***Master Protocol Synopsis Guidance Sheet***

***Please read this document first (prior to completing the General Protocol Synopsis template)***

This document provides general guidance and tips on how to complete the General Protocol Synopsis template. The General Protocol Synopsis provides relevant study information for an effective IRB review, as required by the federal regulations. Please visit the NTR IRB website (or click [here](https://www.unthsc.edu/north-texas-regional-irb/institutional-review-board-forms/)) to access the aforementioned template.

This guidance document will cover the following topics (use hyperlinks to jump to the desired section):

1. [When Researchers Should Use the General Protocol Synopsis Template](#WhentouseMasterProtocolSynopsis)
2. [Brief Description of the Elements (or sections) Comprising the General Protocol Synopsis Template](#ElementsofMasterProtocolSynopsis)
3. [Guidance Resources and Tools Researchers Can Use When Completing the General Protocol Synopsis Template](#ResourcesandToolsforMasterProtocolSyn)
   1. [Studies involving Research Registry or Repository](#Registries)
   2. [Studies involving Existing Material](#ExistingMaterial)
   3. [Studies involving Surveys](#Surveys)
   4. [Studies involving Focus Groups/Interviews](#FocusGroupsInterviews)
   5. [International Research Studies](#International)
   6. [Data Storage and Confidentiality](#DataStorageConfidentiality)
   7. [Recruitment Guidance](#Recruitment)
   8. [Informed Consent](#InformedConsent)
   9. [HIPAA Authorization](#HIPAA)
4. [Protocol submission reminders and tips](#SubmissionReminders)

**When to use the General Protocol Synopsis Template**:

Please note that the General Protocol Synopsis template should be used for ***any*** type of research activity (e.g., survey, focus group/interview, interventional, repository, etc.) ***with the exception*** of projects involving ***only*** a chart review. NTR IRB has a specific Protocol Synopsis template for chart reviews which embeds the requests for informed consent and HIPAA waivers within the template (click on the hyperlink, “[Protocol Synopsis for Research involving Chart Reviews](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Chart-Review-Form-Revised_Nov_19-7.docx),” to access the template).

**Elements of the General Protocol Synopsis Template**

The General Protocol Synopsis template contains specific topics/sections geared toward addressing detailed information needed to make an effective IRB review, as required by federal regulations. Note that the IRB must be able to evaluate the scientific and ethical soundness of a study as well as the potential risk(s) involved. Therefore, specific information must be given to the IRB for a successful review and approval.

Below is a breakdown of the sections and a description of the information NTR IRB needs in order to conduct an appropriate and thorough review.

