TEACHERS COLLEGE
COLUMBIA UNIVERSITY
Institutional Review Board
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212-678-4105 | RH 13 | IRB@tc.edu | tc.edu/IRB

IRB APPLICATION TEMPLATE

SECTION I: PROTOCOL DESCRIPTION

1. Study Title.

Perceptions of Mental Health, Treatment, and Recovery

2. Principal Investigator (*person conducting the research*). Professional title and email.

Primary Investigator: Dr. Anna Freud, Ph.D., Primary Researcher, A.Freud@tc.columbia.edu
Co-Investigator: Dr. Rosa Klein, R.Klein@tc.columbia.edu

If there is more than one researcher on the project, include all names here.

If it helpful for framing your study, you can include 1-2 references.

3. Write an original, brief, non-technical description of the purpose of your research. Include a narrative that explains the major parts of your study and how the data will advance your research hypothesis or question. ***NOTE:*** *This section should be easy to read for someone not familiar with your academic discipline. Provide relevant background information and scientific justification for your study. You may provide citations as necessary. Please adhere to a 350-word limit (not including citations).*

Mental health recovery spurs psychoeducation curriculum development (Peebles, Mabe, Fenley, Buckley, Bruce, Narasimhan, Frinks & Williams, 2009). In this study, we aim to understand how therapists use psychoeducation to describe their perspectives in multiple contexts (online, patient-therapist interactions, interviews, etc.). Specifically, we are interested in psychoeducation used to describe depression and how they may impact how listeners perceive one's mental state or the process of recovery or treatment. We aim to investigate whether a mental health psychoeducation may undermine motivation to seek help (or continue treatment).

Some information that you would include in your protocol description may not be applicable to the consent form. For example, researchers must describe their intentions for the study to the IRB. However, this kind of statement would likely not be included in the consent form as it may bias participant answers. Visit TC IRB's website/How to Submit/Guides/Writing for the IRB for further tips.

This is a four-part study.

- PART 1 PUBLIC DATA: Explore web-based and public data documenting the ways popular media and targeted advertisings portray mental health (in text and visually).

This part of the protocol deals specifically with existing data. If the protocol had only included Parts 1 and 2, it would fall under Exempt Category 4 – Existing Data. Visit TC IRB's website/How to Submit/Guides/Existing Data for more information.

- PART 2 EXISTING DATA: Explore psychoeducational descriptions to document how topics of mental health and wellness are taught in schools.

- PART 3 ANONYMOUS ONLINE SURVEYS: We will survey adults competent to consent about their impressions of psychoeducation of mental health. The purpose of this part is to determine whether exposure to psychoeducation about mental health can impact one's motivation to confront a challenging problem. This study will include vignettes of fictitious mental health patients and mental health psychoeducation. We have three populations of interest for this portion of the study:

Qualtrics is recommended for survey data collection and is available through Teachers College. Researchers should not use SurveyMonkey as it is not available through MyTC. Amazon Mechanical Turk (MTurk) is a way to collect participant data online.

The writer can upload their survey and vignettes with their protocol application in TC Mentor IRB.

  - MTurk – We plan to collect anonymous survey data concerning people's impression of mental health.
  - Persons with Depression – We plan to collect anonymous survey data from people who self-identify as currently depressed or depressed within the last 6 months.
  - Therapists – We plan to collect anonymous survey data from people who self-identify as practicing therapists.

- PART 4 INTERVIEWS AND FOCUS GROUPS: Using a population of convenience and snowball sampling, we plan to individually interview and conduct focus group sessions with the public and trained therapists to gauge their impressions of mental health psychoeducation. We will audio record these interviews however; we will not record identifiers after the audio recording is transcribed. For the focus group sessions, participants' identity will be known to others, and the researchers cannot guarantee that others in these groups will respect the confidentiality of the group. We will ask all focus group attendees to keep all comments made during the focus group confidential and not discuss what happened during the focus group outside the meeting.

TC IRB is concerned with the protection of participants. This type of activity may impact a participant's privacy and confidentiality. The researcher should openly acknowledge any risks and explain ways to mitigate the risk.

