The Community Counseling, Education, and Research Center (CCERC) and the NC State University IRB Guidance

CCERC (opens in a new window) provides low cost/free counseling services to the community while also serving to provide graduate students with preprofessional practicum training **and** an environment to conduct research on wellness and counseling issues. As such, it may be possible for IRB applications to arise in this context, either as part of a proposal for primary data collection, secondary data access and use, or both.

Frameworks of Understanding

It is the NC State University IRB's understanding that the following is true about the CCERC as an institution and its processes:

- CCERC is not a HIPAA covered entity because whilst the CCERC is a healthcare provider, they do not "electronically transmit any health information in connection with transactions for which the U.S. Department of Health and Human Services (DHHS) has adopted HIPAA Privacy Rule standards" (opens in a new window)

- HIPAA rules and regulations are not applied to CCERC client data, however, CCERC expects HIPAA guidelines for privacy and protection of client information to be followed for all CCERC data.

- CCERC data is classified as "red" (highly sensitive) data unless the data that the CCERC shares can be considered a "limited dataset" under HIPAA. If the CCERC data is a limited data set, the NC State IRB will treat CCERC data as "yellow" (moderately sensitive) in review of the IRB application.

- All CCERC counselors are graduate students supervised in their role by doctoral students and Dr. Marc Grimmett.

- CCERC clients are informed about CCERC as a research site at three different points:

    1. During the initial screening to determine if the CCERC is appropriate for the client. CCERC informs all potential clients that CCERC is an educational and research facility. Becoming a CCERC client means that the client will automatically be involved in CCERC educational endeavors, but they are not required to participate in research to be a CCERC client.

    2. During the initial counseling session with the client's assigned counselor. Research is briefly mentioned as a component of the work that the CCERC does. Specific studies and/or participating in a specific study is not discussed.

    3. When a CCERC client is being recruited and consented for an IRB

approved study. The client's CCERC counselor does not recruit them for the specific research study being conducted; the primary investigator or another member of the research team will discuss the specific study with the CCERC client and, if appropriate, consent them to participate in the research being conducted. This aids in diminishing undue influence.

- Some CCERC counselors and managers have access to *only* their own clients' information while other CCERC counselors and mangers have access to *all* client information. It is important to remember that even if a researcher has access to client information due to their role at CCERC, they must still seek gatekeeper permission and individual client permission to use that client information as data for research ***especially*** if the client information to be accessed for research purposes is from one's own clients.

- Several types of client information arise within the CCERC context:

1. Information that is part of normal counseling activities, such as a counseling intake form that all CCERC clients complete and is never collected with the intent to be used for research.
    a. If researchers wish to access this data for research purposes, they will file an application requesting use of secondary data (Word document).
    b. Use of identifiable secondary data is not eligible for exemption unless it can fit into one of the below research categories:
        i. The identifiable data that was once private is now publicly available OR
        ii. The identifiable data is recorded in such a manner that client identities are not readily ascertainable to anyone, including members of the research team OR
        iii. The identities are readily ascertainable but the research qualifies for the NC State University IRB's special FLEX exemption category.

2. Information that is part of normal counseling activities but is also intended to be used as part of a research study, such as the addition and implementation of an existing and validated psychological measure.
    a. If researchers wish to access this data for research purposes, they will file an application requesting use of future secondary data (Word document).
    b. Use of identifiable secondary data is not eligible for exemption unless it is private data that is now public OR the data is recorded in such a manner that client identities are not readily ascertainable, OR if the project is eligible for the NC FLEX exemption category.

3. Information that is solely collected with the intention to be used for research purposes, such as surveys/interviews/novel psychological measures, use of a mobile software application or wearable (such as a heart rate variability

monitor or app), and this use is not part of the CCERC client's normal counseling activities.

a. Any activities done as part of a research study requires prior IRB review and approval and the researchers IRB application will propose primary data collection.
b. IRB review level will depend on the research procedures proposed and the IRB's risk assessment.

