This is a protocol to use as an example of an application the NC State IRB Office likes to see. It is clear, concise, and answers all questions. There are references to uploaded documents that match what is in this protocol's supporting documentation.
Use this protocol as a guide, but do not copy it.

A Weighty Matter: Exploring Narratives of Stigma and Hope

Description tab

Description

For individuals who identify or are perceived by others as overweight, "pleasingly plump," obese, or fat, interacting with the U.S.A.'s health care system can often be unpleasant. There can be audible "tsk" of disapproval from a nurse during a weigh-in. Many hear that their pre-existing medical conditions can only be fixed by going to a gym and losing weight even when their conditions are not related to or caused by the individual's physical size. Others shun health care entirely to avoid stigma and body shaming.

Current research shows that overall health outcomes for this population is reduced even after controlling for co-morbidities. Yet the existing literature does not name nor systematically explore the significance of weight stigma and its functioning to influence health behaviors. Until we understand this phenomenon, we cannot design effective health promotion models and interventions for this population.

Conceived as a qualitative pilot study, this protocol aims to interview health care consumers and primary care practitioners about existing fatphobia. The data will serve as foundational scaffolding used to inform future research and, we hope, help us create a new health behavior model and interventions that is inclusive and promotes the health of individuals at every body size.

Conflict of Interest
N/A

Exemption
Yes

Research conducted by student
No

Additional investigators
No

Will investigators be collaborating
No

List collaborating institutions and describe the nature of the collaboration.
No

What is NCSU's role in this research?
NC State will serve as the primary researchers.

Describe funding flow, if any (e.g. subcontractors)
There is no funding related to this study.

Is this international research?
No

Populations tab

Adults 18 - 64 in the general population: Yes

NCSU students, faculty or staff: Yes

Are you asking participants to **disclose information about other individuals** (e.g., friends, family, co-workers, etc.)?: Yes

Minors (under age 18--be sure to include provision for parental consent and/or child assent): No

Could any of the children be **"Wards of the State"** (a child whose welfare is the responsibility of the state or other agency, institution, or entity)? No

Prisoners (any individual involuntarily confined or detained in a penal institution -- can be detained pending arraignment, trial or sentencing): No

Vulnerable populations (only if they are targeted groups for your study)
Adults age 65 and older: No

Pregnant women: No

Fetuses: No

Students: Yes

Does the research involve normal educational practices?
No

Is the research being conducted in an accepted educational setting?
No

Are participants in a class taught by the principal investigator?
No

Are the research activities part of the required course requirements?
No

Will course credit be offered to participants?
No

How will permission to conduct research be obtained from the school or district? IRB approval is not permission to conduct the research. You need to access a gatekeeper. If you are implementing a survey with NC State populations, please make sure you follow the NC State survey regulation.

I plan to advertise and recruit from two departments on the campus (Food Science and Health and Exercise) because the students, staff, and faculty have both the knowledge and (hopefully) interest to provide evidence-based data on narratives of weight and stigma. After IRB approval, I will contact the respective department chairs at that time via email and ask them for permission to advertise their study in their buildings and via a departmental listserv. These drafted emails are uploaded, as well as the flyers we hope to post in the departmental buildings.

I also hope to recruit from the employees at the NCSU Student Health Center. I will contact the medical director and ask for permission to email the staff listserv about the research.

Will you utilize private academic records?
No

Explain the procedures and document permission for accessing these records.
N/A

Employees: Yes

Describe where (in the workplace, out of the workplace) activities will be conducted.
Recruitment flyers and emails will be posted in buildings and on institutional listservs that employees may access regularly in the course of their workday. Employees are not targeted because of their employment; rather, they are targeted because of their professional interest in health and well-being.

From whom and how will permission to conduct research on the employees be obtained?
After IRB approval, I will contact the respective department chairs at that time via email and ask them for permission to advertise their study in their buildings and via a departmental listserv(s). These drafted emails are uploaded, as well as the flyers we hope to post in the departmental buildings.