4. State your research question(s). Your planned research protocol should be one that can realistically address your research question(s).
   - How does classroom psychoeducation portray mental in popular media?
   - How is psychoeducation about mental health created?

5. Provide the inclusion criteria for the participant population (*e.g., by gender, class, race, occupation, or age*). Provide a rationale for selecting this population for research purposes.

If a study has strict exclusion criteria, researchers must justify their choice to include this criterion. Only adults competent to consent can be given consent forms.

This study will not exclude participants by gender, class, race, or occupation. However, we plan to only recruit adults for this study (over 18 year old) and for one portion of the study we seek to recruit mental health professionals (e.g., therapists).

6. Federal guidelines state that research cannot exclude any classes of participants without scientific justification. Indicate who will be excluded from your study and why (*e.g., persons under 18 years of age*).

Persons under 18 years of age will be excluded from the study as they are not able to consent to participate.

7. Provide the maximum number of participants you plan to enroll for each participant population and justify the sample size.

1,000 online surveys of adults
50 interviews and/or focus group sessions of adults

It is recommended that researchers overestimate the number of participants they will be able to recruit for their study, within reason. Recruiting below the maximum number of participants will not affect your protocol. However, if researchers seek to recruit more than the stated number of participants on an IRB protocol, they must submit a modification to raise the maximum number of participants. Recruiting more than your maximum number of participants can result in a protocol deviation.

8. Describe your recruitment methods. **How** and **where** will participants be recruited (*e.g., flyers, announcements, word-of-mouth, snowballing, etc.*)? Submit a copy of all recruitment letters, scripts, emails, flyers, or social media posts you plan to use to recruit participants for your study as separate documents with your application. You will need to include your IRB Protocol number (*e.g., 18-123*) on all recruitment materials, including announcements, online posts, and email text, etc.

PART 1 PUBLIC DATA: No recruitment, public data.

PART 2 EXISTING DATA: No recruitment, existing data.

PART 3 ANONYMOUS SURVEYS:

These sections match those described in question 3. When dealing with multi-part studies, it is helpful to the reviewers if you follow a consistent pattern so that activities, participants, and parts can be easily matched.

Recruitment materials should be uploaded with your protocol application to TC Mentor IRB as separate files.

- Mturk – Through Amazon's Mechanical Turk.
- Persons with Depression – Flyers, social media (Twitter, Facebook, etc.), population of convenience, and snowball sampling.

Population of convenience is a type of non-probability sampling that involves a sample being drawn from population easily accessible to the researcher. This type of sample usually does not produce results with high external validity and is often used for pilot studies. For information on recruitment visit TC IRB's website/How to Submit/Guides and Resources.

- Therapists – Flyers, social media (Twitter, Facebook, etc.), population of convenience, and snowball sampling.

Snowball sampling occurs when a research participant recruits other participants for a test or study. This method is usually used when potential participants are difficult to find.

PART 4 INTERVIEWS AND FOCUS GROUPS: Flyers, social media (Twitter, Facebook, etc.), population of convenience, and snowball sampling.

9. Describe the location, setting, and timing of data collection (*e.g., face-to-face interview at a mutually convenient location, at the start of the semester*). Include the state, city, school district, etc. ***Note:*** *If you are recruiting participants from institutions other than Teachers College include a site permission form (template located in Mentor/Documentation) or a pending IRB approval from the institution(s) with this submission. If you are conducting any part of your research within NYC DEPARTMENT OF EDUCATION (DOE) Schools, it is required that you receive approval from Teachers College IRB prior to submitting your application to the Department of Education IRB (DOE IRB).*

PART 1 PUBLIC DATA: No specific location, public data.

PART 2 EXISTING DATA: No specific location, existing data.

PART 3 ANONYMOUS ONLINE SURVEYS:

- MTurk – Online.
- Persons who self-identify as depressed – Online.
- Therapists – Online.

PART 4 INTERVIEWS AND FOCUS GROUPS: Audio recorded, face-to-face, in person interviews will occur at a time and place that is convenient for the participant.