- Depending on what data a research team wishes to collect and/or access, a data and access security plan may be necessary. Please review the NCSU OIT Data Classification Table (Google Sheet) to determine what sensitivity level(s) the research data will be.
    - If red or purple data will be collected or accessed for research purposes, a data and access security plan is required to be uploaded to the IRB application's supporting documentation as part of the IRB review process.
    - Some examples of red and purple level data salient to the CCERC include:
        - Identifiable health information (e.g., diagnoses, chart notes, process notes) – Red
        - Identifiable psychological alert – Red
        - Identifiable student behavioral case management/CARES report – Red
        - Identifiable client appointment records – Red
        - Some personal information of minors: home address, data of birth, email address, phone number, social media or online presence data – Red
        - Social security number – Purple
        - Passport number or immigration ID – Purple

Information that must be included in all CCERC IRB applications

- Include the following statement verbatim: "CCERC is not a HIPAA covered entity, so HIPAA rules and regulations do not apply to this study."

- Disclose and discuss
    - What relationship(s) YOU have with the CCERC clients that you plan to recruit for the research
    - How you plan to mitigate any risk of coercion/undue influence related to their recruitment, consent, and enrollment into research.

- Discuss how consent will be sought and documented by the research team. If consent will not be sought, the application must request and meet the criteria for a waiver of consent or be eligible for exemption.

- To meet the criteria for a waiver of consent, researchers must document and

explain how:

1. The research is minimal risk to participants because <provide justification, e.g., the probability and magnitude of harm or discomfort anticipated for the participants is not greater than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests>.

2. Waiving participants' right to consent will not negatively affect participants' rights or welfare because <insert information on why participants rights and welfare will not be harmed due to how you've designed the research and how you plan to use the research data>.

3. The research is not practicable without a waiver of consent because <insert information on why you cannot possibly get participant consent, e.g., no contact information for former CCERC, or the CCERC data you wish to access is not identifiable to any member of the research team and you will not seek to re-identify or contact anyone in the data set, etc.>, and

4. (Only use and complete this fill-in-the-blank *if applicable)* The research is only practicable with the use of identifiable/re-identifiable data because <insert information on why you must use identifiable/re-identifiable data especially when you are not seeking consent to use that data for research>.

- Include and complete one of the following fill-in-the blanks when describing your research procedures:

    - As a normal part of the CCERC counseling experience, clients complete <insert information about what they complete>. I/We would like to use this information as data for research purposes. I have access to this information because <insert information>. The information is currently identifiable but I/we <choose one: will or will not> record identifiers with the information as I/we compile the information into a research dataset. I/We will access this information by <insert information>. I/We will transfer it by <insert information>. I/We will store this information by <insert information>. I/We <choose one: am/are or am/are not> able to re-identify research participants once the information has been compiled into a data set for research purposes.

    - As a normal part of the counseling experience and as part of a past human subjects research protocol approved by an IRB, clients completed <insert information>. I/We would like to use this information and research data for research purposes. The counseling information is currently identifiable but I/we <choose one: will or will not> record identifiers with the information as I/we compile the information into my/our research dataset. I/We <choose one: do or do not> have access to the prior

research protocol data. The prior research protocol data <choose one statement: is identifiable and participants gave broad consent OR is not identifiable and I/we will not seek to reidentify or contact those participants>. I/We will access this information by <insert information>. I/We will transfer it by <insert information>. I/We will store this information by <insert information>. I/We <choose one: am/are or am/are not> able to re-identify research participants once the information has been compiled into a data set for research purposes.

- As a part of a past research project, CCERC participants provided researchers with the following data: <insert information>. I/We would like to use that data as data for my/our proposed research project. I/We <choose one: do or do not> currently have access to this data because <provide justification>. The data <choose one: is or is not> identifiable. I/We will access this information by <insert information>. I/We will transfer it by <insert information>. I/We will store this information by <insert information>. I/We <choose one: am/are or am/are not> able to re-identify research participants once the information has been compiled into a data set for research purposes.

