

#XXXXX - NAME OF PROTOCOL

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Full Board	Approved	Feb 02, 2024	--
Expiration Date	Initial Approval Date	Initial Review Type	
Feb 01, 2025	Feb 02, 2024	Full Board	

Feedback

Approval Comment

Dear Dr. NAME,

The CCSU IRB has reviewed your revised protocol titled "NAME OF PROTOCOL" (#XXXXX) and deemed it approved via full committee review. The approval is good for one year from the date of this message, and your project is subject to continuing review. This email serves as documentation that your study has received approval status with the CCSU Institutional Review Board. You may begin your research.

Any future changes or modifications to the protocol must be submitted for review and approval by the IRB before implementation, except for changes made to avoid immediate harm to subjects or others.

Thank you for submitting your research to the IRB.

Sincerely,

Dr. Jeremy Visone
IRB Chair

General Information

The Institutional Review Board (IRB) is the federally mandated body established to protect human participants in research conducted by CCSU faculty, students, and staff. The role of the IRB is to facilitate, review, and approve university-sponsored research to ensure that the rights and welfare of human participants are protected.

If you are unsure if your study is Human Subject Research, please consult [this page](#).

Principal Investigator

NAME

Lead Unit

Criminology & Criminal Justice

Title

NAME OF PROTOCOL

Original Protocol Number

Optional if previously submitted to CCSU's IRB

General Questionnaire

Are there researchers from other institutions who will be directly involved in the research or will have access to the raw data?

No, this research is NOT joint project with researchers unaffiliated with CCSU.

If you will be recruiting participants from a physical or virtual site other than CCSU, will you need permission or assistance regarding your recruitment procedures? **If so, you may need to procure a gatekeeper letter.**

Yes, this arrangement is limited to recruiting participants from an external site

Describe the plans to recruit participants or to obtain data from an institution other than CCSU. This project does not involve interaction with human participants. However, data for this study will be derived from the case files of former clients at a community justice program for justice-involved women. The program is operated by The AGENCY, Inc, which is a non-profit agency that provides a variety of services for justice-involved individuals.

Please attach a signed gatekeeper letter that fully describes what is being asked of the gatekeeper. If a gatekeeper letter is not available, please indicate the status for procuring the letter. [GATEKEEPER LETTER.DOCX](#)

CCSU Personnel

List the names of all CCSU individuals (faculty, staff, and students) who are authorized to conduct procedures involving human subjects under this proposal, and identify key personnel roles (e.g., co-investigators).

Note: You must update each person listed to add their CITI Certificate.

Instructions to add or update external person or student

- Click "+ Add Info" below to add your first person.
- Click "+ Add Line" to insert additional person.
- Select the [Edit Pencil](#) next to a person to edit their info and add their CITI Certificate.

Person

NAME

Home Unit

Criminology & Criminal Justice

Email Address

EMAIL@ccsu.edu

Phone

PHONE

Researcher Role

Principal Investigator / Faculty Advisor

Permissions

Full Access

Is this person a faculty/staff member, a graduate student, or an undergraduate student?

Faculty/Staff Member

CITI Ethics Training Completion Date

January 26, 2020

CITI Certificate

[CITI CERTIFICcate .DOCX](#)

External Organization

List the names of all External Collaborators under this proposal and identify type of collaborator (External Collaborator Type 1 or External Collaborator Type 2)

Instructions to add or update external person

- Click "[+ Add Info](#)" below to add your first person.
- Click "[+ Add Line](#)" to insert additional person.
- Select the [Edit Pencil](#) next to a person to edit or update.

Contact Full Name

NAME

Institution/Organization/Company

The AGENCY, Inc.

Researcher Role

External Collaborator Type 2

Research Overview

Research Purpose

Faculty/Staff Research

I will not begin any aspects of this research until IRB approval is granted.

I agree

Proposed start date of research activities

March 1, 2024

In 300 to 500 words, please provide a brief summary of the proposed research, including (a) the study hypothesis or research question, (b) objectives and rationale for the study (cite relevant published research), and (c) a summary of the proposed methods (design, recruitment procedures, population to be sampled, sample size, data collection methods).