SECTION II: DESCRIPTION OF STUDY ACTIVITIES & PROCEDURES

10. List what your participants will be asked to do during your study and your data collection process (*e.g., fill out a 25-question, closed-ended, paper survey*). ***Note:*** *Submit copies of all instruments, surveys, interview questions, observation checklists, etc. that you plan to use for data collection as separate documents. Indicate whether data are collected as part of an initial participant screening or the actual study. If you have multiple participant groups (e.g., parents, teachers, and students or control groups and experimental groups), please specify which group you are asking to complete which task(s). If applicable, submit separate translated copies of all questionnaires, interview questions, consent forms, and recruitment materials, for each participant population. Upload a copy of the back-translation (translation into the target language and back into*

English) document using Google-Translate to validate translation accuracy. Alternatively, the translator can sign the "translation verification" form in Mentor/Documentation.

PART 1 PUBLIC DATA: We will analyze public sources to trace psychoeducation descriptions of mental health.

PART 2 EXISTING DATA: Researchers will review existing data to explore psychoeducation in mental health. This existing data may include data previously collected from other researchers. Where applicable, we will engage in a data sharing agreement.

A template for data sharing is available in Mentor IRB/Documentation.

PART 3 ANONYMOUS ONLINE SURVEYS (using Qualtrics):

- MTurk – The study will conducted through Amazon's Mechanical Turk. Adult participants will be randomly assigned and asked to read about common mental health scenarios (e.g., a person with depression) and mental health psychoeducation. After reading the description, participants will be asked to respond to survey questions about the scenario (how likely they perceive a path towards recovery, etc.), and questions about the mental health psychoeducation. These measures will allow us to determine the effects of the psychoeducation on perceptions of mental health. Participants will also be asked to complete a demographic survey.

Any participant compensation should be detailed in the protocol. Consider the following questions:
1. How much compensation is appropriate for the tasks?
2. Are there criteria that must be met for participants to receive the compensation?
3. Are there situations in which the participants may be disqualified from receiving compensation (e.g., failed attention checks)?

  - For MTurk workers, we will pay them up to $1.50 for their participation.
    - Payment will be dependent on the time allotted to complete the survey and the total scenarios participants are asked to review.
  - There will be attention checks within the survey to determine if participants are paying attention.
    - If participants do not pass all attention checks they will not get paid.

- Persons who self-identify as having depression – Adult participants will be asked if they have felt depressed within the last 6 months. Then, they will be randomly assigned to read about a common mental health scenario (e.g., a person with depression). They will then be asked survey questions about their impressions of the psychoeducation. Participants will also be asked to complete a demographic survey.

- Therapists – Adult participants will be asked if they are currently practicing as a therapist and to identify their area of specialty. Then, they will be randomly assigned to read about a common mental health scenario (e.g., a person with depression). They will then be asked survey questions about their impressions of the psychoeducation. Participants will also be asked to complete a demographic survey.

- PART 4 INTERVIEWS AND FOCUS GROUPS: Adult participants will be asked to read about common mental health scenario (e.g., a person with depression). They will then be asked interview questions (individually and in a focus group) about their impressions of the psychoeducation. Participants will also be asked to complete a demographic survey. Audio recorded, face-to-face, in person interviews will occur at a time and place that is convenient for the participant

11. Please check the box(s) that best describes the specific nature of your data.

If your study has multiple activities, please make sure to check all that apply.

In Microsoft Word, double-click the box or type an "X" to mark your selection.	
☒ I will personally collect new data.	☒ I will access existing data.
☐ Somebody else will collect the data via proxy (*please explain*).	☒ I will use a web-based data collection site (*e.g., Amazon's Mechanical Turk (MTurk) or ResearchMatch*).
☐ Other (*please explain*).	