How will potential participants be approached and informed about the research so as to reduce any perceived coercion to participate?
Flyers will be posted in public areas and emails will be sent by PI to generic listservs only. PI will only speak with persons individually if they have first initiated contact with the PI about the research. Supervisors or managers from these departments are not included on the research team and will not be involved in the recruitment, consent, or data collection processes of their employees beyond the department head allowing the PI to post recruitment materials in departmental spaces (physical and digital).

Is the employer involved in the research activities in any way?
Yes

Please explain: The employer is assisting in recruitment of participants by authorizing the PI to use departmental email listservs and physical buildings to advertise the study, including the link to the online Google form to express interest in participating in the research. They are not, however, participating in the screening of or qualitative interviews with participants.

Will the employer receive any results from the research activities (i.e. reports, recommendations, etc.)?
Yes

Please explain. How will employee identities be protected in reports provided to employers?

Raw research data will never be shared beyond the research team and this includes not sharing any raw data with the employer. They will only have access to the de-identified data that is published if they seek the data.

Impaired decision making capacity/Legally incompetent: No

Mental/emotional/developmental/psychiatric challenges: No

People with physical challenges: Yes

Identify the challenge and explain the unique risks for this population.
The individuals I'm targeting for inclusion can have physical restrictions or challenges due to their bone structure, height, genetics, and body fat percentages. We expect that we will attract participants that are more likely to have physical challenges because our study is exploring weight stigma. There also are emotional and psychological risks to talk with individuals about disability and stigma.

Describe any special provisions necessary for working with this population (e.g., witnesses for the visually impaired).
Due to the risk participants may already experience in daily life by their own limited mobility, research methods that include any sort of physical exercise is excluded to mitigate any additional physical risk to participants. I've chosen to use inquiry method to approach participants in a non-pathologizing (and potentially re-traumatizing) manner as they discuss their life experiences surrounding weight stigma, which could include physical challenges.

Economically or educationally disadvantaged: No

Racial, ethnic, religious and/or other minorities: No

Non-English speakers: No

Explain the necessity for the use of the vulnerable populations listed: I'm targeting students and employees because I'm trying to map how fatphobia attitudes change between being a college student and being a professional in allied health fields as well as see if there's any correlation between years of practice and level of fatphobia. Additionally, there is no reason to exclude students and professionals at the university from participating in this study. It is okay to include these people because the research is not related to their status as a student or professional and their involvement will add robust data to the study.

There is a percentage of people who are also overweight that have mobility issues as a result of their weight or something entirely different. Though this group is not targeted, they will be included because their experiences will add robust data to the study that will shape recommendations for practice, especially those who have mobility issues unrelated to weight.

Consent tab

Provide a description of the consent process for each participant group, indicating how and when they will be provided information about the research.

State how, where, when, and by whom consent will be obtained from each participant group. Identify the type of consent (e.g., written, verbal, electronic, etc.). Label and submit all consent forms.

Health care consumers

Potential interview participants will receive a recruitment email from the organization with which they are already affiliated with (see procedures tab for recruitment details). Potential participants who express interest as a response to the flyer and/or the recruitment email will be directed to a secure Google link where they can submit their name, contact information, and best times to reach them with more information about the study. This information will only be accessible to the research team.

Participants will then be contacted by phone by a member of the research team. During the phone call, a verbal script will be used to review the overall aims of the study, study activities, and the risks and benefits of participation. During this interaction, participants will have the opportunity to ask questions related to the research study.

After the phone call, if the individual is still interested in participating in this research, participants will be able schedule an interview time with the research team. They will also receive a secure Qualtrics link to view and download a consent form prior to the scheduled interview. When a participant arrives to be interviewed, the consent form will be reviewed together with the participant. Time will be built into the review for the participant to ask any questions they have and for the research team to answer the participant's questions. The participant must, after the consent form review and Q&A, re-affirm interest before the formal interview process begins.

This allows the participants the time needed to decide whether or not they want to participate in the study.

Health care practitioners

Potential participants will receive a recruitment email from the organization with which they are already affiliated with (see procedures tab for recruitment information). Potential participants who express interest as a response to the flyer and/or the recruitment email will be directed to a secure Google link where they can submit their name, contact information,

and best times to reach them with more information about the study. This information will only be accessible to the research team. Participants will then be contacted by phone by a member of the research team.