- As a part of this proposed research study only, I/we would like to collect data from participants who are also clients at the CCERC. The data I/we would like to collect includes <insert information>. I/We will collect this data through <insert information> means. The data points collected from participants include <insert information>. The data collected from the participants for this research is not a normal part of their CCERC counseling processes.

- If a "data and access security plan" (DASP) is uploaded to the IRB application's supporting documentation, leave the data security tab of the non-exempt IRB application blank OR note on the data management section of the exemption application form to see the uploaded DASP.
  - Please note: At the date of this guidance's publication, CCERC data is classified as red level data unless the data shared can be considered a limited dataset under HIPAA, where it will then be treated as yellow level data by the IRB.
  - All red level data is required to have a DASP uploaded for the IRB to review and the CCERC expects that HIPAA privacy standards are followed when handling CCERC data, despite not being subject to HIPAA.

- If a data and access security plan (DASP) is not uploaded to the IRB application's supporting documentation, the data security tab of the eIRB application must be completed for non-exempt application or the identifiers and data management section of the exemption application form must be completed. Either way, the following content must be included:

- The direct and indirect identifiers accessed/collected of primary participants

- The direct and indirect identifiers accessed/collected of third-party participants

- Why each direct and indirect identifier is needed to answer the research question

- When each identifier will be removed from the research data set, when in the research process, and how it will be done. The NC State IRB expects researchers to discard all direct identifiers wherever possible. If a researcher plans to retain indirect identifiers, state that and how participants will be protected from being re-identified through responsible data use (e.g., aggregation, Ns of 3 or greater, composite client qualitative case studies, etc.).

- What research links exist, why they're needed to answer the research question, and when the links will be destroyed. A link includes identifiable participant information within the research data, such as master list/crosswalk, recordings (audio/video/screen), photography of participants, secondary data that include identifiers, etc.

- What types of devices (NCSU managed, personal, or both) that will access the data. You must consider all members of the research team, including the faculty advisor for a student protocol.
  - If personal devices will be used, detail established data protection process that will be employed, such as regularly updated software, hardware, malware protection, etc.

- For digital research information, say that you will:
  - Use password protection for all files containing research data
  - Use password protection for all devices housing research data
  - Use 2 Factor Authentication for accessing research data
  - Use VPN when using the internet to transfer, access, upload, or download to research data files and folders
  - Use NC State licensed platforms such as Google Drive, Google Gemini, Zoom Pro, Fireflies.AI, Qualtrics, RedCap accounts where appropriate
  - Use of encryption for data files with direct identifiers, containing master list/crosswalks/codes linked to participant IDs, or files with highly sensitive ("red") or ultra-sensitive ("purple") data

- For hard copy research data:
  - Discuss if the hard copy research data has direct participant identifiers on it or if those are removed and how

        - Discuss where the hard copy research data is stored and how it is protected (locked in drawer? locked in an office? badge scan to get in building?)
        - Discuss the master list/crosswalk if it is a hard copy - discuss where it is stored and how it is kept separate from the data files
        - Discuss how the hardcopy data and hardcopy master list/crosswalk are transferred if transferred (from the moment it is collected or generated to when it is destroyed) - please do not transfer them together
        - Discuss who can access the hard copy research data and why
        - Discuss how and when you will securely destroy your hard copy research data

    - Discuss when and how the research data is transferred.
        - For digital data, how it travels from one platform to another and between devices (you will likely transfer data several times throughout the course of the research project). For example, recording an interview either within the NC State managed Zoom application or to a local drive (not cloud storage) and then transferred to the NC State managed Google drive for data cleaning and analysis.
        - For hard copy data, how the data is transferred from the data collection point to the researcher's possession and then into a location to facilitate data cleaning and analysis.

    - Discuss who will have access to research data and why. You must articulate the access all members of the research team will have, including the faculty advisor, and any third parties (e.g., mobile software application and wearable developers, consultants, transcriptionists, etc.)