12. Please check the box(s) that best describe your study activities.

In Microsoft Word, double-click the box or type an "X" to mark your selection.	
☒ Audio recordings	☐ Clinical trials, Experiments, or Randomized Controlled Trials
☒ Documents and Records	☐ Ethnographies, Oral History, and Case Studies
☒ Interviews or Focus Group Sessions	☒ Online (*e.g., Qualtrics, RedCap, or other web-based collection method*)

☐ Observations	☐ Program Evaluations
☐ Other (*please explain*)	☐ Video recordings

13. Please list the *activity*, *occurrence,* and *duration* in which your participants will be engaging.

Name of Task or Procedure (*e.g., individual audio recorded interview*)	Number of occurrences (*e.g., twice*)	Activity Duration (e.g., *30 minutes, each time*)	Total time per participant (*e.g., one day, two interviews, 60 minutes total*)	Describe the data collected
PUBLIC DATA	N/A	N/A	N/A	Public sources to trace psychoeducation descriptions of mental health
EXISTING DATA	N/A	N/A	N/A	Analyze de-identified transcripts about mental health.
ANONYMOUS ONLINE SURVEYS • Amazon's Mechanical Turk (MTurk)	1	Not to exceed 30 minutes	Not to exceed 30 minutes	Using Qualtrics, randomly present psychoeducation to MTurk workers.
ANONYMOUS ONLINE SURVEYS • Persons with Depression	1	Not to exceed 30 minutes	Not to exceed 30 minutes	Using Qualtrics, present psychoeducation to adults who self-identify as having depression and ask about their thoughts and beliefs.
ANONYMOUS ONLINE SURVEYS • Therapists	1	Not to exceed 30 minutes	Not to exceed 30 minutes	Using Qualtrics, present psychoeducation to therapists and ask about their thoughts.

INTERVIEWS AND FOCUS GROUPS • Audio recorded, face-to-face	1	Not to exceed 90 minutes	Not to exceed 90 minutes	Adult participants will be asked to read about a common mental health experiences. Participants will be asked about their impressions.

Total hours of participation for all tasks:

PART 1 PUBLIC DATA: No specific time, public data.

PART 2 EXISTING DATA: No specific time, existing data.

PART 3 ANONYMOUS SURVEYS:

- MTurk – Online – one time, not to exceed 30 minutes (*likely will take 20 minutes*).
- Persons with Depression – Online – one time, not to exceed 30 minutes (*likely will take 20 minutes*).
- Therapists – Online – one time, not to exceed 30 minutes (*likely will take 20 minutes*).

PART 4 INTERVIEWS AND FOCUS GROUPS: Audio-recorded, face-to-face, one time, not to exceed 90 minutes.

Total duration of participation (*e.g., days, months, and/or years*):

The study activities will occur once per participant. Participant interaction will not exceed 90 minutes.

14. If you will be audio/video recording, please state how you will ensure that all participants have consented to be recorded. How will you ensure that individuals who are not participating in your study (*e.g., other children in a classroom*) will not also be recorded?

INTERVIEWS AND FOCUS GROUPS: During the interviews, participants will be asked if they agree to audio recording. Only participants who agree to the audio recording will be allowed to participate. After the audio recording is transcribed, it will be deleted. The transcripts will not contain any personal identifiers.

15. State whether participants will be compensated for their participation. ***NOTE:*** *If you plan to use a lottery system, please state odds of winning here and in the consent form. Also, if you will be offering course credit for study participation, you must discuss this here*

and include the alternative assignment for those who decline to participate in the study. Will compensation be pro-rated if the participant does not complete all aspects of the study? If you pay participants after their participation, please make it clear how you will link names/contact information confidentially to any record of the compensation.

MTurk workers will be paid up to $1.50 for their participation online.

No other participant will be paid.

16. Will deception be used? If so, please provide a rationale for its use. ***NOTE:*** *Upload a debriefing script as a separate document. Include a statement that gives your participants the opportunity to withdraw their participation at that time. Studies involving deception are given Full Board Review unless the deception is minor and risks are minimal.*

No deception will be used.

17. Will you have a control group, or a comparison group? If so, please describe your procedures and explain the purpose of using a control group.

Yes, participants will be randomly assigned into mental health descriptions framed using psychoeducation scenarios.