During the phone call, a verbal script will be used to review the overall aims of the study, study activities, and the risks and benefits of participation. During this interaction, participants will have the opportunity to ask questions related to the research study. After at the of the phone call if the individual is still interested in participating in this research, participants will be able schedule an interview time with the research team. They will also receive a secure Qualtrics link to view and download a consent form prior to the scheduled interview. When a participant arrives to be interviewed, the consent form will be reviewed together with the participant. The participant must re-affirm interest before the formal interview process begins.

This allows the participants the time needed to decide whether or not they want to participate in the study.

Please see uploaded consent forms for each participant group. They are separated because though the procedures are the same, the risks to each participant group is different.

If any participants are minors, describe the process for obtaining parental consent and minor's assent (minor's agreement to participate)
N/A

Are you applying for a waiver of the requirement for consent (no consent information of any kind provided to participants) for any participant group(s) in your study?
No

Are you applying for a waiver of signed consent (consent information is provided, but participant signatures are not collected)? A waiver of signed consent may be granted only if:

- The research involves no more than minimal risk
- The research involves no procedures for which consent is normally required outside of the research context.

Yes.

Would a signed consent document be the only document or record linking the participant to the research?
No (There will be a master list and interviews will be recorded and transcribed)

Is there any deception of the human subjects involved in this study?
No.

Procedures tab

Provide a description of each participant group involved in your study and address each item below for each of these groups (e.g. teachers and students, employees and supervisors).

For each participant group please indicate how many individuals from that group will be involved in the research. Estimates or ranges of the numbers of participants are acceptable. Please be aware that participant numbers may affect study risk. **If your participation totals differ by 10% from what was originally approved, notify the IRB.**

6-12 health care consumers
6-12 health care practitioners
12-24 total participants

How will potential participants be found and selected for inclusion in the study?

Health care consumers will be found through the following professional organizations: Association for Size Diversity and Health (ASDAH), National Association to Advance Fat Acceptance (NAAFA), Obesity Action Coalition (OAC) and Your Weight Matters (YMO). I will also recruit health care consumers through flyers posted at Durham and Wake County libraries, parks and recreation centers, and NC State's Food Science department and Health and Exercise department to diversify the participant pool.

Health care practitioners will be found through affiliation with the following organizations: the Academy of Nutrition and Dietetics (AND), American Association of Nurse Practitioners (AANP), American Board of Obesity Medicine (ABOM), American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Care Advocacy Network (OCAN), and Obesity Medicine Association (OMA). I will also recruit health care practitioners through flyers posted at Durham and Wake County libraries, parks and recreation centers, and NC State's Food Science department, Health and Exercise department, and Student Health Services to diversify the participant pool.

For each participant group, how will potential participants be approached about the research and invited to participate? Please upload necessary scripts, templates, talking points, flyers, blurbs, and announcements.

Both health care consumers and practitioners will be approached to participate through a general email and flyers distributed by lay and professional organizations that potential participants already affiliate with.

Copies of the email and flyer that will be used are uploaded to the supporting documentation of this protocol. Each has a brief description of the study's goals, procedures, time investment, and how to contact the research team for more information via a secure link to a fillable Google form housed on NC State's Google drive.

This Google form collects potential participants name, phone number, email, and best times to reach them and is uploaded for review. This form enables members of the research team to contact possible participants and to screen, to schedule interviews, and to direct them to the online consent form to read and download.

The talking points for the recruitment and screening phone conversation are uploaded.

Describe any inclusion and exclusion criteria for your participants and describe why those criteria are necessary (If your study concentrates on a particular population, you do not need to repeat your description of that population here.) Inclusion and exclusion criteria should be reflected in all of your recruitment materials and consent forms.

Health Care Consumer Participants will qualify if:

- they are 18 years old or older
- Self-identify or have been identified by their health care provider as overweight, obese or fat
- receive their health care in North America
- have not ever been hospitalized or participated in outpatient or residential treatment for an eating disorder.

