**North Texas Regional Institutional Review Board (IRB)**

**IRB Submission Checklist – New Sponsored (FDA-Regulated) Clinical Trials/HUDs**

This document outlines the materials investigators must assemble and submit with their application for initial review by the North Texas Regional Institutional Review Board. ***It is important to note that incomplete submissions will result in the entire application being returned to the Investigator without having undergone IRB review.***

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| --- | --- |
| **Date:** | **PI Name:** |
| **Study Title:**  |

***Items included with the submission:***

[ ]  New Convened Board Protocol Application Form

[ ]  Site-Specific Protocol Information

[ ]  Consent Forms (including HIPAA Authorization) (including assent and parental permission, and sub-study consents, as applicable)

* Required for **all** full Board studies, including Humanitarian Use Device (HUD)/Humanitarian Device Exemption (HDE)
* Include North Texas Regional IRB standard clauses in all consent forms

[ ]  Clinical Protocol from Study Sponsor

[ ]  Investigator’s Brochure and/or Package Inserts, as applicable

[ ]  If your project involves **Drugs**:

* FDA IND Determination Letter

[ ]  If your project involves **Devices**:

* FDA Approval Letter and Risk (Significant or Non-Significant Risk) Determination from Study Sponsor (FDA IDE/HDE Determination or 510(k) Exempt Determination)

[ ]  Recruitment Materials – Brochures, Flyers, Telephone Scripts, Screenshots of Sponsor Recruitment Website

The following documents must be submitted for **all** Key Personnel:

[ ]  Current CITI Training Documentation specific to Human Subject Protection (or equivalent, such as ACRP Certification)

[ ]  COI Disclosure Statements

[ ]  CV (for Principal Investigator)

[ ]  Medical License (for Principal Investigator and other Key Personnel as applicable)

[ ]  Evidence of Institutional Biosafety Committee (IBC) Approval (UNTHSC Only)