    - Discuss when the research data will have direct IDs stripped if your data will always be re-identifiable (e.g., qualitative interviews, surveys with detailed demographics, secondary CCERC data, etc.)

    - Discuss when the research data will be securely destroyed and how it will be destroyed

    - Discussion of any recording processes including what is captured, how it is captured, where the recording will be transferred, stored, and analyzed. Please note: Video recording is considered by federal law as inherently more identifiable than audio-only recording. Therefore, if you wish to video record you need to provide a justification in the IRB application for why audio recording isn't sufficient to answer your research question.

- When identifying and discussing the research risks to primary and third-party participants, you can use and complete the following fill-in-the-blanks (one

paragraph per identified risk):

- The research risk to primary participants is <identify risk, e.g., re-identification, etc.>. The probability of this risk occurring is <select one: highly probable, somewhat probable, unlikely, highly unlikely>. The severity of impact if this risk were to occur would be <select one: life-threatening/disabling, severe and undesirable, moderate, mild>. If the risk were to occur, the harm would be <select one: reversible or irreversible> and duration of harm would be <provide information>. The research risk will be mitigated by <insert mitigation strategies that will be employed, e.g., how vulnerable psychological states will be identified and dealt with in a compassionate and ethical manner in the research design, offering a warm handoff to a licensed professional that can provide aftercare, providing community resources for themes explored/discussed with participants, not collecting identifiers of participants especially if there are mandatory reporting responsibilities, providing training and skill development to participants, etc.>.

- The research risk to third party participants is <identify risk, e.g., re-identification, reputational harm, etc.>. The probability of this risk occurring is <select one: highly probable, somewhat probable, unlikely, highly unlikely>. The severity of impact if this risk were to occur would be <select one: life-threatening/disabling, severe and undesirable, moderate, mild>. If the risk were to occur, the harm would be <select one: reversible or irreversible> and duration of harm would be <provide information>. The research risk will be mitigated by <insert mitigation strategies that will be employed>.

Information to include in a participant consent form that uses CCERC data

- Select and include the most appropriate paragraph(s) below in the "What will you do if you participate in this research" section of the consent form and complete the fill-in-the-blanks:

  - As a normal part of your treatment at CCERC, you <choose one: completed OR will complete> <list data sources and measures you wish to access for research purposes, such as intake form, DSM-5 assessment measures but use a plain language term that clients will understand, etc.>. I/We would like to use this data for research.

  - As a normal part of your treatment at CCERC and as part of another research study, you <choose one: completed OR will complete> <list data sources and measures you wish to access for research purposes, such as intake form, DSM-5 assessment measures but use a plain language term that clients will understand, etc.>. I/We would like to use this data for research.

- As a part of this study, I/we would like to collect the following information from you for this study: <list data you want to collect for research purposes, such as intake form, DSM-5 assessment measures but use a plain language term that clients will understand, etc.>. <Insert details about how this data will be collected from the participants – e.g., online during an interview or survey, etc.> The information that we will collect from you is not part of your normal CCERC treatment.

- Include the following statement verbatim in the consent form
  "The research team will share your data with other CCERC researchers for the purposes of CCERC wellness and counseling related operations."

- Fill-in-the-blanks and create a <u>new</u> section in the informed consent form
  Sharing Research Data with your CCERC Counselor:
  Your research data will not be shared with your current CCERC counselor <insert if appropriate: unless <insert circumstances in which the research data might be shared with the counselor – research measure indicating suicidal ideation that necessitates a warm handoff, research data will be available to the counselor once the client's CCERC services are terminated, etc.>.

- Include the following paragraph verbatim in the consent form:
  If you are a CCERC client:
  Your research participation is neither a requirement nor expectation of CCERC counseling services. Your choice of whether or not to participate in the research study will not affect the CCERC services offered or provided to you. You can choose to stop participating in the research study at any time for any reason and without any penalty to you.