survey instruments, assessments, rater forms, etc (2 copies)
- Patient Emergency Notification/Instruction forms or cards (2 copies)
- Clinical Procedures List (1 copy): a list of study specific treatments & procedures-indicate what items are specifically for this study & which are Standard of Care. Indicate frequency (weekly, monthly, each visit, etc). Include MRIs, blood draws, labs, x-rays, echos, ultrasounds, etc.
- FDA 1572 form (1 copy for each participant)
  - FDA Form 1572 can be found at the following link:
    - <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf>
- Conflict of Interest Form (1 copy for each participant)
  - All necessary forms indicated above can be found at the following address:
    - <http://www.lsuhs.edu/administration/academic/ors/irb.aspx>
- Copy of CITI Training Certificate (1 copy for each participant)
  - Guide for creating a CITI account and completing training:
    - [http://www.lsuhs.edu/administration/academic/ors/docs/CITI\\_Instructions.pdf](http://www.lsuhs.edu/administration/academic/ors/docs/CITI_Instructions.pdf)
  - Collaborative Institutional Training Initiative website:
    - <https://www.citiprogram.org/>
- IBC Application or Request for IBC Exemption (submitted via email)
  - Institutional Biosafety Committee Forms can be found at the following address:
    - <http://www.lsuhs.edu/administration/academic/ors/ibc.aspx>
- Document Submission List Memo (1 copy): specifically identify all attachments being submitted; include title & date of protocol, amendments, investigators brochures, etc; if there is more than one consent form or amendment, specify the number of documents; submit this list as a separate memo- the list will provide an inventory of items submitted for review