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New Study Consultation Request Form

The purpose of this form is to provide the North Texas Regional Institutional Review Board (NTR IRB) with specific information about a potential new study submission and to request a consultation with an NTR IRB staff member before submitting a project for review. The consultation will involve a brief meeting, either in-person or via telephone, with an NTR IRB staff member and is intended to take place prior to submitting a project for review. During the consultation, NTR IRB staff will answer questions from the principal investigator (PI)/study team, as well as provide education and guidance (as needed). Consultations are always available upon request for any type of study but are not required.

Consultations are recommended for (but not limited to) the following types of topics prior to submission of a new study:

- 1st time submitting a study to the NTR IRB
- Questions about whether a proposed study is considered human subject research
- Questions about "engagement" in research
- Questions about type or level of review
- Questions about inclusion of Vulnerable Populations in a project
- Studies involving multiple institutions or Reciprocity/Reliance agreements (Consultation strongly recommended to avoid unnecessary work or dual IRB review.)

Who should attend the consultation?

- Principal Investigator
- Research team member(s) who will be responsible for the IRB submission

To request a Consultation, please complete all sections of the form below, and submit the form.

Note: Please DO NOT send your study protocol to the NTR IRB when submitting this form! Protocols will only undergo review by the IRB once formally submitted in IRBNet.

Principal Investigator:

Contact Information to Schedule Consultation:

Name: Position:

Telephone: Institution/Department:

E-mail: Best time to contact:

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Reason for consult (check all that apply):

- ☐ 1st time submitting a study to the NTR IRB
- ☐ Multisite/Cooperative Research
- ☐ Questions regarding IRB forms
- ☐ Research Involving Drug(s) or Medical Device(s) (may or may not be FDA-regulated)
- ☐ Clinical Trials (either Sponsored or NIH-funded)
- ☐ Research Involving Mobile Applications, Stand-alone Software, Machine Learning Algorithms
- ☐ Repository or Registry Creation
- ☐ Guidance on putting together a Global Protocol
- ☐ Vulnerable Populations
- ☐ Research Involving Medical Records
- ☐ Research Involving Student Records
- ☐ Data Security in Storage and Transmission
- ☐ Informed Consent and/or HIPAA Authorization
- ☐ International Research
- ☐ Process for Reciprocity/Reliance Agreements
- ☐ Checklist of items needed specific to a project for a complete IRB submission
- ☐ Other (please explain):

Please briefly expand on the issues/topics and questions you would like addressed during the consult (in follow-up to the items checked in the “Reason for Consult” section above):

If you have discussed this study/question with someone in the North Texas Regional IRB office, please identify who you communicated with and the date (if available):

Please briefly describe the nature and purpose of your study:

Timeframe for consultation meeting?

- ☐ Urgent (JIT or grant deadline)
- ☐ In the next week
- ☐ In the next two weeks
- ☐ In the next month
- ☐ In the next two months

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