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| **Section** | **Description** |
| Project Details | *Study title, Name of the Principal Investigator, Department/Institution, and Funding Agency and Proposal/Protocol Number* |
| 1. Purpose of the Study | *Briefly sketch the background leading to the present proposal, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.* |
| 1. Background and Significance | *Briefly sketch the background leading to the present proposal, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.* |
| 1. Preliminary Studies | *Summarize preliminary studies conducted by the investigator pertinent to this proposal (e.g., You have completed a pilot project in preparation for this study, etc.). State "none" if applicable.* |
| 1. Investigator Experience | *Provide a brief synopsis of the principal investigator’s expertise, experience, and capability to perform this research. Submit a copy of the curriculum vitae of the principal investigator in IRBNet.* |
| 1. Experimental Design and Methods | 1. *Methods and Procedures* - *Describe the procedure (s) in sequential detail. Describe the methods. Clearly identify any experimental elements of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.* 2. *Data Analysis and Data Monitoring* - *Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).* 3. *Data Storage and Confidentiality* – *Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release. For specific language, please refer to the NTR IRB’s* [*Data Storage and Security Guidance*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Guidance-and-Procedures-for-Investigators-Data-Storage-and-Security-Final-October-2021.docx) *document.* 4. *Setting* - *Describe briefly where the study will be conducted (e.g., private outpatient clinics, physicians’ offices, etc.).*   *NOTE: If other institutional review boards (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other institutions’ IRBs must be obtained before initiation of the project (but are not essential for North Texas Regional IRB review to begin).*   1. *Laboratory methods and facilities* - *Indicate where specific laboratory tests will be performed (e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc.). If None, state “N/A”.* 2. *Estimated Period of Time to Complete the Study* – *Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if the study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hours, etc.). Where possible, use a table or “bullet-point” format to clearly illustrate the flow of activities and procedures.* |
| 1. Human Subjects | 1. *Sample Size*: *Specify the approximate number of subjects to be enrolled in this study at this site.* 2. *Describe both Inclusion AND Exclusion Criteria.* *BE SPECIFIC! Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.* 3. *Describe intended gender, age range, intended racial and ethnic distribution. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities), a justification must be provided.* 4. *Identify the source(s) from which you will obtain your study population.* 5. *Describe plans for recruitment of subjects.* *All materials (e.g., flyers, ads, emails, letters, postings, handouts, social media language, website link, etc.) that will be used for recruiting subjects must be submitted to the IRB for review. For specific guidance, please refer to the* [*NTR IRB Recruitment Guidance*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Recruitment-Guidance-10.22.21-FINAL.docx) *document.* |
| 1. Risk/Benefit Assessment | 1. *Describe any* ***potential RISKS OR DISCOMFORTS*** *in detail. Please note that potential risks include informational risks (such as breach of confidentiality) as well as other risks, such as physical risks (direct injury or harm to the subject), reputational injury, and emotional risks. Describe the procedures for protecting against or minimizing potential risks. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Be sure to describe any anticipated adverse events that might occur during the course of the study, and describe the methods for detecting adverse reactions.* 2. *Describe the* ***level of risk.*** *(Either* ***Minimal*** *or* ***More than Minimal****; note that the federal regulations define minimal risk as, “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.)* 3. *Describe the* ***proposed benefits*** *of the study, whether they are direct benefits to study participants and/or benefits to society/science. (If there is NO direct benefit to subjects, please include such a statement in the protocol synopsis as well as in the consent document(s), if any.)* 4. *Describe* ***how the anticipated benefit justifies the risk****. Additionally, explain how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.* |
| 1. Payment/Compensation | *Describe any payments for subject participation (e.g., compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort).* ***Remember: payments are NOT benefits.*** |
| 1. Subject Costs | *Describe any anticipated costs to research subject, whether they be financial or something else. If none, state such.* |
| 1. List of Key Personnel | *List all individuals directly involved in the conduct, design or reporting of research involving human subjects in this study, including anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc. Please describe the roles/responsibilities of each person who is listed as key personnel on this project.* |
| 1. Literature Cited | *If any, the references should be limited to relevant and current literature pertinent to the proposed research.* |

**Guidance Resources and Tools to use when completing the General Protocol Synopsis Template**

As you are addressing the various sections of the protocol synopsis, please review and use the NTR IRB guidance documents listed below. (***Please click on the respective hyperlinks within the table to access the guidance documents***).

*Note: Visit the* [*NTR IRB website*](https://www.unthsc.edu/north-texas-regional-irb/instructional-guidance-and-sources-for-human-subject-investigators/) *for guidance on other human subject regulatory and research design topics, such as, but not limited to: Elements needed in an informed consent document, Re-contacting subjects, HIPAA regulations, Re-consenting subjects, when minors become adults in a research study, Serious Adverse Event reporting, and Protocol Violation reporting.*

