# 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.***

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

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

☐ NTR IRB Wizard/New Project Application

☐ Protocol Synopsis

☐ 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)