Application Cover Memo

Cover memo prepared by Marina Pastore Rampazzo on 07/14/2021 at 12:36 PM

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ATTACHMENTS Tips/Reminders:

Recruitment materials should clearly indicate that the study is research (i.e., "This is a research study...", "Researchers at UNC are conducting a study...").

Exempt Information Sheet/Consent form should not state that the research project was "approved" by UNC. Exemptions are determined or granted, rather than approved. (i.e., "This study was reviewed by the Institutional Review Board and determined to be exempt from the Federal regulations.").

If a consent or information sheet is not included or is missing elements, please use the stip "

Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

1. Would you like your application evaluated for a possible exemption?

   Yes

Will your study either involve prisoners as participants or be FDA-regulated?

No

In order to be eligible for exemption, your research must fit into one or more of the following categories. Check all of the following that apply, understanding that most research falls into one or two categories.

Category 1

✗ The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and NOT to your location at a university.

And the research specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

✗ Research on regular and special education instructional strategies.

✗ Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

Does your study involve minors under the age of 18?

No

The research involves the use of one or more of the following

✗ Educational tests (cognitive, diagnostic, aptitude, achievement).

✓ Survey procedures.

✓ Interview procedures

✗ Observation of public behavior.

If at least ONE of the following criteria are true:

✗ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

✓ Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

✗ The information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to the participants AND there are appropriate provisions in place to protect subject privacy and confidentiality.

Explain. If not applicable enter N/A.

** The response here should make reference to all the items checked above. ** "The research involves the use of one or more of the following": The items checked should match the rest of the application. ** For "If at least ONE of the following criteria" is true:" we can exempt if any one items is selected and justified. Items 1 & 3 reflect the use of identifiers and you should check A.9 to make sure what they select makes sense. **If ONLY item 3 is selected, the study requires limited IRB review. ** For the second item regarding risk: They should provide justification here for *why* the nature of the survey/interview/whatever does not pose any risks to subjects. This response should match section A.6. If they select any economic, legal, or social risks, this item likely doesn't apply. See Macro: Exempt - Explain "no risk" **Generally for exempts, they can collect identifiers OR sensitive information, but not both. If it's both, consider bumping up to expedited when identifiers are stored associated or linked to responses.

Category 3

Research with adults involving Benign Behavioral Interventions (BBI) through one of the following:

✗ Verbal responses

✓ Written responses (including data entry)

✗ Audiovisual recording

And at least one of the following are true:

✗ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects

✗ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

✔ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
If this category is selected, please also explain how the intervention fits the BBI definition: brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and there is no reason to think the subjects will find the interventions offensive or embarrassing.

Explain. If the research involves deceiving the subjects regarding the nature or purposes of the research, please explain how subjects will be prospectively informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

IF NOT APPLICABLE ENTER N/A .
**Everything in the box for category 2 applies here as well. *Most* category three studies are also category 2. There is typically the behavioral intervention and at the very least some demographic or other survey questions. **A lot of study teams will select this when their study is really only a category 2. They just see verbal/written responses and they think it applies. Please stip to remove if there is no BBI in the study. Check A.4 first because sometimes they're not described well and can be difficult to spot. ** The response here should briefly describe the BBI being used. A benign behavioral intervention is anything introduced in order to affect a participants' behavior/responses/etc. If participants are assigned to different conditions, or presented with different stimuli, this category applies. (e.g. "Some participants read article A and some read Article B, then all answer the same questions." "All participants will interact with an electronic system and complete a number of tasks before being interviewed about their experience."). **Part of the regulations state that participants must opt in to the intervention. Many studies either deceive participants or withhold certain information. (e.g. "Participants are told they will complete a survey on current events when the focus is really on [specific hot button political issue]." "Participants will read an article with fictionalized statistics and then respond to a survey about the topic."). If this is done, participants must be told ahead of time that some information will be withheld and/or that they will be deceived. This can be as simple as a sentence in the consent form. This is NON-NEGOTIABLE for an exemption. If study teams don't want do do that, the other option is to change the application type to full form and request "a waiver or alteration of elements" in D.3. **The regulations do not require that participants be debriefed after participation is complete, however we would recommend in the vast majority of cases that participants are given the full information. They can also offer an option to withdraw their data. See Macro: Exempt 3 - Deception. **If the last option is selected (identifiers are selected) they should provide the additional information requested. If the intervention doesn't meet that criteria, this likely needs to be bumped up to expedited.

