

## Steps for TTUHSC Faculty to obtain Covenant IRB Approval

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Work with the Clinical Research Institute—they will make sure everything is done

**OR**

1. Prior to research commencing at Covenant Medical Center, the local Principal Investigator must send following documents to St. Joseph Health (SJH) Center for Clinical Research at [HRPP@stjoe.org](mailto:HRPP@stjoe.org) **AND** to the Institutional Official for Covenant Health [Brian.Schroeder@stjoe.org](mailto:Brian.Schroeder@stjoe.org):
  - a. Study Protocol
  - b. Consent form (if applicable)
  - c. A signed SJH Annual Financial Interest Disclosure (**see page 2 below**) for each local investigator who wishes to participate in the project
  - d. CVs for ALL study personnel
2. SJH and Dr. Schroeder will then review the documents and let you know if there are questions or additional training required.
3. SJH will have access in the iRIS system to every study involving Covenant Hospital in order to view all study documents, CV of the PI, and IRB communications
4. After any questions have been addressed, SJH will e-mail their “clearance” letter to you
5. You submit the SJH clearance letter to the TTUHSC IRB as a Study Document in iRIS.
6. When submitting the study in iRIS, it is **ESSENTIAL** that you list Covenant Medical Center as a participating Department in the IRB application.
7. TTUHSC IRB will NOT approve your study until you submit the SJH IRB clearance letter. The TTUHSC IRB prefers (but does not require) that you wait until you have received the SJH clearance letter before submitting your application to the TTUHSC IRB.

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**NOTE THAT St. Joseph Health has the option to conduct a separate IRB review of any proposed project.** This will likely be the case for any project deemed greater than minimal risk.

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Version: 1.0

## Financial Interest Disclosure

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**Please disclose the combined level of financial interest that you, your spouse/domestic partner, and your dependents have had (in the previous 12 months) with companies/entities that (i) sponsor clinical research, and/or (ii) develop, manufacture, or sell medications, medical devices, and/or biologics:**

<p>Investments or ownership interest of any value including, but not limited to, stocks and options exclusive of interest in publicly-traded, diversified mutual funds:</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Description and Amount: _____</p>
<p>Received (or anticipate receiving) income of any amount including, but not limited to honoraria (direct or donated), consultant fees, royalties, or other income:</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Description and Amount: _____</p>
<p>Fees for speeches, lectures and/or presentations, or travel/meeting grants:</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Description and Amount: _____</p>
<p>Research grants, foundation funds and/or philanthropy:</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Amount: _____</p>
<p>Proprietary interest of any value including, but not limited to: patents, trademarks, copyrights, and licensing agreements:</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Amount: _____</p>
<p>Employment, office, directorship, partner, trustee, membership on a Board of Directors or Advisory Committee (or personal compensation):</p> <p><input type="checkbox"/> No financial interest</p> <p><input type="checkbox"/> Financial Interest: Company/Entity: _____ Amount: _____</p>

**Other Disclosures:**

Do you, your spouse/domestic partner, or your dependents hold an interested position (e.g. senior administrative official, Board of Directors membership, Advisory Committee, etc.) within the St. Joseph Health organization that involves any of the following:

- Licensing, technology transfer, patents
- Investments of the organization
- Gifts to the organization when the donor has an interest in the research
- Financial interests of senior administrators, directors, or other similar positions
- Other financial interests

☐ No ☐ Yes, Explain: \_\_\_\_\_

Do you, your spouse/domestic partner, or your dependents hold any collaboration agreements with non-commercial entities (i.e. professional or academic collaborations) that may have financial implications?

☐ No ☐ Yes, Explain: \_\_\_\_\_

Do you, your spouse/domestic partner, or your dependents have any personal interest or involvement with commercial or non-commercial research organizations and or research interest not indicated above that could pose or be perceived as a conflict?

☐ No ☐ Yes, Explain: \_\_\_\_\_

I have read and agree to abide by the policies which govern Financial Conflicts of Interest in Research as established by the St. Joseph Health organization and the IRB. I also agree to submit on an Ad Hoc basis disclosures that would constitute a financial interest as indicated above.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name