**Guidance Document for Research Involving Existing Materials (Data and/or Human Biological Specimens)**

When a research project involves the use of existing materials (data and/or human biological specimens), additional elements need to be included in the Protocol Synopsis.

This document contains guidance on specific elements that need to be included in the Protocol Synopsis for studies that involve existing materials. Please note that the elements that are outlined in this document are *in addition to* the basic protocol elements that are outlined in the main Protocol Synopsis template.

The following guidance is separated into two parts:

A) Existing Data

B) Existing Human Biological Specimens

If your research will involve either or both types of existing materials, please include the elements (outlined below) in your Protocol Synopsis. Please note that failing to include any of these specific elements in your Protocol Synopsis may result in your submission being returned to you for additional information and/or revisions.

**A) Existing Data:**

***Address the following items within the Background and Significance portion of the general/main Protocol Synopsis template (B. Background and Significance) -***

1. **Describe the parent project.** 
   * Describe the original project from which the data originated, including where the data are currently stored.In other words, describe how the data came into existence (e.g., survey, student records, internal quality assessment, etc.).
2. **Please describe how the data were legally and ethically obtained.** 
   * Describe how it was verified that the data were legally and ethically obtained. In other words, describe how the data came to be. This may be demonstrated by submitting a copy of an IRB approval letter from the outside entity or by submitting a copy of a clinical consent document or research consent form, indicating that the subjects gave their permission for the data to be used for research purposes. Another option is to submit a statement (e.g. copy of an email, etc.) from an appropriate authority at an organization and/or a testing site from which the data were obtained, giving permission for the data to be used for this study (and/or future research studies) and verifying that the data were legally collected. A copy of such documentation should be included in the new project submission.

***Address the following item within the Methods and Procedures portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

1. **Describe the existing data.**
   * Description of the data: *Describe the data that will be analyzed in this study, including the source of the data (survey/questionnaire, medical record, research record, etc.), the type of health information present (if any), the format of the data (i.e., electronic and/or hard copy), and how the data will be labeled, and the* *classifications of the data (i.e., unidentified, unlinked, identifiable, coded, etc.).*
   * Describe whether any identifiers (e.g., subject’s name, date of birth, medical record number, date of medical services, etc.) will be present in the data set when the data are received by researchers. If identifiers *will be* obtained, describe (in the protocol synopsis) the specific identifiers.
   * When appropriate, describe the process for “stripping” the data of identifiers: *Describe where and when this will occur, who will perform the stripping process, where the master list will be maintained (if appropriate), what identifiers will remain after this process, and who will have access to the identifiable information.* ***IRB Guidance Note****: Data should be rendered de-identified upon study closure and not left identifiable indefinitely.*

***Address the following item within the Data Analysis and Data Monitoring portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

1. **Analysis of the data.**
   * Setting/location: *Describe where the data will be analyzed (i.e., state your specific institution or outside entity).*
   * Procedures for Data Analyses: *Describe the plans for statistical analysis of the data and the names of the key personnel that will be involved.*
   * Estimated Period of Time to Complete the Study: *Describe the stages and overall time frame for data acquisition and analysis procedures (e.g., the approximate amount of time from start to completion).*

***Address the following item within the Data Storage and Confidentiality portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

1. **Describe how data will be transferred.**
   * Transfer in of data to your institution/investigators from the outside source. *In this section, describe the process for how the data will be transferred to investigators. List the name of the organization(s) that will be sending the data and provide the name of the person(s) at that organization(s) who will be responsible for overseeing the transfer of the data to your institution. If data will be received from more than one entity, please describe appropriately.*
   * Transfer out of the data from your institution to outside researchers: *In this section, describe how the data will be transferred from your institution to outside organizations or individuals. List the name of the organization(s) that the data will be sent to and specify the name of the person(s) from that organization who will be responsible for receiving the data.*
   * Transfer of the related data internally (to/from other collaborating researchers *within* your institution): *In this section, describe the process for how the data will be transferred from or to other investigators within your institution. Note: IRB review and approval of the investigator’s research project to which the data will be transferred is required before the transfer can occur.*
2. **Data Storage and Security/Special Precautions**
   * Short term storage of data: *Describe where the data (electronic and hard copy) will be stored when they are received by researchers and during analysis.*
   * Long term storage of data: *Describe where the data will be stored after this project is completed. If appropriate, describe when the data will be destroyed.*
   * Data Storage and Security: *Describe how the data will be secured during storage. The investigator must take necessary steps to maintain confidentiality of the data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to the 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 related and the purpose of the release.*
3. **Ownership of Data:** 
   * Describe what individual/entity will own the data after they are transferred to your institution. Indicate if the outside entity will retain any ownership, or access to the data, after transfer.

**Other IRB Submission Tips for Existing Data Projects:**

* + Given the elements/components associated with the project, please contact the Contract Manager in the Office of Sponsored Programs (OSP; ospcontracts@unthsc.edu) to see if any agreement is needed for this study (e.g., Data Usage Agreement (DUA), Memorandum of Understanding, etc.). Please include correspondence (e.g. copy of executed agreement or an email/statement from OSP, stating that a DUA is not required) in your submission.
  + **Please include the following documents in your submission:**

1. A copy of the data collection instrument(s).
2. Documentation from the Clinic/Testing Site/Organization from where data will be obtained.
3. If it was not feasible to obtain Informed Consent from the subjects, please complete the Waiver of Informed Consent document.
4. For projects that involve the use of subjects’ identifiable health information: If it was not feasible to obtain HIPAA Authorization from the subjects, please complete a Waiver of HIPAA Authorization form.