Overview: Purpose and Objectives of the Study: The purpose of this proposed project is to develop a scale to assess criminogenic thinking in justice-involved women. Criminogenic thinking (also referred to as criminal thinking) is commonly defined as thinking patterns that facilitate antisocial/self-destructive behavior (Walters, 1995) and is a leading risk factor for reoffending (Bonta & Andrews, 2017). Providing interventions that address this risk factor are important in the process of breaking the “revolving door” of justice-system involvement (NAME, 2018). While criminogenic thinking is routinely included in the risk assessment process for case management/supervision of justice-involved clients who are transitioning to the community from incarceration or serving their sentence in the community on probation, existing tools have been largely or solely developed on justice-involved men. Nonetheless, criminogenic thinking tools are utilized with justice-involved women under the assumption that criminogenic thinking operates similarly across gender. However, an emerging body of literature has suggested there are gender differences in criminogenic thinking (Solinas-Saunders & Stacer, 2022; Vaske, Gehring, & Lovins, 2016), and a recent pilot study I co-authored found gender-specific criminogenic thinking scales may predict outcomes for justice-involved men and women better than an existing gender-neutral scale (NAME, 2021). This proposed project seeks to build on the pilot study and assess the reliability and validity of a criminogenic thinking scale for justice-involved women. This project will involve a collaboration with The AGENCY, Inc. The AGENCY is a nonprofit agency that operates a number of facilities for justice-involved clients, including a community justice program specifically for justice-involved women called PROGRAM. The criminogenic thinking scale and client outcome data for this project will be obtained from the PROGRAM. One of the tools that I co-developed is the Criminogenic Thinking Profile (CTP; NAME, 2012). This criminogenic thinking scale is currently used in the PROGRAM, and items from the scale were used to identify the gender-specific criminogenic thinking scales in the pilot study mentioned above (NAME, 2021).

Overview: Proposed Methodology The methodology for this proposal study does not

involve direct contact with human participants. Instead data for this study will be derived from the case files of former clients at a community justice program for justice-involved women. In order to conduct this project, I will be accessing the hard copies (paper copies) of the closed case files of all clients who have attended the PROGRAM because the specific CTP item-level information needed to do the research is not entered into the program's electronic file system. There are likely going to be about 300-400 closed cases for analysis. Data collection will occur on-site. I will create a unique electronic database specifically for this project that will include CTP items and other assessment data, client outcomes, and demographic information from the program. I will not be collecting client case file numbers or other personally identifying information so the database will be fully deidentified to maximize client confidentiality. I have used a similar methodology in several prior IRB approved studies that involved data collection of closed files at programs for justice-involved clients.

Funding Sources

Please indicate how this study is funded.

This protocol is not funded

Human Subjects

Describe the expected demographics for the proposed research sample.

All of the data obtained from this project will be from adult women. It is expected that the data set will be ethnically diverse. Information about their sexual orientation will not be obtained.

The categories below indicate populations that are considered vulnerable to coercion or undue influence. Check each category that is applicable to your recruitment of participants.

Prisoners

Please explain why the category or categories you selected are necessary for the completion of this research project.

This project is specifically seeking to develop a criminogenic thinking scale for justice-involved women. This is an area of need in the case management/supervision of justice-involved women as existing scales in this area have been developed for justice-involved men.

Describe any relationship that members of the research team might have with the prospective participants.

N/A- this project does not involve any active recruitment of participants. All data will derived from closed case files.

Do you plan to recruit students through a class that you or another one of the investigators instruct?

No

Describe the proposed recruitment procedures in detail, and attach all recruitment materials.

N/A: No participants will be recruited for this project

Attach Recruitment Materials

Email wording, flyers, etc.

[THIS STUDY DOES NOT INVOLVE RECRUITMENT MATERIALS.DOCX](#)

Informative Name

Describe the criteria for participant inclusion and any screening procedures of prospective participants. If any inclusion/exclusion criteria are based on demographics, please explain the rationale.

N/A: No participants will be recruited for this project

Describe the minimum number of eligible participants needed for the proposed research and/or the anticipated number of participants who will make up your sample.

It is anticipated that the sample size will be between 300-400 cases.

Describe any compensation of participants or indicate if there is no compensation. SONA credits are considered compensation. If participants are compensated, provide a detailed explanation of how compensation would be affected should a participant not complete a task or withdraw from the research activity.

N/A

Describe the research procedures. Procedures could include interviews, self-administered surveys or questionnaires, focus groups, psychometric or educational testing, or follow-up for longitudinal studies. Procedures could also include web-based data collection, analyzing data obtained from institutional records, or analyzing secondary data sources both publicly available or with limited access. Attach a copy of all materials that will be used for collecting data. Data from closed case files will be entered into a unique electronic database created for this study. Data from closed case files will be entered into a unique electronic database created for this study. This will entail: 1) Items from the Criminogenic Thinking Profile (CTP, which is numeric data), 2) demographic information: age, ethnicity, years of education, and marital status (a blend of numeric and qualitative data). 3) risk assessment data- this is administered at intake (along with the CTP) and at discharge, and assesses client's risks and needs in areas such as antisocial behavior, employment, substance use, peers/relationships; the information is used by the program to gauge client's risk for future justice issues and provide case managers with insight into where they might best intervene to produce a positive outcome for the client. This portion of the client record is numeric with client received numeric scores in each area. 4) program outcome data- this portion of the client record contains information on the nature of the client's discharge from the facility, length of stay, and issues that came up during the program (e.g., program violations). This data is qualitative and will have to be numerically coded by myself for analysis. No personally identifying information will be entered.