Health Care Consumer Providers will qualify if:

- they are 18 years old or old
- hold a terminal degree in a health care field (e.g. an M.D., D.O., D.N.P.)
- provide primary health care to patients in North America
- be in good standing with their certifying professional organization at the time the interview is conducted.

Both the health care consumers and practitioners need to be 18-years-old or older because we want participants who have enough life experience to be able to adequately reflect on their experiences in a mature manner.

We needed to limit the geographic location of potential participants to enable research tools such as a crosswalk to meaningfully function and to track scope, trends, and "isms" that qualitative research is designed for. Therefore, participants must either receive or practice health care in the United States of America.

Because we are interviewing health care consumers on their experience of weight stigma in primary health care, we felt it was important to exclude consumers who have been treated for an eating disorder. This serves, first and foremost, as a participant protection to reduce the likelihood that the interview protocol could trigger or re-traumatize participants. This exclusion criteria also reflects our own areas of professional expertise and limitations therein. Neither of us are licensed mental health professionals. We are not trained to adequately judge and manage for the safety and well-being of individuals with this background and do not wish to overstep our professional role.

For health care practitioners, it was important that we only gather data from individuals who are in good standing with their professional certifying organization so that we and others can trust the validity of the data we're gathering.

Is there any relationship between researcher and participants - such as teacher/student; employer/employee?
No

For each group of participants in your study, provide a step-by-step description of what they will experience from beginning to end of the study activities
Health care consumers

1. Will receive a recruitment email and/or flyer sent through an organization they currently affiliate with that serves as a community resource, addresses weight stigma in health care, or educates individuals on matters of food and wellness.

2. If interested in participating, they will access a Google form housed on NC State's Google drive, where they will give the research team their name, phone number, email, and the best times to reach them.

3. A member of the research team will call the potential participant. Using an approved verbal script (see upload), the participant will be told about the study's goals, activities, time commitment, and risks and benefits of participating. The research team member will allow time for the potential participant to ask any questions, and inquire if the individual is interested in participating. This conversation is expected to take 10 minutes.

4. If individuals affirm interest in participating, they will be screened for inclusion in the study by the research team member. The screening questions are included as part of the verbal script uploaded in the supporting documentation; the information collected as part of the screening includes age, sex, how the individual identifies with their body weight (underweight, normal weight, overweight, big, fat, or obese) and how their doctor has labeled the consumer's weight (underweight, normal weight, overweight, big, fat, or obese), if they receive their primary health care in the United States, and if they have ever received treatment for an eating disorder. This screening is expected to take 5

minutes. The notes from the screening conversation will be on a document with only a code. There will be no direct identifiers like name, phone, or email on the screening notes. The code will link the notes to the person via a master list.

5. If participants do not qualify, they will be thanked for their time, please see the verbal script used for the full conversation.

6. If after the phone conversation participants qualify for inclusion in the study, the research team member will schedule an interview session at a private location convenient to the participant and at a mutually agreeable time. The scheduling is expected to take 5-10 minutes.

7. Participants will be sent a secure link to access a consent form to read through prior to the interview. Reading the consent form is expected to take 10 minutes.

8. At the interview, a member of the research team will review the consent form with the participant and the participant will affirm consent and sign the consent form. This is expected to take 5-10 minutes.

9. The participant then will be interviewed by a member of the research team with the uploaded interview protocol. Participants will be prompted to speak from their own experience and, when discussing other individuals or institutions, to describe them in terms of role, not name. This interview is expected to last between 45 and 90 minutes in total. The interview will be audio recorded.

10. The participant will be thanked for their time at the end of the interview.

11. To ensure accuracy of data, participants will be asked to engage in member checking. Participants will be able to read through their transcript and make clarifications as appropriate. Once data is synthesized and themes emerge, participants will have the opportunity to provide a review of the themes. This will occur by using NC State's Google drive, and sharing specific folders with specific participants. That way there is no permanent link in email regarding member checking activities. When all member checking is complete, access to the data and themes will be revoked.

<u>Primary health care practitioners</u>

1. Will receive a recruitment email and/or flyer sent through an organization they currently affiliate with that addresses obesity in health care.

