**Guidance Document for Research Involving Surveys**

**When a research project involves the use of surveys, additional elements need to be included in the Protocol Synopsis.**

**This document contains guidance on the survey-related elements that need to be included in the Protocol Synopsis. Please note that the survey-related elements that are outlined in this document are *in addition to* the basic protocol elements that are outlined in the main Protocol Synopsis template.**

**If your research project will involve the use of surveys, please include the survey-related 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.**

**Survey-Related Elements that Need to be Included in the Protocol Synopsis**

1. **Describe whether you will contract with an organization (agent) outside your institution to conduct the survey.**

***Note: “Contract” refers to any formal agreement that an investigator has entered into with an entity/organization outside of the investigator’s own institution, in which the other entity/organization will assist with the distribution of the survey (the investigator may be paying the contractor for these services). Some examples of this include using services such as Amazon Mechanical Turk (MTurk), Qualtrics Panel, etc.***

* ***If you will contract with an organization (agent) outside your institution to conduct the survey, please also****:*
1. Provide information about the organization (agent) and their role in the conduct of this study.
2. Within the Protocol Synopsis, include the plan for keeping the data confidential/secure. If available, a copy of the Terms of Use should also be uploaded into your submission.
3. Once the fully-executed contract with the organization has been completed/is available, you should upload the document into your submission for documentation. *(Note: The NTR IRB will not hold initial approval if the contract has not been finalized; however, you may not be able to begin the study/use the contractor’s services until the contract has been finalized.)*
4. If using an online/electronic platform/service, please make sure to contact your organization’s IT/Security department to ensure the service you will be using is allowable by your institution.
5. **Describe how the survey will be conducted.** Please refer to the examples (below) and include the information (in the protocol synopsis) regarding each method that will be used in your project.
* ***In person.*** If the survey will be conducted in person, describe the location(s) where the survey will be distributed and who will oversee this process.
* ***Via an internet survey (using software such as Formstack, Qualtrics, REDCap, etc.).*** If the survey will be conducted via an internet survey, provide the name of the software that will be used. *(As noted above, if using an online/electronic platform/service, please make sure to contact your organization’s IT/Security department to ensure the service you will be using is allowable by your institution.)*
* ***email.*** If the survey will be conducted via email, describe how you will obtain the email addresses.
* ***mail survey (U.S. Postal Service, campus mail, etc.).*** If the survey will be conducted via mail, describe how you will obtain the mailing addresses. Additionally, include information about how you will receive the surveys from study participants (e.g., will the PI/study team be providing participants with a pre-paid/stamped envelope?).
* ***telephone****.* If the survey will be conducted by phone, describe how you will obtain the phone numbers.
1. **Provide a description of the survey instrument(s). What type of questions/topics will the subjects be asked about?**

**REMINDER: Upload a copy of the survey/questionnaire to be used into your submission!**

1. **Describe how the subjects will be recruited to participate in the survey.**

*How will potential participants hear about your study? Flyers? Brochures? Referrals?*

1. **Describe whether any individual identifying information (e.g., names, addresses, phone numbers, email addresses, etc.) will be used to recruit subjects for this study.**
* ***If identifying information will be used to recruit subjects for this study, please also:***

(a) Describe the source and process for obtaining this information:

(b) Describe whether any of the identifying information that is used during the recruitment process will be “linked” to the subjects’ individual survey responses or to the survey data. If so, your data security plan will need to discuss the plan/process for keeping the identifiers private/confidential.

1. **Describe whether the subjects will be asked to provide any identifying information on the survey instrument (such as their name, address, phone number, social security number, employee ID, etc.).**
* ***If the subjects will be asked to provide identifying information on the survey instrument, please also:***
1. Describe the identifying information that you will collect. Your data security plan will need to discuss the plan/process for keeping the identifiers private/confidential.
2. **Describe how you will obtain informed consent from the subjects before they begin the survey. Please refer to the consent processes (below), and include information (in the protocol synopsis) about each consent process that will be used. \*Please note that if you have questions about the most appropriate consent method, contact the North Texas Regional IRB office.**

***\*Examples of the NTR IRB Consent Form Templates can be found here:***

[***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)

[***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)

* ***Written (signed) informed consent.***
	+ If consent will be obtained via written (signed) informed consent, submit a copy of the consent form(s).
	+ *E.g., in person, real-time*
* ***Study cover letter/research statement.***
	+ If consent will be obtained via a study cover letter/research statement please submit: (a) a copy of the study cover letter/research statement; AND (b) a completed “Waiver of Documentation of Informed Consent” form.
	+ *E.g., online survey, de-identified survey*
* ***Oral/Verbal consent***.
	+ If consent will be obtained via oral consent, submit: (a) a copy of the verbal consent script; AND (b) a completed “Waiver of Documentation of Informed Consent” form.
	+ *E.g., phone*
1. **Describe whether you will ask the subjects for any health information on the survey.**

Protected Health Information (PHI) under HIPAA is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual.

