

TTUHSC EI PASO

Regulatory Lite



A hint of research compliance tips for your everyday life

Are Research Compliance and the IRB the same thing? No! Here are some key differences:

TTUHSC El Paso IRB (IRB)	Research Compliance Unit (RCU)
Committee that performs ethical reviews of proposed research. Has the authority to approve, require modifications to secure approval, or disapprove all human research conducted at TTUHSC El Paso. May also suspend or terminate approval of research not being conducted in accordance with IRB requirements or that is associated with unexpected harm to subjects	Unit that oversees all compliance requirements related to human subject research. Supports the responsible and ethical conduct of research to ensure adherence to all regulations and policies guiding research. Serves as a resource to both the IRB and TTUHSC EI Paso faculty, staff, and students engaged in research in concerns associated with research compliance
Has authority to inspect research facilities and obtain records and information by way of conducting audits. Delegates this authority to the RCU	Has the authority and is delegated the authority by the IRB to conduct audits of human subject research
Identifies and evaluates concerns and can delegate audits to the RCU	Conducts audits on behalf of the IRB using agreed-upon findings and corrective actions listed on a matrix
Reviews research conducted by TTUHSC El Paso faculty, using TTUHSC El Paso facilities or private records (such as medical records) overseen by TTUHSC El Paso, or research where TTUHSC El Paso receives funds to conduct the research prior to beginning research activities	Conducts audits, reviews research export controls, enforces effort reporting deadlines and escalates non-compliance, creates and provides in-house training and tools on aspects of research, manages and oversees compliance with ClinicalTrials.gov at TTUHSC El Paso
IRB Administrators screen submissions submitted through iRIS for accuracy and completeness, provide formal and informal regulatory, ethical, and methodological advice and assistance to research personnel in preparation of applications submitted for review, as well as assistance with iRIS related issues	Research Compliance Officer and Senior Analyst conduct audits, and oversee research export controls, effort reporting deadlines, assign in-house trainings, oversee ClinicalTrials.gov, and provide assistance with research-related issues
Reviews audit reports for findings and to ensure that study details submitted to and approved by the IRB are being implemented as previously approved	Ensures that approved research is being conducted in compliance with federal regulations and institutional policies and provides reports to the IRB
Under the oversight of the Office of Research, independent of the Research Compliance Unit	Under the oversight of the Office of Research, independent of the IRB

While Research Compliance and the IRB work independently of each other, both are committed to ensuring that research is conducted with the highest standards of integrity and excellence through teamwork and professionalism.

- For more information on research compliance-related items and more you can submit questions to the <u>Research</u> Compliance Unit.
- For more information on IRB-related items and more you can visit their page at <u>Institutional Review Board</u> Administration.

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