18. Will you need bilingual interpreters or interviewers, and if so, what will you do to ensure participant confidentiality? What are your procedures for recruiting interpreters and interviewers?

No bilingual interpreters are needed.

Studies including bilingual interpreters that are not part of the research lab should download the Transcription Nondisclosure Template (on TC Mentor IRB/Documentation) and adapt it for their translators.

SECTION III: DESCRIPTION OF RESEARCH RISKS & BENEFITS

19. Describe the potential risks to your participants. Risks can be physical, psychological, economic, or social. What is the likelihood of these risks occurring, and/or their seriousness (*e.g., exposure of sensitive data*)? How will you work to minimize these risks? ***NOTE:*** *The IRB regards no research involving human participants as risk-free. You may describe minimal risks for your study (such as discomfort, boredom, fatigue, etc.), or state that the research will involve minimal risk, similar to an activity (named) that participants would perform in their daily lives.*

ANONYMOUS SURVEYS: This is a minimal risk study. Participants who may experience mental health concerns or may be depressed may find some of the questions uncomfortable. All participants are adults competent to consent and can choose to skip any question or stop at any time. No identifiers will be collected on the surveys.

INTERVIEWS AND FOCUS GROUPS: This is a minimal risk study. Participants may feel uncomfortable responding to questions about mental health. All participants are adults competent to consent and can choose to skip any question or stop at any time. Participants will be assigned pseudonyms instead of using their real name.

For the focus group sessions, participants will be informed that other focus group participants will know their identity and the researchers cannot guarantee that others in these groups will respect the confidentiality of the group. As a researcher, I ask that all individuals keep all comments made during the focus group confidential and not discuss what happened during the focus group outside the meeting.

When the research environment includes bystanders, participants, or non-researchers, you cannot guarantee full confidentiality. It is important that the consent form and protocol acknowledge the limits of confidentiality.

20. What are your plans for ensuring necessary intervention in the event of a distressed participant and/or your referral sources if there is a need for psychological and/or physical treatment/assistance?

We do not predict distressed participants as part of this study. We will remind participants that the study is voluntary, they do not have to complete the study if they do not want to, and they can skip any question that they do not want to answer. The online study portion of the study will not include identifiers. For the interview data (individual interview and focus group session) all identifiers will be removed in the final reporting of the data.

This language can also be included in your consent form.

21. What qualifications and preparations enable you to estimate and minimize risk to participants?

All of the researchers are CITI trained. The researchers have years of experience working with human subjects

All research staff must be CITI trained **before** participating in research. The CITI training certificate, awarded at the completion of the CITI course, should be uploaded into TC Mentor IRB/PI Documentation prior to submitting an IRB protocol application. Studies listing researchers who do not have their CITI training in TC Mentor IRB will be subject to revisions.

22. Describe any possible direct benefits to your participants. Most research will not have any direct benefits to participants. Occasionally, a study design will include a diagnosis, evaluation, screening, counseling or training, etc., that has a concrete benefit to participants, independent of the nature or results of a research study.

There are no direct benefit to participants.

SECTION IV: CONFIDENTIALITY PROCEDURES & PARTICIPANT PRIVACY

23. Please check the box(s) that best describes your data. ***Note:*** *Sensitive data potentially poses substantial threat to research subjects and can become problematic for the researcher, researched collection, and/or the dissemination of research data (Lee & Renzetti, 1990). Substantial threat may include threat to reputation, employment, or access to resources. Sensitive data may include studies of domestic violence, immigration status, political activism, homicide, death, trauma, assault, and/or mental, sexual, or physical health* (Lee, R. M., & Renzetti, C. M. (1990). The problems of researching sensitive topics: An overview and introduction. *The American Behavioral Scientist, 33*(5), 510–528).

