1. POLICY

The IRB at the Health Sciences Center (HSC) charges an IRB research review fee to industry-sponsored human research projects. The Norman Campus does not charge an IRB research review fee.

Specific Policies

1.1 Fee Structure

The HSC IRB shall charge a one-time, non-refundable IRB research review fee of $2,500 to all industry-sponsored human participant research projects. This fee does not apply to federally-funded research, investigator-initiated research, or research supported by grants from non-profit foundations or organizations.

The HSC IRB shall charge a non-refundable continuing IRB research review fee of $750 to all industry-sponsored human research projects. This fee does not apply to federally-funded research, investigator-initiated research, or research supported by grants from non-profit foundations or organizations.

The HSC HRPP shall charge a one-time, non-refundable HRPP administrative fee of $2,000 to all industry-sponsored human research projects that rely on a non-OU IRB.

1.2 Budget Preparation

The investigator or Office of Research Administration (ORA), as appropriate, shall include the IRB research review fees as a separate line item in all industry-sponsored budgets or payment schedules. Also, the investigator may negotiate a separate budget line item for IRB preparation and submission.

1.3 Invoicing and Collection

1.3.1 Upon receipt of an IRB submission, the HSC IRB shall generate and send an invoice to the investigator or his/her designee for each initial and continuing review of the industry-sponsored human research project. Payment is due within 30 days of receipt of invoice.

1.3.2 The IRB shall send past due notices to the investigator or designee for payments not received within 45 days of the invoice, followed by a letter of collection for payments not received within 60 days. In the event the IRB does not receive payment within 90 days, the IRB may send a demand letter to the sponsor.

1.3.3 The IRB reserves the right to administratively withdraw IRB approval for any IRB research review study that is over 90 days past due and to take any legal action against the sponsor to recover payment.

1.4 Deposits and Accounting

1.4.1 The IRB staff shall maintain a current accounting of IRB research project review fees invoiced and fees collected.

1.4.2 The IRB makes deposits with the HSC Bursar’s Office according to HSC policy. The IRB staff shall maintain deposit records.

1.4.3 Alternatively, the investigator or designee shall submit a cost transfer from the appropriate study account to the HRPP. The University’s account system shall maintain accounting records of the transactions.
2. SCOPE
This SOP applies to all Investigators who utilize an HSC IRB as the IRB of record or the HSC HRPP.

3. RESPONSIBILITY
3.1 The HRPP Director is responsible for the management and conduct of the IRB research review fee policy and procedures assuring compliance with University policy.

3.2 The IRB staff is responsible for the appropriate invoicing, collection, and accounting of IRB research review fees charged to industry sponsors. The IRB staff is responsible for making deposits of these payments within 24 hours of receipt with the HSC Bursar’s Office.

4. APPLICABLE REGULATIONS AND GUIDELINES
The University of Oklahoma Health Sciences Center Administrative Policies, Financial Services, Section 510.

5. REFERENCES TO OTHER APPLICABLE SOPS
None

6. ATTACHMENTS
306-A HSC IRB Sample Invoice
306-C HSC Cash Receipts Policy, Section 510

7. PROCESS OVERVIEW
7.1 The HSC VPR, in collaboration with the HSC Senior Vice President and Provost, will determine the fee structure for the IRB research review fee.

7.2 The investigator or ORA, as appropriate, is responsible for including the IRB research review fees as a separate line item in all industry-sponsored budgets and payment schedules. Also, the investigator may negotiate a separate budget line item for IRB preparation and submission.

7.3 The IRB staff is responsible for generating a weekly report listing research studies submitted to the IRB for the previous week. The HRPP Director is responsible for reviewing the report to verify that the appropriate industry sponsors are invoiced.

7.4 The IRB staff will use the IRB Report to generate an invoice for each initial and continuing review industry-sponsored project received by the IRB. The IRB research review fee is due upon receipt of the invoice by the sponsor. The IRB staff will generate an aging report to monitor accounts receivable. If payment is not received within 45 days following invoicing, the IRB shall send a past due letter, followed by a letter of collection for payments not received within 60 days. In the event the IRB does not receive payment within 90 days, the IRB shall send the sponsor a demand letter.

7.5 The HRPP Director, in collaboration with the Director of Compliance, may decide to administratively withdraw IRB approval for any research study fees that are over 90 days past due and will consult with Legal Counsel regarding the appropriate legal action against the sponsor afforded to it by applicable law to recover payment.

7.6 The IRB staff processes payments received, endorses the checks, verifies amounts collected, and delivers deposits to the Bursar’s Office within 24 hours of receipt of the payment.

7.7 The IRB staff will verify the amount deposited against the Deposit Voucher to confirm that the amount received was appropriately deposited with the Bursar’s Office.

APPROVED BY: _______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020