Attach Data Collection Materials

*** Please note that most online survey questions cannot be set to "Required"**

Surveys, interview scripts, etc.

[IRB REVISED.DOCX](#)

Informative Name

Describe where and when the data collection will take place.

Data collection will occur at The AGENCY, Inc. as early as March 2024

Describe the number of times participants will be asked to provide data and how long each data collection session will last.

N/A

List all study team members who will administer the proposed research procedures, and describe the specific activities that each person will be responsible for.

Instructions to add or update members

- Click "+ Add Info" below to add your first person.
- Click "+ Add Line" to insert additional person.
- Select the [Edit Pencil](#) next to a person to edit or update.

Is this person affiliated with CCSU?

Yes, this person is affiliated with CCSU

CCSU Personnel

NAME

Describe the specific activities that this person will be responsible for.

Will any audio or video recording occur as part of this study?

No

Will any deception or incomplete disclosure of informed consent be used in this study?

No

Describe all potential risks and discomforts associated with participation whether physical, psychological, economic, or social. Examples include pain, distress, invasion of privacy, embarrassment, breach of confidentiality, and minimal or everyday risks such as the time spent in the study. Most studies incur some type of risk to participants.

This study does not involve interaction with human participants.

Describe the measures that will be implemented to minimize risks and discomforts to participants. Risk mitigation can include practices such as informing subjects of support resources, providing thorough consent processes, protection of data, etc.

No personally identifying information from participants will be recorded.

Describe any potential benefits that the individual participants might experience *as a result of participating in this study*. If there are no direct benefits to participants, this should be stated. Benefits beyond those at the individual level (such as benefits to the community, society, scientific community) can also be included..

NOTE: Compensation/payment (e.g., money, gift cards, SONA credit) for participation is not considered a benefit.

Women make up an increasing portion of the justice-involved population. Failing to adequately assess relevant risk factors negatively impacts their trajectories and public safety. In order to reduce the cycle of reoffending and continued justice-involvement, the thinking patterns that facilitate antisocial/self-destructive behaviors must be addressed. This can be effectively accomplished with reliable and valid tools for this endeavor. This proposed project is attempting to help address a gap that currently exists in the assessment of criminogenic thinking.

Describe what identifiable data will be obtained from the participants. **NOTE:** Audio, photo, and video recordings are generally considered identifiable unless distinguishing features are masked. Other examples of identifiable data are names, social security numbers, email addresses, account numbers, phone numbers, and date of birth.

No identifiable data will be obtained. No demographic data beyond age and race will be obtained.

Describe how confidentiality of participant information will be maintained and where and for how long research data will be stored.

Data will be stored in a password protected electronic file. Only the PI will have access to the file.

Informed Consent Process

Are you requesting a waiver of documentation of informed consent because you believe your study qualifies for a consent waiver based on the limited scenarios outlined in the federal regulations found at 45 CFR 46.116(f)(3):

In order for the IRB to waive or alter consent as described in this subsection, the following must be true:

1. The research involves no more than minimal risk to the participants;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
5. Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

Yes

Check the box next to the appropriate condition(s) below to justify this waiver request.

The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

Check the box(es) next to the informed consent process option for this proposed research, and attach a copy of the consent form, script, or information sheet for the option.

N/A

Attach Consent Materials

Attachments

Attach all supplemental materials here that are relevant to your proposed research.

Investigator Certifications

Potential Conflicts of Interest: Potential conflicts of interest exist when there are actual or perceived conflicting interests between an individual's private interests and his or her professional obligations to CCSU such that an independent observer might reasonably question whether the individual's professional actions or decisions may be compromised by considerations of personal gain, financial or otherwise.

Each investigator will disclose all significant financial interests: (I) that would reasonably appear to be affected by the research, educational, or service activities/outcomes, (II) that would reasonably appear to be affected by the funding or proposed funding from an external sponsor, or (III) in entities whose financial interests would reasonably appear to be affected by such activities.

I have read the above text, and I certify that I have no conflicts to disclose.

Scientific Misconduct Statement: CCSU does not tolerate scientific misconduct as defined by the Public Health Service (PHS): "Misconduct in science is defined as (1) plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research."

CCSU's Policy on Misconduct in Research and Scholarship can be found [here](#).

I have read the above text and I am familiar with CCSU's policy on scientific misconduct. Everything I have reported on this form is accurate and true to the best of my knowledge. I also understand that deception on this form may result in the rejection of my application and/or the revocation of IRB approval for this project.

Administrative Details Form

Determinations

Study Review Type

Full Board

Study Status
