**Instructions:**

This protocol template is to be used as a guide. You may use a different format, order, or add additional information as needed. **Information provided in this template is intended to be a prompt, if something does not apply to your study, delete it.**

Use good version control of your document as you make edits. Keep an electronic copy of your final draft. You will need to modify this copy when making future changes.

**Delete all instructional text** from the final copy, indicated by italics.

**Protocol Title:** <Include full protocol title as listed in the IRB application forms>

**Principle Investigator:** <Include the principle investigator’s name as listed in the IRB application forms>

**Study Objectives:** <In this section, provide your study hypothesis/objectives. What is the question to be answered? Describe the purpose, specific aims or objectives as concise as possible. If multiple aims, number then and include them all.>

**Background: <**Describe relevant prior experience. What does current literate say about the topic? Are there any gaps in current knowledge and what is the importance of this study to fill in those gaps? Describe any relevant preliminary data.>

**Inclusion/Exclusion Criteria:**

* Describe criteria that will define who are included or excluded.
	+ Example: Age 18 or older.
* Describe how you will screen individuals for eligibility.
	+ Example: How will you confirm that those enrolled are over age 18?
* If you will exclude certain populations include scientific justification for that exclusion.
	+ Example: if excluding men or women a scientific justification may be that the disease being studied is not found in men/women. If excluding non-English speaking persons, a scientific justification may be that the study survey has not been validated in other languages.

**Study Statistical Considerations:**

* Describe and explain the study’s primary and secondary endpoints.
* Describe the data analysis plan, including any statistical procedures.
* Provide a power analysis.
* Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.

**Study Recruitment:** <Describe the study’s recruitment plan in detail.>

**Study Locations**

* Describe sites or locations where the research team will conduct the research.
* If recruiting at a non TAMU-CC site, add a Letter of Support as supporting document showing you have their agreement to allow you to use their site.

**Subject Identification**

* Identify where or how your team will identify potential subjects.
	+ Example 1: Subjects will be identified by search X (specify record types) records for Y (specify search criteria).
	+ Example 2: Faculty members teaching X classes (specify qualifying classes) will be asked if we can introduce the study in their classrooms. Interested parties will use contact information to reach out to investigators to participate.
	+ Example 3: X (identify listserve) is a listserve that includes members with (include qualifying characteristics that matches inclusion/exclusion criteria). X listserve will be contacted and request permission to send out recruitment email to listserve members.
	+ Example 4: We will post the recruitment flyer (see <specify recruitment flyer file name provided as an attachment) on these locations: <specify locations>. The flyer provides contact information on how to reach the study team if interested in participating. The flyer has a QR code or survey link interested parties can click to access the informed consent and decide to participate.

**Subject Approach**

* Describe when the subjects will be approached and identify any barriers that could affect the consenting process. Now that subjects have indicated their interested, what happens next? Some things to think about…
	+ Avoid having subjects approached during emergencies, such as prior to entering surgery, or when distracted, such as during a community event where other distractions are possible.
	+ If the consenting process may be compromised by the setting, describe how this will be minimized. For example, waiting after the emergency is over or letting the subjects take the consent home to think it over when no longer distracted or approaching during lulls that naturally occur.
	+ Confidentiality concerns. Be sure to describe how subjects confidentiality and privacy will be protected during the approach, i.e. don’t force consent in a public place.
* If you are including vulnerable populations, state what additional safeguards will be in place to minimize the potential for coercion.
	+ Example: If recruiting employees, what measures are in place that they do not feel forced to participate? How are you ensuring their supervisors do not know whether they chose to participate or any outcome of their participation?
	+ Example: If recruiting non-English speaking persons, what are you doing to address the language barrier both in writing documents and verbal conversations.

**Procedures Involved**:

* Describe and explain study design and procedures.This section must include all research procedures to be performed. Failure to include a procedure that is performed will be a protocol deviation. Be sure to accurately define those procedures that are being done for standard of care or per normal operating processes (i.e. Ask yourself, but for this study would this be done on subjects. If the answer is yes, then you can describe but clearly state that this is a standard procedure/process done that subjects will experience no matter their decision to participate in research).

**Data management:**

**Data sources**

* Describe where the data comes from?
* Who owns the data? Make sure you have permission to use the data for research.

**Data collection**

* Describe how the data will be recorded: What does the data look like when you receiving it? What are the data fields and are there identifiers include?
	+ Think about ways to reduce identifiers collected. For example, collect age versus date of birth. Set Qualtrics to not collect IP addresses.
	+ See [600.01 Template, Data Collection Sheet](file:///C%3A%5CUsers%5Cllind%5CDesktop%5CCorrected%20IRB%20Internal%20Forms%5C600.01%20Protocol%20Template%5C600.01%20Template%2C%20Data%20collection%20sheet.xlsx); [Template for a Regulatory Binder](https://tamucc-my.sharepoint.com/%3Af%3A/g/personal/rebecca_ballard_tamucc_edu/EhVs5fC5IVxChLvFMnLYep0BlOWpvTIGQNj6Fzyx8ffklQ?e=aO9FAn)
* Will the data be identifiable or are you de-identifying? If de-identifying, describe process.
	+ See [example](https://tamucc-my.sharepoint.com/%3Ai%3A/g/personal/rebecca_ballard_tamucc_edu/EdylZ4fQq0BOqocgu0BmS4wBIAhh98Y3Nd3Zu7_Us7JxtQ?e=7cFfTw) of how to set Qualtrics to be anonymous.
* Describe procedures used for quality control of collected data.

**Data security**

* Describe data security. Example: Data will be kept on a password-protected university-owned computer with access limited to only those listed on the IRB protocol.
* Use limited data set: Assign a code (Subject 001) to the research data. Remove all identifiers from the research data. Store the code sheet that connects the code to the research data (Example: Subject 001 is Johnny Smith) in a different location. Storing the key separate from the lock so if someone gets access to one or the other, they do not have access to both to re-identify the research data.

References

* Provide the citations for all publications and presentations referenced in the text of the protocol.