Category 4

✘ The research involves secondary uses of identifiable private information or identifiable biospecimens.

And one of the following is true:

✘ The identifiable private information or identifiable biospecimens are publicly available.

✘ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

✗ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Category 5

✗ The project is a research or demonstration project.

Additionally the following must also be true.

✗ The program under study is designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

✗ The research is conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

✗ The Federal department or agency conducting or supporting the research and demonstration projects will establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project will be published on this list prior to commencing the research involving human subjects.

Category 6

✗ The research involves taste and food quality evaluation or is a consumer acceptance study.

Either of the following is true:

✗ Wholesome foods without additives are consumed.

✗ If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following agencies:

Please check which of following

✗ The Food and Drug Administration.

✗ The Environmental Protection Agency.

✗ The Food Safety and Inspection Service of the U.S. Department of Agriculture.

Consent Process for Exemptions

1. While the full regulatory requirements for consent do not apply, some exempt research does involve talking to or interacting with human participants. Under these circumstances, there is still the expectation that you will tell people what you are doing and why, and invite their voluntary participation. If this describes your study, then describe the process for obtaining consent from the subjects. This may or may not include a written consent document or script; if you plan to use a written document, please upload as an attachment as the end of this application process. Example consent document for exempt research.

This should describe how they are getting consent. It should include how the information will be provided to subjects (e.g., with survey; when they are called on the telephone) and how participants may ask questions (e.g., PI contact information included in the consent information), and how consent will be confirmed (e.g., read consent form and agree to proceed with survey, verbally confirm). For exempts, it doesn't need to be a separate form/document, but we do need to know what they're telling people. Included within the recruitment email or within a survey are both acceptable.

Often we get the consent language here. We do not want it here because we review it as an attachment and if it is here as well we risk updating in one place but not the other. See macro:

Exempt – Consent Process (only text provided)
Please remove the consent text from this section and upload it as a Word document in the Attachments section. Additionally, please describe your consent process in this section.

If this is a benign behavioral intervention where deception/withholding is being used, this section should also contain how participants will be prospectively informed and how they will be debriefed afterwards.

Important note: There is no regulatory requirement to obtain consent, however we do expect participants to be informed. Avoid any language such as "signed consent waiver" as these regulations don't apply.

General Information

1. General Information

1. Project Title

   Exempt 2 & 3 Annotated Application

2. **Brief Summary**. Provide a **brief non-technical description** of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

   Purpose: This section should summarize the purpose of the research project.

   Participants: This section should describe the population they are studying by having them complete a survey and/or undergo a benign behavioral intervention.

   Procedures (methods): This section should include survey, focus group, interview, etc. for exempt 2. If includes BBI, should also be briefly described for exempt 3.

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

   Yes

If yes, provide IRB study number here (and explain in the COVER MEMO why this is relevant to the current study and why it would be useful for the IRB to know).

If you are sending stips, ask for the explanation in the cover memo if it is not provided.

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

   No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.
   - List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
   - If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
   - If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

   The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Liaison	Last Name	First Name	Department Name	Role	
University of North Carolina at Chapel Hill (UNC-CH)					
	Grubbs	Marie	Office of Human Research Ethics	Principal Investigator	view
	Cantrell	Celeste	Office of Human Research Ethics	Co-investigator	view
★	Pastore Rampazzo	Marina	Office of Human Research Ethics	Co-investigator	view
	Yocum	Dustin	Office of Human Research Ethics	Co-investigator	view

If your research includes personnel from a UNC Health Network Entity (NE), the UNC Health Office of Research Support and Compliance (ORSC) will review your IRB application and/or submitted UNC Health Collaboration Survey. You may be contacted by ORSC for additional information. IMPORTANT: In addition to obtaining IRB approval, you must also receive ORSC clearance for project personnel employed by the NE site(s). Project personnel MAY NOT proceed with research activities until you have obtained both approval from the IRB and clearance from the NE. Upon completed ORSC review, an ORSC NE Clearance Form will be provided and uploaded to the IRB application Study Documents section.

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Office of Human Research Ethics

3. Funding Sources

1. Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?

   Yes

Is UNC-CH the **direct** recipient of any Federal funding for this study? You should answer 'yes' *only* if you are the grantee. You should answer 'no' if you are the recipient of a sub-award or contractor under the grant.

