

Guidance for Serving as IRB of Record Document

- **Q:** In what cases will the UTHSA IRB consider serving as IRB of record for another site or individual who does not have an appointment at UTHSA, UHS, or STVHCS?
A: The UTHSA IRB office may determine whether serving as IRB of record is appropriate on a case-by-case basis. In general, however, the UTHSA IRB will consider serving as the IRB of record in the following situations:
 - The role of the external site or personnel is limited to activities such as data analysis, consultation, or other administrative roles;
 - The study is minimal risk and the role of the external site or personnel is either limited or very straightforward (e.g., administration of a single survey, assisting with recruitment of subjects); and/or
 - The study is eligible for review under an existing IRB authorization agreement (MOU, SMART, etc.)
- **Q:** When will the UTHSA IRB typically not consider serving as the IRB of record?
A: The UTHSA IRB will typically not consider serving as the IRB of record in certain situations including:
 - UTHSA is not engaged in research.
 - The UTHSA-IRB does not have sufficient knowledge of the local context (as required by federal guidelines) to assume IRB oversight for external sites or personnel
 - The UTHSA-IRB does not feel they cannot adequately oversee the external site or personnel in manner that will ensure the protection of human subjects; and/or
 - Studies for which administrative or institutional policies otherwise prohibit or limit options for serving as IRB of record
- **Q:** If the UTHSA IRB agrees to serve as IRB of record for external personnel or collaborators, do the external personnel or collaborators need to complete human subjects training?
A: Yes. External entity would be responsible for ensuring the completion of human subjects training. Institutional assurance will be documented during the reliance process.
- **Q:** How do I submit a request for the UTHSA IRB to serve as IRB of record?
A: For instructions on how to submit a request for the UTHSA IRB to serve as IRB of record, please see: <https://www.uthscsa.edu/vpr/services/approval/getting-approval-your-human-study>