**B) Existing Materials (Human Biological Specimens):**

***Address the following items within the Background and Significance portion of the general/main Protocol Synopsis template (B. Background and Significance) -***

* **Describe the parent project.** 
  + Describe the original project from which the biospecimens originated, including where the biospecimens are currently stored.
  + Describe the project to which the biospecimens will be transferred.
* **Please describe how the Human Biological Specimens were legally and ethically obtained.** 
  + Describe how it was verified that the biospecimens were legally and ethically obtained. In other words, describe how the biospecimens came to be. This may be demonstrated by submitting a copy of the IRB approval letter for the collection of the biospecimens from the outside entity or by submitting a copy of a clinical consent document or research consent for, indicating that the subjects gave their permission for the biospecimens to be used for research purposes. Another option is to submit a statement (e.g., a copy of an email, etc.) from an appropriate authority form an organization and/or testing site from which the biospecimens were obtained, giving permission for the biospecimens to be used for this study (and/or future research studies) and verifying that the biospecimens were legally collected. A copy of such documentation should be included in the new project submission.

***Address the following item within the Methods and Procedures portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

* **Describe the biospecimens.**
  + Description of the biospecimens: *Describe the biospecimens that will be analyzed in this study. Describe the number of biospecimens that will be included, the type of human biological material (tissue, blood, sputum, urine, bone marrow, cell aspirates), and how the biospecimens will be labeled.*
  + When appropriate, describe the process for “stripping” the biospecimens of identifiers: *Describe where and when this will occur, who will perform the process, where the master list will be maintained (if appropriate), what identifiers will remain after this process, and who will have access to the identifiable information.* ***IRB Guidance Note****: Data should be rendered de-identified upon study closure and not left identifiable indefinitely.*
* **Describe how biospecimens will be transferred.**
  + Transfer in of biospecimens to your institution from outside researchers: *In this section, describe how the biospecimens will be transferred to investigators. List the name of the organization(s) the biospecimens will be received from and the name of the person(s) at that organization(s) who will be responsible for overseeing the transfer of the biospecimens to your institution. If biospecimens will be received from more than one entity, please describe appropriately.*
  + Transfer out of the biospecimens from your institution to outside researchers: *In this section, describe how the biospecimens will be transferred from your institution to outside organizations or individuals. List the name of the organization(s) and individuals the biospecimens will be sent to and the name of the person(s) who will be responsible for receiving the biospecimens at that organization.*
  + Transfer of the biospecimens internally (to/from other collaborating researchers): *In this section, describe how the biospecimens will be transferred from or to other investigators within your institution. Note: IRB review and approval of the investigator’s research project to which the biospecimens will be transferred to is required before the transfer can occur.*

***Address the following item within the Data Analysis and Data Monitoring portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

* **Analysis of the biospecimens.**
  + Setting/location: *Describe where the biospecimens will be analyzed. (i.e., state your specific institution or outside entity).*
  + Laboratory methods and facilities: *Describe the procedures/processes that will be used to analyze the biospecimens, including the laboratory, equipment, and key personnel that will be involved.*
  + Estimated Period of Time to Complete the Study: *Describe the stage and overall time for the entire study (start to completion).*

***Address the following item within the Data Storage and Confidentiality portion of the general/main Protocol Synopsis template (E. Experimental Design and Methods) -***

* **Data Storage and Security/Special Precautions**
  + Short term storage of the biospecimen: *Describe where the biospecimens will be stored when they are received at your institution and during analysis.*
  + Long term storage of biospecimens: *Describe where the biospecimens will be stored after this project is completed.*
  + Human Biospecimen Storage and Security: *Describe how the biospecimens will be secured during storage. The investigator must take necessary steps to maintain confidentiality of the human biospecimens. This includes coding human biospecimens and choosing an appropriate and secure sample storage mechanism which will prevent unauthorized access to the biospecimens. State who will have access to the human biospecimens. If human biospecimens with subject identifiers will be released, specify the person(s) or agency to whom the information will be related and the purpose of the release.*
* **Ownership of Biospecimens**
  + Describe what individual/entity will own the biospecimens after they are transferred to your institution. Indicate if the outside entity will retain any ownership, or access to the biospecimens, after they are transferred.

**Other Submission Tips for Projects involving Existing Biospecimens:**

* + Given the elements/components associated with the project, please contact the Contract Manager in the Office of Sponsored Programs (OSP; ospcontracts@unthsc.edu) to see if any agreement is needed for this study (e.g., Data Usage Agreement (DUA), Memorandum of Understanding, etc.). Please include correspondence (e.g. copy of executed agreement or an email/statement from OSP, stating that a DUA is not required) in your submission.
* **Please include the following documents in your submission:**

1. Documentation from the Clinic/Testing Site/Specimen Repository.
2. If it was not feasible to obtain Informed Consent from the subjects, please complete the Waiver of Informed Consent document.
3. For projects that involve the use of subjects’ identifiable health information: If it was not feasible to obtain HIPAA Authorization from the subjects, complete a Waiver of HIPAA Authorization form.