2. If interested in participating, they will access a Google form housed on NC State's Google drive where they will give the research team their name, phone number, email, and the best times to reach them.

3. A member of the research team will call the potential participant. Using an approved verbal script (see upload), the participant will be told about the study's

goals, activities, time commitment, and risks and benefits of participating. The research team member will allow time for the potential participant to ask any questions, and inquire if the individual is interested in participating. This conversation is expected to take 10 minutes.

4. If individuals affirm interest in participating, they will be screened for inclusion in the study by the research team member. The screening questions are included as part of the verbal script uploaded in the supporting documentation; the information collected as part of the screening includes age, sex, their terminal degree in a health care field, if they provide primary health care to patients in the US, whether or not they are in good standing with their professional certifying organization, how the individual identifies with their body weight (underweight, normal weight, overweight, big, fat, or obese) and how their own doctor has labeled the practitioner's body (underweight, normal weight, overweight, big, fat, or obese). This screening is expected to take 5 minutes. The notes from the screening conversation will be on a document with only a code. There will be no direct identifiers like name, phone, or email on the screening notes. The code will link the notes to the person via a master list.

5. If participants do not qualify, they will be thanked for their time, please see the verbal script used for the full conversation.

6. If after the phone conversation participants qualify for inclusion in the study, the research team member will schedule an interview session at a private location convenient to the participant and at a mutually agreeable time. The scheduling is expected to take 5-10 minutes.

7. Participants will be sent a secure link to access a consent form to read through prior to the interview. Reading the consent form is expected to take 10 minutes.

8. At the interview, a member of the research team will review the consent form with the participant and the participant will affirm consent and sign the consent form. This is expected to take 5-10 minutes.

9. The participant then will be interviewed by a member of the research team with the uploaded interview protocol. Participants will be prompted to speak from their own experience and, when discussing other individuals or institutions, to describe them in terms of role, not name. This interview is expected to last between 45 and 90 minutes in total. The interview will be audio recorded.

10. The participant will be thanked for their time at the end of the interview.

11. To ensure accuracy of data, participants will be asked to engage in member checking. Participants will be able to read through their transcript and make clarifications as appropriate. Once data is synthesized and themes emerge, participants will have the opportunity to provide a review of the themes. This will

occur by using Google drive housed on NC State's Google Drive, and sharing specific folders with specific participants. That way there is no permanent link in email regarding member checking activities. When all member checking is complete, access to the data and themes will be revoked.

For both participant groups, during the initial conversation and the interview, the researcher will take notes on an NC State managed iPad that is not connected to the internet at the time of collection and any future internet connection is done using VPN. The notes will not have any direct participant IDs on them and the iPad is password protected and the notes file is password protected.

Are you requesting the use of existing information to be used as data for this research project or are you requesting secondary data to be used as data for this research project? (Discuss the following: access, transfer, storage, destruction, (re)identifiable nature of the data and if data is subject to FERPA or HIPAA)
No. Though I ask about health, these records are not subjected to HIPAA because this research and the researchers are not considered covered entities. Health care providers will be directed not to share any identifiable health information regarding their patients and to make sure they share information in accordance with HIPAA.

Data Security Tab

Describe data security during collection, storage and reporting
Mark all items below that apply to your study

Use of Existing Data
Will you be receiving already existing data without identifiers for this study? No

Will you be receiving already existing data which includes identifiers for this study? No

Means of Data Collection
Will data be collected in a way that would not allow you to link any identifying information to a participant? No

Will any identifying information be recorded with the data (ex: name, phone number, IDs, e-mails, etc.)? Yes

Will you use a master list, crosswalk, or other means of linking a participant's identity to the data? Yes

Will it be possible to identify a participant indirectly from the data collected (i.e. indirect identification from demographic information)? Yes

Data Collection Methods
Audio recordings? Yes

Video recordings? No

Images? No

Digital/electronic files? Yes

Paper documents (including notes and journals)? No

Physiological Responses? No

Online survey? No

Protection of Data
Restricted Access (who, what, when, where)? Yes

Password Protection (files, folders, drives, workstations)? Yes

Suggestion of anonymous browsing? No

Locks (office, desks, cabinets, briefcases)? Yes

VPN (transfer, upload, download, access)? Yes

Encryption (files, folders, drives)? Yes

Describe all participant identifiers that will be collected from each data collection method (surveys, interviews, focus groups, existing data, background data collected via host site or software). Discuss why it is necessary to record identifiers at all and describe the deidentifying process.