Yes

Funding Source(s) and/or Sponsor(s): Please list all entities that are providing monetary support or supplies (e.g., study drug, gifts, devices at no cost, or others that provide in-kind services).

Sponsor Name	UNC Ramses Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail

National Institutes of Health (NIH)	Currently Not Available	Federal				view

2. Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

   Yes

Internal UNC Chapel Hill funding

Department Name	Detail
Office of Human Research Ethics	view

3. Is this research classified (e.g. requires governmental security clearance)?

   No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

✔	Grant Application
✘	Industry/Federal Sponsor Master Protocol
✘	Student Dissertation or Thesis Proposal
✘	Investigator Initiated Master Protocol
✘	Other Study Protocol

5. Is this a Clinical Study?
   Check YES if this study involves research using human volunteers that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. Do NOT check yes merely because you are conducting research in a clinical setting or using clinical data.
   Click here for additional definition of "Clinical Study"

   No

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH (click for details)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

   Yes

The next questions will determine if there are HUMAN SUBJECTS (click for details)

2. Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

   Yes

3. Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).
   OR
   Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations?

   No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.)

   No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

   No

6. Is the UNC Chapel Hill IRB taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC Chapel Hill? Or you are asking the UNC Chapel Hill IRB to cede review to an External IRB. If so, a reliance agreement will need to be executed prior to conducting any research activities.

   No

Location

1. Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States?

   Yes

Research conducted in foreign countries requires knowledge of local customs and cultural norms. Please review the International Research Guidance and Worksheet. Attach the completed worksheet to your submission. The International Research Guidance and Worksheet is not required if you are relying on an external IRB. In the attachments section, click International Research Guidance and Worksheet and select the Not Yet Available / Not Applicable checkbox.

Please review the OHRP International Compilation of Human Research Standards for information regarding the conduct of research in any country or countries you intend to involve.

All UNC students, faculty, and staff traveling internationally for this study are required to submit their itinerary to the Global Travel Registry.

Will your research project involve the Galapagos Islands, Ecuador?

No

If yes, your application will be reviewed by the UNC Center for Galapagos Studies. This Center will be included in routing for approvals after you submit.

Please specify any countries in which the research will be performed

✔ Malawi

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

This should be straightforward but we often get one or two lines only. We don't need an extensive background on exempt studies but do want some information as to how they got to this research question and why it is important. You can stip if they have not provided much. See macro below:

A.1.1. – Provide background: *Because you have not provided a grant application or other type of proposal, please provide a more extensive background and literature review, including references.*

If the only thing they've left out is references, but you can understand the rationale behind the study, it's not necessary to stip for references. Students don't always have a fully-developed rationale, so be cognizant of their limitations.

Beware: This is where some NHSRs are hiding! If they state something like "The survey results will be used to design marketing materials for the Tarheel Movie Festival" or "The results will be used by the clinic to improve the services they offer." please consider whether this project is intended to contribute to generalizable knowledge.

A.2. Subjects

A.2.1. Total number of subjects proposed across all sites by all investigators (provide exact number; if unlimited, enter 9999):

200

A.2.2. Total number of subjects to be studied by investigators being provided oversight by the UNC IRB. (provide exact number; if unlimited, enter 9999):

100

A.2.3. If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

A.2.1 and A.2.2 above should match if UNC is the only site involved.

If the numbers require an explanation that should be provided here.

Examples:

- The survey will be sent to all undergraduates and we anticipate conducting interviews with 30 students
- 50 participants will be assigned to Article A, 50 to article B, and 50 will read no article

If they request an unlimited amount (9999) make sure it's justified. If they're using Mturk, they have control over how many participants they can include. If they're sending something via mass UNC email, they may not have a good idea of how many to anticipate.

A.2.4. Do you plan to enroll subjects from these vulnerable or select populations:
If you will include children, prisoners or nonviable neonates or neonates of uncertain viability, please check the appropriate category below and complete the additional sections.

You should check "Pregnant women" if you specifically intend to recruit women who are pregnant or are not excluding pregnant women in biomedical research that is greater than minimal risk. Do not check if you are conducting a survey of the general public or conducting secondary data analysis or chart review not aimed at pregnant women.

