IRB Inter-Institutional ("reciprocity") Agreements

A reliance or "reciprocity" agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an IRB of another institution. Typically such arrangements involve an IRB authorization agreement (IAA), or memorandum of understanding (MOU). Such agreements may cover single studies, categories of studies, or all human subjects research under an organization's Federalwide Assurance (FWA).

Note that not all reciprocity or reliance agreements are alike. The list below, outlines current inter-institutional agreements involving UNTHSC and describes such variability. Some agreements are linked to a specific research study; other are for groups or categories of research projects.

Institution	*Types of Protocols Covered by IRB Agreements*
Advarra (Schulman Associates IRB)	Select industry-sponsored clinical trials
Baylor Scott and White IRB	Select Clinical Research Management (CRM) Program student projects only
Centers for Disease Control (CDC)	CDC-funded projects involving TB Clinic at Tarrant County Public Health
Cook Children's Hospital (Fort Worth)	TCOM Medical Student Honors Program projects only
Copernicus Group IRB	Select industry-sponsored clinical trials
John Peter Smith Health Network	**North Texas Regional IRB is IRB of record**
North Texas (Medical City) IRB	All research projects conducted at UNTHSC sites are covered by this agreement; any activity conducted at Medical City sites must be reviewed by Medical City IRB
Quorum Review, Inc	Select industry-sponsored clinical trials
SMART IRB Reliance *	Multi-site NIH-funded studies
UT Arlington	Specific collaborative projects: case-by-case basis
University of North Texas - Dallas	**North Texas Regional IRB is IRB of record**
University of North Texas-Denton	Specific collaborative projects: case-by-case basis
University of North Texas HSC	**North Texas Regional IRB is IRB of record**
UT Southwestern Medical Center	Specific collaborative projects: case-by-case basis
Univ. of Washington	Specific collaborative projects: case-by-case basis
Univ. of Wisconsin-Madison	Specific collaborative projects: case-by-case basis

* Note that SMART IRB Reliance projects have specific terms and conditions and apply only to NIH-funded multi-site studies. Consult separate guidance for SMART IRB.

Further, Institutions may also have specific internal standard operating procedures (SOPs)/policies to address requests for providing review for another organization or for delegating review. Policies may specify the phase/risk level of protocols to be considered for outside review, criteria for evaluating outside IRB qualifications if delegating, relationship to the outside organization, and/or other restrictions or requirements. Institutions entering into agreements for IRB review must each maintain the agreements on file and submit them to OHRP and/or FDA upon request.

In all cases, the Agreement only authorizes the delegation of IRB review from one institution to another. These IRB Agreements **only** relate to IRB review and approval of the designated project (or projects). That's it.

IRB Agreements do NOT automatically allow investigators from one institution to conduct research activities at another institution, simply because the agreement is in effect for another investigator or project. Every institution has its own policies and procedures for who can conduct research at that site, and can decide if an existing reciprocity agreement is relevant, or if a new MOU (Memorandum of Understanding) is required. Again, each institution's rules rule.

Finally, at the University of North Texas Health Science Center (and also at John Peter Smith Health Network) investigators must agree to abide by various reporting requirements to their respective institutions, through a separate "principal investigator agreement" describing their roles and responsibilities when authorized to have their research reviewed by another IRB. Thus, investigators need to have **local** approval BEFORE they can seek IRB review from another institution.

As you can see, the conduct of research at other institutions, even when there is some form of Inter-Institutional Agreement, can be quite complex.

Bottom Line: Before attempting to initiate research at another institution, check with the North Texas Regional IRB Office for guidance and process well ahead of time. As stated above, not all Inter-Institutional IRB agreements are alike, nor are they "all-inclusive".

Click here for the IRB Authorization Agreement Form.

Contact the North Texas Regional IRB Office at (817) 735-0409, or email NorthTexRegIRB@unthsc.edu for additional information or details.