IDs associated with Recruitment

During recruitment, I will collect participants' names, phone numbers, and emails as well as a few indirect identifiers (age, sex, and for the health care practitioners, community of professional practice and area of focus for their terminal degree). All of this information is necessary to appropriately screen individuals for inclusion in the study. Direct participant IDs generated from the recruitment process will be logged on a master list, but the master list will also assign a random numeric code that will be used on all other documents the research team generates in the course of this research (such as naming conventions for the interview audio files, interview transcriptions and coding, and the research team's process notes during the interviews).

IDs associated with Consent

The completed consent forms will have a direct participant name, which I need to document consent. The participant's name will be cross-referenced to the master list. The participant's completed consent form with their name will be will be stored securely in a locked drawer in a locked office on NC State's main campus

IDs associated with Data Collection - Interviews

I am collecting the participant's voice because I plan to audio-record the interviews. The recording is necessary so that I can generate accurate transcriptions for data analysis. The audio files will be securely deleted after the audio files are transcribed and checked for accuracy. No direct IDs will be recorded on any interview notes.

All participants are told not to share identifiable information about third parties.

If recording identifiable information about participants, discuss any links between the data and the participants and why you need to retain them. Discuss destruction of links or removal of identifiers.

An individual's direct identity is linked to the research data in two places: the audio-recorded interview via voice recording and in the master list. The audio-recorded interview will be deleted as soon as it transcribed and verified for accuracy. The transcription itself will be de-identified. The master list will be kept securely under encryption and will only be accessible via password protected access by the research team. I need to retain participant identifiers in order to follow up with participants for possible future research related to this topic as described in the consent form

Discuss if you'll be working with your departmental IT to create a data management plan and if you're using NC State managed devices, NC State Google Drive or other NC State non-networked device. If using a personal device, discuss data protection.

I have consulted with our departmental IT. Please see the primary data access and management plan that is uploaded to this protocol. I will be using NC State managed computers, devices, and data management platforms such as Google applications housed on NC State's network drives to collect, store, and analyze the research data that is de-identified. The raw data will be stored securely on an S drive managed by NC State that is encrypted. All data will be accessed through VPN and password protection is used for files. Data with direct identifiers (e.g. master list, raw audio interview files) will be collected, stored, and transferred only via VPN and the files will be encrypted.

Describe any ways that participants themselves or third parties discussed by participants could be identified indirectly from the data collected, and describe measures taken to protect identities. (Data can be reidentified by researcher access, technology employed, researcher expertise, and triangulation of data or other information. Discuss the probability of reidentification and the magnitude of harm to participants should the data be reidentified. Discuss the probability of reidentification occurring and the magnitude of harm should it occur).

Participants could be identified by the researcher through their raw recorded audio files and possibly even the redacted transcribed interview document depending on the content shared in the qualitative interview. The likelihood that re-identification would occur is unlikely because I am:

- Prompting participant to not use their names (or the names of other parties) in the course of the qualitative interview.

- Recording the interview on an NC State managed device accessible only to the research team and stored securely when not in use.

- Transferring the raw audio files of interviews via VPN and encryption alone for storage and transcription.

- Saving all files under a randomly generated participant code, which is only able to be linked to a participant's identity through the master list. The master list is encrypted and only accessible to the PIs.

- Scrubbing the interview transcriptions of any direct participant identifiers prior to any data analysis by the research team.

- Use of NC State Google drive for member checking, so no permanent link is made in email

- Not recording any identifiable information in any interview notes.

- When member checking is done, the individual will only be able to access their own de-identified transcript from a private folder accessible only to the researcher and that participant housed on NC State's Google Drive. I will direct participants to only access the transcribed file from their own computer, on a secure (non-public) network, and with their browser in private/incognito mode. Once the member checking is complete, the participant's access will be removed.