Only check UNC-CH Student athletes, athletic teams, or coaches if you have specific plans to enroll these subjects. This is not applicable for intramural or club sports. For definitions and guidance see SOP 1201: Vulnerable subjects in research.

- ✗ Children (under the age of majority for their location)

  Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.
- ✗ Pregnant women
- ✗ Nonviable neonates or neonates of uncertain viability
- ✗ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)

  If an enrolled participant becomes incarcerated during the course of the research, they must be removed from the research project until such time as the IRB (and OHRP for NIH funded projects) approves the study to include prisoners, unless there is an immediate risk to the participant from ending treatments under the protocol.
- ✗ UNC-CH Student athletes, athletic teams, or coaches

A.2.5. Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply. This is not applicable to secondary data analysis or chart review.

Based on your responses, the consent form builder will insert the required text into your consent form template.

- ✗ Decisionally impaired individuals

  (e.g., Mini mental state examination (MMSE), Montreal cognitive assessment (MOCA))
- ✗ Children who are wards of the State (Foster children)
- ✓ Non-English-speaking individuals
- ✗ UNC-CH Students
- ✓ UNC-CH Employees
- ✗ People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim.

  This would include studies that might uncover or expose child, elder or domestic abuse/neglect. (See SOP Appendix A)

A.2.6. If any of the above populations are checked (excluding 'Decisionally impaired individuals' and 'Children who are wards of the State (Foster children)'), please describe your plans to provide additional protections for these subjects.

Note that this list is broken up this way intentionally. The first list is about groups you are targeting (Q4), while the second list (Q5) is those likely to be included based on you you are recruiting and who you are targeting. Most common are UNC students and employees since many survey studies are being advertised on campus.

For UNC students/employees, the response should mention that it will be made clear to subjects that participation will have no bearing on their employment nor standing with the university. If this is subject pool for course credit, they may need to clarify that there are other options outside of the research to get course credit.

For Non-English Speaking, translated documents should be provided or since it's a survey study only we can consider just having a translator facilitate but that is not preferred and would likely only be allowed for really minimal risk surveys.

To address Q.4: The only items we should see are pregnant women (only if specifically targeted, and there is no pregnancy finding necessary for exempt) or " UNC-CH Student athletes, athletic teams, or coaches". If the latter is selected, please seek athletic approval.

The response to question #7 may include children for Category 2 only where the study involves educational tests or the observation of public behavior when the investigators do not participate in the activities being observed. Category 2 surveys and interviews cannot include children.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	18
	years
Maximum age of subject enrolled	99
» If no maximum age limit, indicate 99	
	years

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

A.4.1. Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

No

A.4.2. Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

We often get very low effort responses here as well. We don't need too much but want the survey/interview administration described. See useful macro below:

A.4.2. Describe study procedures
Please fully describe the study procedures. Please provide more information on what data you will be obtaining and how you will utilize it to accomplish your study aims.

Items to consider:

- When/where will these activities be completed (electronic or in person?)
- Will interviews be recorded?
- If there's a pre/post design will they link individuals' responses over time? If so, how?
- If a benign behavioral intervention, it should be fully described here. If there are different conditions, describe the differences between them.
- If information is being manipulated or withheld, that should be included as part of the study

design.

- Item A.4.3 below should be consistent with what's described here. Stip for any mismatch.
- Often recruitment or other irrelevant information is included here, and you can stip that it be moved this can be moved to section B (or other applicable section)

A.4.3. Will this study use any of the following methods?

✔	Audio Recording
✔	Video Recording
✘	Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
✘	Pencil and paper questionnaires or surveys
✘	Electronic questionnaires or surveys
✘	Telephone questionnaires or surveys
✘	Interview questionnaires or surveys
✘	Other questionnaires or surveys
✘	Focus groups
✘	Diaries or journals
✘	Photovoice
✘	Still photography
✘	Unencrypted Messaging with Participants (e.g., text messages, unencrypted emails)

A.4.4. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

Not usually relevant to exempt 2 & 3. Can be left blank.

A.4.5. Are there cultural issues, concerns or implications for the methods to be used with this study population?

Yes

Please explain

Usually not relevant, but if a specific cultural population being recruited, or the survey is being conducted in an international setting there may be some concerns about how it is perceived in that setting. Generally will accept any response that we get that shows they have thought about it and it is not a major concern.

