**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)