- If and/or when we report this data for presentation, publication, or future research purposes, I will work hard to obscure identities so that I am reporting what I learned from the research, but not the specific details of how I learned it in ways that might identify participants. I also may change identifying details of a unique participant if I present data results as a case study.

If identification of participants were to occur, there would be minimal risk to health care consumers and some but likely minimal risk to health care providers regarding their employment. I state some minimal risk to providers because the data of their experience and personal views of marginalized bodies in health care settings could alienate current or future patients, employers, or colleagues. Please see the risks and benefits tab of the application for details.

Third parties could be identified in this research through the content shared in the audio-recorded interviews with health care consumers and health care practitioners. The likelihood that identification of third parties would occur is minimal because we are:

- Prompting participant to not use the names of other parties in the course of the qualitative interview and instead, describing others in terms of role (e.g. "patient," "employer," etc.)

- Scrubbing the interview transcriptions of any direct third party identifiers prior to any data analysis by the research team.

- Only publicly reporting data about third parties that is de-identified.

- Not recording any identifiable information in any interview notes.

For all recordings of any type:

- **Describe the type of recording(s) to be made**
- **Describe the safe storage of recordings**
- **Who will have access to the recordings?**
- **Will recordings be used in publications or data reporting?**
- **Will images be altered to de-identify?**
- **Will recordings be transcribed and by whom?**

I will be audio recording the qualitative interviews with health care consumers and health care practitioners. These audio files will be created and stored on NC State managed devices accessible only to the research team using naming conventions that only can be linked to a participant's direct identity with the use of a master list.

The raw audio will be shared via VPN and encrypted with a professional transcription service that will sign a certificate of confidentiality.

When the transcriptions are received by the research team, they will be cross-checked with the raw audio files for completeness. Once the check is complete and the transcription has been scrubbed of any participant or third party direct IDs, the raw audio files will be securely deleted in consultation with the departmental IT team.

No audio will be used in reports, publications, or presentations.

Describe how data will be reported (aggregate, individual responses, use of direct quotes) and describe how identities will be protected in study reports. Reporting data may sometimes reidentify your participants. If needed, you can adjust how you report your data to protect the identities of your participants. Discuss.

Some of the data will be reported in aggregate; other data will be presented through the use of direct quotes as this is a qualitative study. At no point will I include direct identifiers of participants or third parties in the direct quotes. We will also be careful to report participants data in such a way to not be so granular in the data that identification is likely. If necessary, we will use the research data to create a composite health care consumer or health care practitioner to report data in cases where identification is likely.

Will anyone besides the PI or the research team have access to the data (including completed surveys) from the moment they are collected until they are destroyed? This includes sharing data with sponsors, journals, or using the data for

future research endeavors. If you are sharing the data, this should be in your consent form.

The raw data will only be accessible to the research team composed of the PI, research assistants, faculty point of contact, and a professional transcription service.

The de-identified data will be accessible to the research team and may be shared with others for the purposes of presentation, publication, or future research without further notification or consent from the participants. This is discussed in the consent form.

Risks and Benefits Tab

Provide information about the risks to participants in your research. Risks can arise from recruitment, data collection, data analysis, and reporting. Take a minute and think about how your research and methods may impact your participants.

Please indicate any reasonable risks in the categories below:
Risks as a result of methods employed
Social/Reputational Yes

Psychological/Emotional No

Financial/Employability Yes

Legal No

Physical No

Collection/Access Use of Private or Sensitive Information
As a result of you using these data for research purposes, the following risks may occur:
Academic (affect grades, graduation) No

Employment (affect job) Yes

Financial (affect financial welfare) No

Medical (harm to treatment) Yes

Insurability (harm to eligibility) No

Legal (reveals unlawful behavior) No

Private behavior (harm to relationships/reputation) Yes

Describe the nature and degree of risk that this study poses. Describe the steps taken to minimize these risks. You CANNOT leave this blank, say 'N/A', none' or 'no risks'. You can say "There is minimal risk associated with this research." For each 'Yes' selected above, describe the probability of the risk occurring and the magnitude of harm should the risk occur. Discuss how you are mitigating those risks through participant selection, study design, and data security.