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| **Guidance Topic/Document** | **Description** |
| [Studies involving Research Registries or Repository](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Guidance-for-Research-Registry-and-Repository-Protocols-Dec.-2021-Clean.pdf) | *This guidance document is intended to assist NTR IRB investigators with crafting the appropriate information to include in the Protocol Synopsis of a project which is intended to be either a research registry (data bank) or a research repository (tissue/biospecimen bank).* |
| [Studies involving Existing Material](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Existing-Materials-Data-and-Human-Biological-Specimens-Guidance-Document-November-2021.docx) | *This document contains guidance on the existing materials (data and/or Human Biological Specimens) and related elements that need to be included in the Protocol Synopsis.* |
| [Studies involving Surveys](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Survey-Guidance-Document-October-2021.docx) | *This document contains guidance on the survey-related elements that need to be included in the Protocol Synopsis.* |
| [Studies involving Focus Groups/Interviews](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Focus-Group-and-Interview-Instructional-Guide_Revised_December-2021-FINAL.pdf) | *This packet provides guidance to investigators designing focus group/interview research studies. This includes the information required for an effective IRB review as well as guidance regarding consent, recruitment and designing research-related documents for focus group and/or interview studies.* |
| [International Research Studies](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/International-Research-by-North-Texas-Regional-Researchers_Rev-Jan-2018-Final.pdf) | *Federal regulations require that all international research with human subjects must have the appropriate safeguards in place to protect the rights and welfare of the subjects. This document provides guidance on the federal requirements that are required for conducting international research.* |
| [Data Storage and Confidentiality](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Guidance-and-Procedures-for-Investigators-Data-Storage-and-Security-Final-October-2021.docx) | *This document provides investigators with IRB recommended language for data storage and security. The recommended verbiage can be incorporated into the Protocol Synopsis (see section E.6.Data Storage and Confidentiality).* |
| [Recruitment Guidance](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Recruitment-Guidance-10.22.21-FINAL.docx) | *This document is intended to provide general guidance on various recruitment strategies as well as what should be included within the recruitment materials to meet regulatory criteria. Consider these approaches as you are developing the Recruitment section of the Protocol Synopsis (see section F. 5. Recruitment). Note that recruitment is part of the consenting process, and federal regulations require IRB review and approval of the information presented to potential research subjects.*  *For a sample/template of a telephone recruitment script, please click* [*here*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/TELEPHONE-RECRUITMENT-FOR-A-SURVEY-OR-INTERVIEW_Revised-Jan-2018-final.doc)*.* |
| Informed Consent | 1. [*Consent Form Template (General)*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Consent-Form-Template-General-FINAL-Aug-10-2021.docx)*: This template includes all of the required elements of informed consent (per the federal regulations, with regard to human subjects research, and sponsor-driven, such as ClinicalTrial.gov requirements), and can be used to develop a consent form for any category of research project (Exempt, Expedited, or Full Board).* 2. [*Consent Statement/Cover Letter Template*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Consent-Statement-Cover-Letter-Template-FINAL-Aug-10-2021.doc)*: This template should ONLY be used for studies in which the principal investigator is requesting a Waiver of Documentation of Informed Consent, as the subjects will not be signing (documenting) their agreement to participate by signing a consent form. Please note this template replaces the NTR IRB’s previous versions of the “Research Statement/Consent Cover Letter” templates.* 3. [*Waiver of Informed Consent*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Informed-Consent-Form-B_REVISED-Jan-2019.docx)*: In some instances, under certain requirements, federal regulations permit the IRB to grant a waiver of informed consent or allow an adaptation to the required elements of an informed consent. Click on the* [*hyperlink*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Informed-Consent-Form-B_Revised-1_29_19.docx) *to access the application for requesting a waiver of informed consent.* *For additional information regarding this type of waiver, please visit* [*here*](https://www.unthsc.edu/north-texas-regional-irb/informed-consent/#studies)*.* 4. [*Waiver of Documentation of Informed Consent*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Documenation-ICF-Form-A_Revised-Jan-2019-2.docx)*: Under federal regulations, the IRB can waive the requirement to obtain****documented, or written****informed consent (i.e. signature). Click on the* [*hyperlink*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Documenation-ICF-Form-A_Revised-Jan-2019-2.docx) *to access the application for requesting a waiver of documentation of informed consent. For additional information on a written informed consent waiver, please visit* [*here*](https://www.unthsc.edu/north-texas-regional-irb/informed-consent/#documentation)*.* |
| HIPAA Authorization | *HIPAA Authorization Templates: Health Insurance Portability Accountability Act (HIPAA) regulations were designed to protect confidentiality of individual’s medical records and protected health information. HIPAA regulations apply to human subject research under the Privacy Rule, which require investigators to request subject authorization for the*[*use*](https://www.unthsc.edu/research/glossary-of-research-terms/#Use-terms/)*and*[*disclosure*](https://www.unthsc.edu/research/glossary-of-research-terms/#Disclosure)*of*[***protected health information (PHI)***](https://www.unthsc.edu/research/glossary-of-research-terms/#PHI)*. HIPAA regulations define PHI as*individually identifiable health information*. Identifiable means the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Therefore, investigators must include a valid HIPAA Research Authorization request during subject consenting if they will be collecting, using, retaining or disclosing PHI. Please see below for links to our HIPAA templates:*   * 1. [*UNTHSC HIPAA Authorization Template*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/HIPAA-Research-Authorization-Template-Revised-January-2018-Final-2.docx)   2. [*JPS HIPAA Authorization Template*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/HIPAA-Authorization-TEMPLATE-JPS-Version.docx)   [*HIPAA Waiver*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/HIPAA-Research-Waiver-January-2019-REVISED.docx)*: There are some types of research where it is impracticable for the researcher to obtain written Authorization from research participants (e.g., secondary data analyses). Under the Privacy Rule, HIPAA Authorization may be waived or altered (in whole, or in part) if specific criteria are met. For waiver criteria, or additional information about a waiver, please click* [*here*](https://www.unthsc.edu/north-texas-regional-irb/research-hipaa-guidelines/#waiver)*.*   1. *For more details about HIPAA requirements and elements, please click* [*here*](https://www.unthsc.edu/north-texas-regional-irb/research-hipaa-guidelines/)*.* |