* ***If you will ask the subjects for health information on the survey, please also:***
1. Describe the health information that will be collected on the survey.

(b) Describe whether any of the health information that you collect will be linked (connected) to any of the subject identifiers (listed below).

 1. Names;

2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

 4. Phone numbers;

 5. Fax numbers;

 6. Electronic mail addresses;

 7. Social Security numbers;

 8. Medical record numbers;

 9. Health plan beneficiary numbers;

 10. Account numbers;

 11. Certificate/license numbers;

 12. Vehicle identifiers and serial numbers, including license plate numbers;

 13. Device identifiers and serial numbers;

 14. Web Universal Resource Locators (URLs);

 15. Internet Protocol (IP) address numbers;

 16. Biometric identifiers, including finger and voice prints;

 17. Full face photographic images and any comparable images; and

 18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

* ***If you will ask the subjects for health information on the survey AND the health information will be linked (connected) to any of the subject identifiers (above), please also:***

(a) Submit a HIPAA Research Authorization; or

(b) Submit a request for a Waiver of HIPAA Authorization.

*Note: The HIPAA Research Authorization template and the HIPAA Research Waiver form are available on the NTR IRB website. Contact the NTR IRB staff for guidance to determine if your project will need a HIPAA Research Authorization or a HIPAA Research Waiver.*

1. **Potential Risks**

**a. Include a statement (in the “Risks” section of the protocol synopsis) to reflect the potential risks of the study (such as breach of confidentiality, psychological/emotional, reputational, etc.). \*Reminder: every research study includes some level of risk, no matter how minimal.**

**b. Describe the procedures that will be in place to help reduce/manage the potential risks to subjects:**

**Some examples:**

* **For risk of breach of confidentiality: Data will be kept on a secured, password-protected server, only accessible to appropriate research personnel.**
* **For psychological/emotional risks: Research personnel will clarify to potential study participants that they are not required to answer anything they are not comfortable with.**
* **For reputational risks (i.e., if information about a subject could cause harm to the subject’s reputation, employment status, student status, civic or criminal liability): Data will be kept confidential.**
1. **Describe whether you will re-contact or follow up with the subjects after they complete the survey.**
* ***If you will re-contact or follow-up with the subjects, please also:***
1. Describe the procedures for re-contacting subjects.

*Note: Please submit any documents (such as telephone scripts, follow-up letters, emails, etc.) that will be used to follow up with subjects.* ***The consent document should also include a clause that indicates subjects will be re-contacted in the future for the purposes of this study, and how they will be re-contacted.***

1. **Describe whether the subjects will be compensated for completing the survey.**
* ***If the subjects will be compensated, please also:***

(a) Describe the amount of (how much) compensation the subjects will receive and the form of the subject payment; and

(b) Describe how the subjects will receive the compensation (e.g., in person, by check sent via postal mail, etc.).

*Note: If you plan to include subject compensation, the NTR IRB recommends that you contact your institution’s Accounting Department prior to IRB submission to determine their requirements and work out the appropriate details to prevent future protocol modifications.*

1. **Please include the following documents in your submission:**
2. A copy of the survey instrument(s).
3. Any recruitment materials (e.g., flyers, advertisements, email scripts, phone scripts, etc.) that will be used during the recruitment process.
4. Any documents that will be used during the consent process (e.g., consent form, study cover letter/research statement, oral consent script, etc.).
5. For projects that involve use of a study cover letter/research statement, please submit a completed “Waiver of Documentation of Informed Consent” form.
6. For projects that involve the use of subjects’ identifiable health information, please submit a HIPAA Research Authorization or a Waiver of HIPAA Authorization form.
7. Any documents (such as telephone scripts, follow-up letters, emails, etc.) that will be used to follow up with the subjects.