1 PURPOSE

1.1 This procedure establishes the process for billing Sponsored Projects for IRB review fees.

1.2 The process begins when an initial, amendment, or renewal application meeting certain criteria outlined below is reviewed and approved by the IRB.

1.3 The process ends when the IRB Office staff has submitted a journal entry to Sponsored Projects.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Commercial/Industry-sponsored research reviewed by the LSUHSC-NO IRB should be billed after initial approval, after each renewal approval, and after approval of an amendment that was requested by the sponsor.

3.2 Foundation-sponsored research reviewed by the LSUHSC-NO IRB should be billed after initial approval, after each renewal approval, and after approval of an amendment that was requested by the sponsor. Lower rates may be accepted from private foundations if dictated by foundation policy; documentation is required.

3.3 Federally-sponsored research where use of a single IRB is required AND where LSUHSC-NO is acting as the reviewing IRB, should be billed for all non-LSUHSC participating sites after initial approval, after each renewal, and after approval of an amendment where consents were changed.

3.4 Research requesting reliance that will be reviewed by a Commercial External IRB such as WIRB or Advarra should be billed after initial approval of a Reliance Request.

3.5 Any requests from a Principal Investigator or Sponsor for exceptions to the billing policy should be directed to the Executive Director of Office of Research Services.

4 DEFINITIONS

4.1 Reviewing IRB (or IRB of Record): An IRB that provides the ethical review of the research for another organization (in this case, LSUHSC-NO) and is designated to do so through an approved Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP). Note: Commercial IRBs will not have FWAs, but must be registered with OHRP.

4.2 External IRB: An IRB from an external institution or organization that the HSC IRB may rely on for the ethical review of Human Research.

4.3 Participating Site: An institution that participates in a Multi-Site Study or a Collaborative Study

5 RESPONSIBILITIES

5.1 Specific responsibilities for IRB Office staff and Grants & Contracts Office are described throughout this document.

6 PROCEDURES

6.1 *IRB Administrative Reviewer Responsibilities*

6.1.1 **Before** execution of a CTA, the Grants & Contracts Office should confirm with a member of the IRB Staff that all potential IRB fees have been appropriately budgeted for and/or referenced within the CTA.

6.1.2 **After** approval of an initial, renewal, or amendment application requiring billing

6.1.2.1 Consult "**Current LSUHSC-NO HRPP Fee Schedule**" to confirm the amount that should be charged to the research account.

6.1.2.2 Log the study information into the "**IRB Billing Log.**"

6.2 *Designated Billing IRB Staff Member Responsibilities*

6.2.1 On a regular basis, the designated IRB staff member responsible for billing will check the "**IRB Billing Log**."

6.2.1.1 For initial review of studies that require billing, either:

6.2.1.1.1 The designated staff member will create a journal entry(ies) using the "**Journal Entry Template**" as outlined in 6.2.1.2.1; *or*,

6.2.1.1.2 Sponsored Projects may provide a "**Clinical Trials IRB Fee Status sheet**" for the IRB to complete.

- When the "**Clinical Trials IRB Fee Status sheet**" is received, the designated staff member will enter the *IRB Fee Amount* for each study, as applicable.
- In *Notes*, document the type of review(s).
- Create a journal entry(ies) using the "**Journal Entry Template**" to match the fees charged on the "**Clinical Trials IRB Fee Status sheet**" as outlined in 6.2.1.2.1.

6.2.1.2 For amendment and renewal reviews that require billing, the designated staff member will create journal entry(ies) using the "**Journal Entry Template**."

6.2.1.2.1 On the Sponsored Proj Journal tab:

- *Batch Description* should be 'IRB Fees.'
- *Date* should match the date you are creating the entry
- *Journal Source* should be 'ONL.'
- *Journal Entry* should be 'JESP0XXXXX' or if Sponsored Projects gives you a specific number, replace Xs with numbers.
- *Journal Prepared By* should be the name of the staff member creating the entry.
- The *Account* numbers should be 532500 for the Debit line(s) and 491160

for the Credit line(s).

- *Fund* should be 113 for all lines.
- *Department* for the Debit lines(s) should be the department number of the PI. *Department* for the Credit line(s) should be 1622300.
- *Program* for the Debit line(s) should be 10001. *Program* for the Credit line(s) should be 51000.
- *Class* for the Debit line(s) should be 35200. *Class* for the Credit line(s) should be 90160.
- *Year* should be left blank.
- *Project Number* for the Debit line(s) will be specific to each project. It can be found in the Master Research Agreements database in the Chartstring column or the Grants & Contracts Office can pull the information from PeopleSoft Financials. *Project Number* for the Credit line(s) should be 5622000015. A journal entry cannot be submitted without this number.
- *Currency* should be USD
- *Amount* is determined using the Current LSUHSC-NO HRPP Fee Schedule. The Debit line(s) should always be shown as a positive; the Credit line(s) should always be shown as negatives.
- *Description* should include the IRB number and review type. *Description* for the Debit line should match the corresponding Credit line.
- All Debit lines should be grouped together and listed first. All Credit lines should be grouped together and listed after Debits.

6.2.1.2.2 On the Supporting Documents tab:

- Attach a copy of the Determination Letter.

6.2.1.2.3 On the List to ORS from SPA tab:

- If Sponsored Projects provided a "**Clinical Trials IRB Fee Status sheet**," then copy that list onto this tab. If not, leave this tab blank.

6.2.1.2.4 Sponsored Projects will complete all other tabs.

6.2.1.3 The completed journal entry and/or fee status document should be emailed to nosponproj@lsuhsc.edu.

7 MATERIALS

7.1 Current LSUHSC-NO HRPP Fee Schedule (T:\Pub\IRB\IRB FEE STRUCTURE)

7.2 IRB Billing Log (T:\Pub\IRB\IRB FEE STRUCTURE)

7.3 Journal Entry Template (T:\Pub\IRB\IRB FEE STRUCTURE)

7.4 Clinical Trials IRB Fee Status sheet (T:\Pub\IRB\IRB FEE STRUCTURE)

7.5 Master Research Agreements Database (T:\Pub\Nicole_Barron\Office of Research Services)

8 REFERENCES

8.1 None