> The only risk that I possibly foresee for health care consumers that participate in this research is, in the unlikely event that they are identified from the research as reporting experiences of weight stigma with their primary care provider, that their

primary care provider may refuse to further treat the participant. I do not expect this to happen due to how I am collecting, storing, and reporting research data and that this is a pilot study. However, if this risk were to occur, the harm to the participant would depend on the participant's current health care coverage and other participating providers.

For health care practitioners, there are more types of risks associated with their participation as a result of their job. These risks include risks to their reputation and livelihood if they are identified in this research as perpetuating weight stigma. Patients and employers could choose to terminate their relationship with the participant. I do not expect this to happen due to how I am collecting, storing, and reporting research data and that this is a pilot study. However, if this risk were to occur, the harm to the health care practitioner could be significant.

All identified risks to participants have been communicated via the consent process and planned for through research design and data security and management.

If you are accessing private records, describe how you are gaining access to these records, what information you need from the records, and how you will receive/record data. Private records may include: educational, medical, financial, employment. Some of these private records may be subject to laws such as FERPA and HIPAA. Your content here should match what you've discussed on the procedures tab.

I am not accessing private records.

You have indicated that you will ask participants to disclose information about other individuals (see Populations tab). Describe the data you will collect and discuss how you will protect confidentiality and the privacy of these third-party individuals.

Before the recorded interview begins, I will prompt individuals to speak from their own experiences and to describe third parties in terms of role (e.g. "patient," "employer" etc.).

Recorded files will be transcribed. In that process, any identifying information inadvertently disclosed will be replaced with pseudonyms. When we report the data, it will be either in aggregate or in de-identified quotes that will make it statistically improbable for identification of third parties to occur.

If you are collecting information that participants might consider personal or sensitive or that if revealed might cause embarrassment, harm to reputation or could reasonably place the subjects at risk of criminal or civil liability, what measures will you take to protect participants from those risks?

Sharing personal experiences regarding weight and stigmas associated with real or perceived issues with weight can be difficult for some individuals, particularly those who are identified by others as overweight, big, fat, or obese or if they themselves identify as overweight, big, fat, or obese.

Participants will be reminded before beginning the interview that they can stop the interview at any time and can skip any question that they feel uncomfortable about answering. Furthermore, our exclusion criteria prevents those with additional vulnerabilities around body image and weight as assessed by prior eating disorder treatment from participating in this research.

If any of the study procedures could be considered risky in and of themselves (e.g. study procedures involving upsetting questions, stressful situations, physical risks, etc.) what measures will you take to protect participants from those risks?

None of the study procedures in and of themselves are risky as the procedures include interviews. The risk to this research comes from the data generated and any feelings participants may as a result of the questions posed. My data security plan does an excellent job of protecting participant confidentiality and minimizing risks, however if during the interview process the participant needs a break or to stop, I will remind them that they can do so.

Potential Benefits
(Potential benefits do not include any form of compensation for participation)

Describe the anticipated direct benefits to be gained by each group of participants in this study (compensation is not a direct benefit).
There is no direct benefit to participants.

If no direct benefit is expected for participants describe any indirect benefits that may be expected, such as to the scientific community or to society.
Indirect benefits include a deeper understanding of issues around stigmatization of weight and how people of varying weights are received, perceived, and treated in the medical community. This could help to target trainings, education, and practices of creating an inclusive environment that addresses weight issues as appropriate and not in an alienating or shaming manner.

Compensation Tab

Describe any compensation that participants will be eligible to receive, including what the compensation is, any eligibility requirements for that compensation, and how that compensation will be delivered. Examples of compensation include: monetary compensation, research credits, raffle/drawing, novel items. *Make sure to check with your department regarding issues of tracking payments as your department accounting office may have requirements that affect your human subjects privacy (such as the mandatory tracking of anyone who receives compensation).* This tracking may influence the confidentiality/anonymity of your research and must be addressed in this application.

There is no compensation for participants.

Explain compensation provisions if the participant withdraws prior to completion of the study.

There is no compensation for participants who withdraw.