The Community Counseling, Education, and Research Center (CCERC)
https://sites.ced.ncsu.edu/ccerc/

CCERC provides low cost/free counseling services to the community. The basis for this service is that it provides low cost counseling, serves as an educational experience for graduate students to complete their practicum, and it provides multiple opportunities for research on issues related to wellness and counseling.

- When clients sign up for services at the CCERC, they are informed from the beginning that this is a center that not only provides low cost counseling but it does so because it is an educational and research facility. Participants do not have to participate in research if they want to be a client here, but they are aware of the research taking place, can consent to be in the research, and are a part of the educational only endeavors.

- The counselors at the CCERC are graduate students that are supervised in their role by doctoral students and Marc Grimmett.

- CCERC is not a HIPAA covered entity and HIPAA rules and regulations do not need to be applied to the research.

- Some of the counselors and managers at the CCERC have access to only their client information and some have access to all client information.

- Clients at the CCERC are told about the research goals of the center at three different points:
  - During the initial phone screening to determine if the CCERC is appropriate for the client.
  - During the initial counseling session with the client’s assigned counselor (though research is only briefly mentioned).
  - During the Informed Consent process approved by the IRB for specific research projects. The researcher for the project will take the client/potential participant aside and tell them about research. The participant’s counselor does not recruit participants for the specific research being done.

- CCERC collects information that is a part of their normal counseling and not for research.
  - Example: All clients complete the intake form, and the intent is not solely for research.

- CCERC collects information that is a part of their normal counseling and also used as data for research.
  - Example: All clients complete the intake form as a normal counseling experience, but researchers can request to access this intake form to be used as data for research purposes.

- CCERC collects data from research participants (who are the clients) that is not a part of the clients’ normal counseling experience.
  - Example: Some clients complete personality tests and surveys done for research purposes (approved by the IRB) and other researchers want to access this already collected data to be used as a part of their own research project.
  - Example: Some clients will complete a survey/interview for a research project only.

Updated 4/18/18
Language to Use in Discussing this Research in the IRB Application

Always State on Description Tab - First Box: CCERC provides low cost/free counseling services to the community. The basis for this service is that it provides low cost counseling, serves as an educational experience for graduate students to complete their practicum, and it provides multiple opportunities for research on issues related to wellness and counseling.

Always State on Description Tab - First Box: When clients sign up for services at the CCERC, they are informed from the beginning that this is a center that not only provides low cost counseling but it does so because it is an educational and research facility. Participants do not have to participate in research if they want to be a client here, but they are aware of the research taking place, can consent to be in the research, and are a part of the educational only endeavors.

Always State on Description Tab - First Box: CCERC is not a HIPAA covered entity and HIPAA rules and regulations do not need to be applied to the research.

Select the Relevant Language for the Procedures Tab - Bottom two boxes and the Data Security Tab, first text box:

- As a normal part of their counseling experience, client’s complete ________, I would like to use this information from this ________ as data for research purposes. I have access to this information because ________. The information is currently identifiable but I will/will not record identifiers with the information as I compile the information into a research dataset. I will access this information through ________. I will transfer this information by ________. I will store this information by ________. I am/am not able to re-identify participants once the information has been compiled into a data set for research purposes.

- As a normal part of their counseling experience and as a part of a past research project, client’s completed ________. I would like to use this information and data from this ________ as data for this research research project. The information is currently identifiable but I will/will not record identifiers with the information as I compile the information into a research dataset. I will access this information through ________. I will transfer this information by ________. I will store this information by ________. I am/am not able to re-identify participants once the information has been compiled into a data set for research purposes.

- As a part of a past research project, participants provided researchers with the following data: ________. I would like to use that data as data in this current research project. The data is/is not identifiable. I have access to this data because ________. The data will be transferred to me by ________. I will store the data by ________. I am/am not able to re-identify participants once the information has been compiled into a data set for research purposes.

- As a part of this research project only, I would like to collect data from participants who are also clients at the CCERC. The data I would like to collect include ________. I will collect this data through ________. I will store this information by ________. I am/am not able to re-identify participants once the information has been compiled into a data set for research purposes.

Always address the following on the Data Security tab:

- Articulate the identifiers that are collected and retained (or not) about primary participants.
- Articulate the identifiers that are collected and retained (or not) about secondary/third party participants.
- Articulate information about your access to private records and what those records include and if they are about primary and secondary/third party participants. Make sure to state WHY you need these IDs associated with the data and if you will retain IDs why you need to retain them.

Always address the following on the Risks tab in the text boxes

- Identify the risks to the primary participants and state how you are mitigating these risks.
- Identify the risks to the secondary/third party participants and state how you are mitigating these risks.
- Mitigating risks can include: providing resources, not collecting IDs, having a counselor at the ready, providing training and skill development, addressing vulnerable status of current psychological state.

Updated 4/18/18
Language to Use in Discussing this Research in the Informed Consent Form

Always State: In the Consent Form, in the Confidentiality Section: The information in the study records will be kept confidential to the full extent allowed by law. Data will be stored securely in ________. No reference will be made in oral or written reports which could link you to the study. Your directly or indirectly identifiable data will not be shared with your current counselor. The researchers may share your data with other researchers at the CCERC for wellness and counseling related research performed by the CCERC.

Always State: In the Consent Form, add a section “If you are a CCERC client”: Your participation in this research is not a requirement for you. You do not have to be in this study in order to receive the services that CCERC has offered you. Your choice to participate in this study or not participate in this study will not influence any services you receive from the CCERC and you may choose to stop participating at any time without penalty.

Select the Relevant Language for the Consent Form Section “What will happen if you take part in the study?” You may select multiple statements if you have multiple data collection methods:

○ As a normal part of your counseling experience, you completed/will complete ________. I would like to use information from this _____ as data for research purposes.

○ As a normal part of your counseling experience and as a part of a past research project, you completed ________ I would like to use this information and data from this _____ as data for this research project.

○ As a part of this research project, I would like to collect information from you to use as data for research. I would like to collect information about _______. I will collect this information through _____. The information collected from you in this way is for research and it is not a normal part of your counseling experiences.

Requesting a Waiver of Consent: If you as a researcher want to access existing identifiable information from the CCERC and/or access existing data from research done at the CCERC, you can request a waiver of consent. A waiver of consent allows you to access this information/data for your current research without getting consent from participants that the information/data is about.

If you want to request this, your research must meet certain criteria and in your IRB application you must state that your study meets this criteria and how it meets this criteria. In the IRB application on the Consent tab, you will answer “yes” to applying for a waiver of consent. Then, a new box will pop up. In that box address the following points:

● This research involves no more than minimal risk to participants in this study because the probability and magnitude of harm or discomfort anticipated in this research is not greater than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests.

● The waiver will not adversely affect the rights and welfare of the participants because _______.
  ○ State here how HIPAA regulations do not apply.
  ○ State the nature of the data collection and how that will not affect the participant's welfare

● This research could not practicably be carried out without the waiver because _______.
  ○ List reasons that you CANNOT get consent. Examples include, some clients no longer attend the CCERC and have you do not have current contact information. Another example is that the data from other research or the information from the paperwork at the CCERC is not identifiable.

Commented [J19]: This will have to be stated on a case by case basis. Their data should not be shared with their counselor while they are seeing their counselor, however if their counselor will need to access the data after treatment, then this section will be augmented to meet the needs of the study.