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Psychological

- ✘ Emotional distress
- ✘ Embarrassment
- ✔ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.2. Describe any potential psychological risks checked above and what will be done to minimize these risks

Consequences of breach of confidentiality should always be checked at least once. The macro below is helpful explaining.

A.6. Risk - Breach
As risk of breach of confidentiality is a risk in any research that stores data, please check "Consequences of breach of confidentiality" and describe what will be done to minimize the risk of breach of confidentiality.

A.6.3. Social

- ✘ Loss of reputation or standing within the community
- ✘ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.4. Describe any potential social risks checked above and what will be done to minimize these risks

No Answer Provided

A.6.5. Economic

- ✔ Loss of income
- ✔ Loss of employment or insurability
- ✔ Loss of professional standing or reputation
- ✔ Loss of standing within the community
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.6. Describe any potential economic risks checked above and what will be done to minimize these risks.

Generally these should not be selected as if these are probable concerns it may need expedited review. Be sure to check this against what they say about risks in the Exempt explanation. If they selected, "Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation." that needs to be reconciled somehow. Generally, the researcher has overstated these risks and just selected any hypothetical, worst-case scenarios. If the research itself is not steering toward content that would go toward the risks or is not in a setting that would magnify these risks, then they do not need to be selected.

If these are risks we can consider for a limited IRB review if there is identifiable information but definitely need to think about the appropriate level and how probable these risks are.

A.6.7. Legal

- ✔ Disclosure of illegal activity
- ✘ Disclosure of negligence
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.8. Describe any potential legal risks checked above and what will be done to minimize these risks

Illegal activity + Identifiers will usually lead to expedited review.

Generally these should not be selected as if these are probable concerns it may need expedited review. Be sure to check this against what they say about risks in the Exempt explanation. If they selected, "Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation." that needs to be reconciled somehow. Generally, the researcher has overstated these risks and just selected any hypothetical, worst-case scenarios. If the research itself is not steering toward content that would go toward the risks or is not in a setting that would magnify these risks, then they do not need to be selected.

If these are risks we can consider for a limited IRB review if there is identifiable information but definitely need to think about the appropriate level and how probable these risks are.

A.6.9. Physical

- ✘ Medication side effects
- ✘ Pain
- ✘ Discomfort
- ✘ Injury
- ✘ To a nursing child or a fetus (either through mother or father)

A.6.10. Describe any potential physical risks checked above, including the category of likelihood and severity, and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25 - 50%)
- Likely (approximate incidence of > 10 - 25%)
- Infrequent (approximate incidence of > 1 - 10%)
- Rare (approximate incidence < 1%)

Describe severity of risks using the following grading scale:

- Mild- No disruption to the subject's ability to perform daily activities; may include non-prescription intervention only
- Moderate- Temporary interference with daily activities; may include prescription intervention
- Severe- Interference with daily activities; medically significant but not life threatening
- Life threatening

Examples:

Rare (< 1%) and Severe: blindness
Rare (< 1%) and Mild: dry skin, dry mouth, transient headache

If you are using these terms differently than described above, please provide your study-specific definitions.

Phase 1 trials: Due to limited experience, incidence may be better described as the number of events that have occurred in the total number of animals/humans studied.

There should be no physical risks for survey/BBI studies. Paper cut does not count.

A.6.11. Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

Psychological counseling could come into play, but if that's the case, expedited is likely more appropriate.

A.6.12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study?

No

A.9. Identifiers

A.9.1. Check which of the following identifiers you already have or will be receiving, or select "None of the above."

- ✔ Names (this would include names/signatures on consent forms)
- ✔ Telephone numbers
- ✘ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✔ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✘ Fax numbers

✔ Electronic mail addresses
✘ Social Security numbers
✘ Medical record numbers
✘ Health plan beneficiary numbers
✘ Account numbers
✘ Certificate/license numbers
✘ Vehicle identifiers and serial numbers (VIN), including license plate numbers
✘ Device identifiers and serial numbers (e.g., implanted medical device)
✘ Web universal resource locators (URLs)
✘ Internet protocol (IP) address numbers
✘ Biometric identifiers, including finger and voice prints
✔ Full face photographic images and any comparable images
✘ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
✘ None of the above

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

✘ with the research data (i.e., in the same data set and/or physical location)
✔ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:
Best practice is to keep identifiers separate from the responses. But if this is exempt/low risk not a deal breaker. But check against what they say in exemption and risk mitigation of breach of confidentiality. Things to consider: If they indicated video recording in A.4.3, they should select "Full face photographic images and any comparable images." Audio recording does NOT mean that "Biometric identifiers" should be checked. If this study is about a medical topic and they include "Medical record numbers" here, this likely needs expedited review.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

A.10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

Coding, anonymous responses, use of pseudonyms, etc. is all good.

