





Covenant
HEALTH
Institutional Review Board

All Physicians and Study Coordinators (Affiliates of Covenant Health)

April 1, 2020

Dear Study Site,

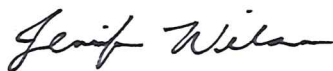
On behalf of the Covenant Health IRB I would like to thank you for choosing Covenant Health as your facility of choice to care for our patients. As your partner in ethical review we are pleased to partner with you to ensure that your clinical trials are conducted with the highest level of integrity. This year, we are undertaking a strategic initiative to better serve your research needs.

-  **Giving Patients a Voice in Clinical Research**
-  **Continuous Process Improvements**
-  **Accommodating the Growth Complexity of Clinical Research**
-  **Expanding Our Expertise with Advanced Training**

Please note, the fees are waived for National Cancer Institute studies. The fees for external IRB studies are reduced by 50%.

We have updated our 2020 Fee Schedule so that we can continue to invest in these initiatives that will enable us to better serve you. Please note, our new Fee Schedule will take effect on January 1, 2020.

Sincerely,



Jennifer Wilson, BS, CHRC
Research Operations Administrator


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<u>Services Rendered</u>	<u>Covenant Health IRB of Record</u>	<u>External IRB Ceded Review by CH</u>
Initial Review		
Initial Study Review (includes protocol, study materials and 1 Consent Form)	\$1,500	\$750
Review of Principal Investigator (PI)/Change of PI/Co-PI	\$1,000 / PI	\$500 / PI
Each Additional Informed Consent Form (ICF) (Per ICF/per PI)	\$500	-0-
Continuing Review		
Continuing Review of Study (Applies only to studies that are open to accrual)	\$1,000	\$500
Ongoing Oversight (<i>Non-Exempt Research not Requiring Continuing Review</i>) (e.g., <i>Annual Status Report, waived for Capstone Projects</i>)	\$630 / PI	-0-
Change to Research After Initial Approval		
New / Revised Informed Consent (per consent)	\$600 / PI	-0-
Protocol Amendment / Clarification Letter (No revision to ICF)	\$500 / PI	-0-
Protocol Amendment (With Revision to the ICF)	\$700 / PI	-0-
Review of the Revised Product Information (i.e. Clinical Investigator Brochure, Package Insert, DSMB Reports)	\$420 / Document	-0-
Review of Recruitment Services & Supplemental Materials	\$300 / Document	-0-
Close Out of Research		
Study Close Out (With Sponsor Approval)	\$320 / Study	-0-
Other Services and Fees		
IRB Exemption Review (Waived for Capstone Projects)	\$1,097 / Study	-0-

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Examples: A new study with one consent form and one PI is \$2,500. A new study with one consent form and two PIs is \$3,500. A new study with two PIs and two consent forms is \$4,000. A continuing review that is open to accrual is \$1,000. A continuing review closed to accrual is \$0.