***Protocol Submission Reminders and Tips***

Please bear in mind the following tips and suggestions when preparing your protocol for IRB review:

* Provide a clear and complete description of the research activities in the protocol synopsis. This will facilitate a timely and effective review of your new project. Conversely, vague, confusing or missing elements will delay the review (and approval) of your project.
* Leave an inch at the bottom margin of the Protocol Synopsis (and other research supporting documents, e.g., consent document, recruitment materials, etc.). Upon NTR IRB approval, an electronic IRB approval stamp will automatically be inserted into the bottom, left hand corner of each page of the approved documents. (Note: NTR IRB staff are unable to move the location of the stamp, as this is an automated process that occurs within the IRBNet system.)
* In the General Protocol Synopsis, please use Times New Roman or Arial font (11 or 12) for ease of review.
* In addition to the General Protocol Synopsis, please include (in your IRBNet submission) all other relevant and NTR-IRB required documents, including:
  + [*Consent Form*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Consent-Form-Template-General-FINAL-Aug-10-2021.docx) - THE CONSENT FORM MUST BE A SEPARATE DOCUMENT. It is important that the consent form follows the IRB-prescribed format and includes all of the required elements of informed consent as well as other certain elements of informed consent, when appropriate.
  + *HIPAA Authorization Form (for studies collected/using protected health information)*
  + *Recruitment Materials* (ads, flyers, emails, etc.) to be used in the study.
  + *Study-Related Documents* [e.g., questionnaires, survey instruments, sponsor/coordinating site protocol (for clinical trials or multi-site studies), investigator’s brochure, etc.]
  + *(If needed/appropriate) Request(s) for Waiver(s) of:* [*Informed Consent*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Informed-Consent-Form-B_REVISED-Jan-2019.docx)*,* [*Documentation of Informed Consent*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Waiver-of-Documenation-ICF-Form-A_Revised-Jan-2019-2.docx)*, or* [*HIPAA Authorization*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/HIPAA-Research-Waiver-January-2019-REVISED.docx) (Note: an appropriate justification for the waiver request must be included).
  + *Evidence of Human Subject Protection Training (e.g., CITI)* for ALL Key Personnel listed in the protocol synopsis. NOTE: For projects deemed by the sponsor (e.g., NIH) to be a Clinical Trial, please include evidence of Good Clinical Practice training.
  + *Conflict of Interest (COI) Form*s – COI forms must be completed and signed by EACH person who is listed as key personnel in the protocol synopsis. Note: COI forms are required for Expedited and Full Board category studies. COI forms are not required for Exempt category studies.
  + Principal Investigator CV, as well as a copy of a current provider license (if needed).
  + Grant Application, Notice of Award, Award Letter, etc.
  + For projects involving non-English speaking only subjects, include a Translation Verification Memo (signed/dated by the translator). The memo should list the documents that were translated as well as an attestation from the translator indicating that the translation was performed to the best of their abilities. The memo must be notarized. NOTE: Notarization may be waived in instances where the translation is performed by qualified and fluent UNTHSC personnel. Experience and/or credentials should be included in the memo as supporting evidence of fluency.
* **General Protocol Submission Guidance:**
  + Please submit all documents in IRBNet ([www.irbnet.org](http://www.irbnet.org)). Register as a New User (if you haven’t done so already), and select “Create New Project” in the left-hand navigation bar. Please refer to the [IRBNet Manual](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/IRBNet_user_manual-revised-8-27-2019.pdf) for additional guidance and details on how to navigate a new protocol submission within IRBNet.
  + Please note the following:
    - **THE PRINCIPAL INVESTIGATOR MUST HAVE FULL ACCESS TO THE IRBNET PROTOCOL PACKAGE IN ORDER FOR IT TO BE REVIEWED BY THE IRB.**
    - Please use a **very descriptive file name** for each document submitted as a pdf or word.doc file.  Example: “MMSE scale” is much better than “Scale 1”. “Recruitment flyer” is better than “Ad 1”, and so forth.
    - The Principal Investigator (PI) must electronically sign the submission package in IRBNet before the project is formally submitted to the North Texas Regional IRB. This will require the PI to log into IRBNet and sign the package.

**\*As a general reminder, Full Board submissions MUST be received by CLOSE OF BUSINESS (5:00 PM CT) on the day of the submission deadline in order to be considered for the upcoming IRB Meeting.\***

**Please contact NTR IRB at** [**NorthTexRegIRB@unthsc.edu**](mailto:NorthTexRegIRB@unthsc.edu) **if you have any questions.**