

# St David's HEALTHCARE

*Institutional Review Board*

<b>TITLE:</b> Fee Schedule for Institutional Review Board Services	<b>FUNCTIONAL CATEGORY:</b> Research
<b>ORIGINAL DATE:</b> 1/30/2017	<b>VERSION #:</b> 2
<b>REVISION/REVIEW DATE:</b> 1/30/2017	

## SCOPE:

This Policy Applies to:

x	St. David's Hospital
x	Heart Hospital of Austin
x	St. David's Medical Center
x	St. David's North Austin Medical Center
x	St. David's South Austin Medical Center
x	St. David's Round Rock Medical Center
x	St. David's Georgetown Hospital
x	St. David's Rehabilitation Hospital
x	St. David's Surgical Hospital
x	St. David's Surgery Centers
x	St. David's Medical Staff

## PURPOSE:

The purpose of this policy is to set forth the fees for St. David's HealthCare Institutional Review Board (SDH IRB) review and oversight of research studies.

## IRB REVIEW FEE SCHEDULE:

SDH IRB will charge the following fees for studies submitted on or after January 27, 2017:

- For grant (State or Federal) or industry sponsored protocols and HDE/HUDs:
  - The fee for initial review is **\$2,500** to offset the SDH IRB costs for reviewing and processing submitted protocols, including IRBNet fees. These studies are also subject to the continuing review fees below.
  - All sponsored studies that are reviewed by SDH IRB by full board or expedited review will be subject to a continuing review fee of **\$750**. Continuing review fees will be assessed on renewal submissions and at the time of study closure.
  - All sponsored studies that are reviewed by SDH IRB by full board or expedited review will be subject to an amendment review fee of is **\$250** per submission for

an amendment (revised protocol or ICF, addition or removal of investigators, sponsor advertisements, investigator brochures, etc.). Individual submissions may contain multiple amendments for a single study (e.g. a revised protocol and ICF would be considered a single amendment submission).

- For non-sponsored, investigator-initiated protocols:
  - The fee for initial review is **\$500** to offset the SDH IRB costs for reviewing and processing submitted protocols. These studies are also subject to the continuing review fees below.
  - All non-sponsored, investigator-initiated studies that are reviewed by SDH IRB by full board or expedited review will be subject to a continuing review fee of **\$250**. Continuing review fees will be assessed on renewal submissions and at the time of study closure
- The administrative fee for a Waiver of Oversight to an external IRB (e.g. a commercial IRB) for grant (State or Federal) or industry-sponsored studies is **\$1,000**. This fee covers IRBNet fees and supplements the SDH IRB cost for processing submitted protocols. Studies under the oversight of an external IRB will not be charged continuing review fees or amendment review fees.
- For multi-site studies with external (i.e., non-St. David's HealthCare) sites, please contact the IRB to discuss.

For studies that transitioned from Austin Multi-Institutional Review Board (AMIRB), SDH IRB accept the following fees for SDH IRB review:

- The fee for all annual continuing reviews is **\$200**.

#### **IRB REVIEW FEE POLICIES:**

IRB fees are non-refundable and will be billed at the time the service is completed.

IRB fees are due within 30 days of invoice. Protocols with outstanding invoices may be subject to suspension of enrollment and/or withholding of continuing review at the discretion of the SDH IRB and/or the Office of Research.

In exceptional circumstances, some studies may receive a waiver or discount of these fees. This will be based on the nature of the study and the extent of funding provided by the sponsor of the study. Examples where a waiver of fees may be appropriate include certain humanitarian device studies or expanded access and compassionate use studies where only minimal funding is provided by the sponsor. Fee waivers or discount requests will be reviewed on a case-by-case and will be determined by the SDH IRB or Office of Research.

#### **PROCEDURE:**

**ATTACHMENTS/REFERENCES:**