☐ Completely anonymous data (*both sensitive and non-sensitive*)	☒ Non-sensitive data with identifiers
☐ Sensitive data with identifiers	☐ Other (*please explain*)

24. For data with identifiers please describe your method for de-identifying the data to maintain confidentiality. ***Note:*** *The term de-identified data refers to subject data from which all information that could reasonably be used to identify the subject has been removed or replaced. For example, the researcher may use the safe-harbor method to remove specified identifiers (name, address, phone, or any other unique identifier, etc.) from a dataset; the partially de-identified method to remove most, but not all identifiers from the data set (may require a data use agreement); or the generation of variables method to replace study subjects' identifiers, like using a unique code or pseudonym. To be truly de-identified data, the investigator cannot have codes that link to identifiers.*

All data will be de-identified. There will be no names used in reporting of any data.

25. If you are working with sensitive identifiable data, please explain why identifiers are necessary to carry out your research. Sensitive identifiable data should never be sent as an email attachment. ***NOTE:*** *If you are collecting private, identifiable heath information as part of your research, please see our website* ***www.tc.edu/irb*** *under Forms and Guidelines for the Health Insurance Portability and Accountability Act (HIPAA) document.*

Not applicable.

SECTION V: DATA SECURITY

26. Please respond to the following sections.

Please check the box(s) that best describes how you will transfer your data.	
☒ I will use a Virtual Private Network (VPN) for secure data transfer or other form of encryption *(e.g., Teachers College's secure remote network access*).	☐ Not applicable (*e.g., data will <u>not</u> be accessed remotely or transferred. It will exist only on a locally stored password-protected hard drive*).

Please see TC IRB's Data Security Plan for more information related to transferring and storing data.

Please check the box(s) that best describes how you will store your data.	
☒ On a password-protected local or external computer hard drive.	☒ On Teachers College's local password-protected network.
☒ On Teachers College's Google Drive, in a password-protected folder.	☐ In Teachers College's Dropbox (*faculty only*).
☐ Other (*e.g., cloud-based, password-protected storage*) (*please explain*).	

Researchers should select as many options as possible to protect their data. For a guide, please review TC IRB's Data Security Plan.

Please check the box(s) to affirm your data security plans.	
☐ I will encrypt my data (e.g., *conceal data by converting it into a code*).	☒ I will use anti malware protections and automatic software updates.
☒ I will block unauthorized access to my data (*e.g., firewall*).	☒ I will disable file and media sharing if I do not need it.
☒ I will delete old files from cloud-based backups and local hard drives.	☒ I will take care of privacy settings immediately upon setup.

27. Teachers College classifies all data associated with ongoing research studies as confidential, meaning only project staff, academic advisors, collaborators and other

individuals at the college on a need-to-know basis may have access to it. Confidential data at a minimum should be stored on a password-protected computer, or in a password-protected file or folder if the computer is shared. Paper and other physical media should be kept under lock and key. All computers accessing data should have anti-virus software installed.

Please check the box below:
☒ Yes, I acknowledge and understand how Teachers College classifies research data.

SECTION VI: INFORMED CONSENT PROCEDURES

Informed consent is a process, not just a form.

28. What are your procedures for obtaining a participant's informed consent to take part in the research?

Participants will be presented with an informed consent form (either in person or online) based on which study activity they are recruited to complete. They will be asked to read the consent form and if they agree to participate, they will be asked to either sign (in person) or click, "I agree" (online).

This wording should match the description included in your consent forms.

29. How will you describe your research to potential participants?

Participants will be informed this is a study exploring the impact of mental health psychoeducation. They will also be informed that the researchers are interested in understanding their perceptions of mental health, treatment, and recovery.

30. What will you do to ensure participants' understanding of the study and what it involves?

All participants for the new data collection portion will be presented with an informed consent form (online or in-person) before participating in the study. They will also be given the researchers' contact information if they have questions about the study.

31. Use this section to provide a request for a full or partial waiver of informed consent, and justify this request. Indicate "*not applicable*," if you are not requesting a waiver. ***Note:*** *You may cite criteria from the following link regarding Federal regulations and guidelines:* **www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116**

Not applicable.

Note for Researchers: *Templates are available in Mentor/Documentation. Drafts of forms will not be accepted. Please proofread all files.*