The response to this question should also describe where/how data will be stored (i.e., stored in a secure server, stored in the REDCap database, etc.).

A.10.2. Describe how data will be transmitted among research team (i.e., personnel listed on this application).

#3 below should typically be "no." Otherwise we're likely looking at expedited review." (unless participation is truly anonymous)

A.10.3. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?

No

A.10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study? Please note that all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable information is automatically issued a Certificate of Confidentiality (CoC). You should also select "Yes" if your study is NIH funded and has been issued a CoC under this updated NIH policy.

NOTE: Investigators utilizing ANY federal funding to conduct this research should review the COC website to determine if their funding agency issues COCs automatically (as the NIH does) or if they might need to apply for the COC via the online COC system. Unfunded and non-federally funded investigators may also apply for a COC via the online COC system.

No

Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

- ✔ In person
- ✘ MyChart

To utilize MyChart for research recruitment purposes, please complete the form (click here), and upload a PDF copy of the completed MyChart request to your application.

- ✔ Participant pools
- ✔ Presentation to classes or other groups
- ✘ Letters
- ✔ Flyers
- ✘ Radio, TV recruitment ads
- ✘ Newspaper recruitment ads
- ✔ Website recruitment ads
- ✘ Telephone script
- ✘ Email or listserv announcements
- ✘ Follow up to initial contact (e.g., email, script, letter)
- ✘ N/A
- ✔ Other

If other, please specify

If "Other" is selected, then the recruitment method need to be specified here.

B.1.2. **Research for Me @UNC**
A comprehensive study listing and engagement site intended to fulfill the mission of improving transparency and awareness of research at UNC.
All study involving direct interaction with participants must be listed on this site; you may choose whether to further utilize your listing for participant recruitment.
Instructions:

- Choose Basic or Recruitment
- Click on link to open listing submission form in a new tab
- Submit online form

✔ **Basic Listing** **(Click here to open basic submission form)**

For studies that do not want to be contacted by potential participants. Submit very basic information in lay language, but no details or team contact information will be displayed.
Exception from this kind of listing is rare, but may be requested for consideration via this form.

✘ **Recruitment Listing** **(Click here to open recruitment submission form)**

For studies that want to utilize the free recruitment features of the website. Participants can view more details about your study and contact the team to express interest.
You control the timeframe for display. Get a unique URL and QR code for use on other materials. Site is promoted to patients and the public by NC TraCS.

View examples, manage submitted listings, find FAQ, and download PDFs at researcherdashboard.unc.edu
Please direct all questions and feedback to Research for Me

B.1.3. Describe how subjects will be identified

This item is often answered incorrectly. See macro for how subjects will be "identified"

Should describe how they are going to conduct their search for the people they want in their study. In exempt 2/3 it is usually really general and they go about posting flyers on campus, sending emails on a listserv, announcing in class, etc.

This is more important for more targeted studies but we still want them to describe their search for their participants.

If they mention classes/listservs/facebook groups, etc, ask what kind so we can assess whether or not selection of subjects is equitable. We don't necessarily need a comprehensive list

B.1.4. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

Same as above for exempt 2/3.

Things to consider:

- If they indicate the use of social media, use the social media stip to get more info
- If they indicate "snowball sampling" ask them how they will operationalize that. Generally, study teams should not be given potential participants' contact without their permission. It can be allowable if the topic is benign or related to participants' professional roles (i.e. recruiting school librarians this way may be fine but recruiting those with Type II diabetes may not)
- Everything selected in B.1.1 should be addressed. Stip for any inconsistencies.

B.1.5. Describe how you will protect the privacy of potential subjects during recruitment

This may or may be relevant depending on the recruitment method. I think this item may only open if the third option (identifiers) is selected in Category 2/3

B.1.6. Describe how subjects will be contacted, if not addressed above

They should have already told you, but if they didn't, ask here! Everything they checked in B.1.1 should be reflected somewhere.

B.3. Subject Contact, Duration and Privacy

B.3.1. Number of contacts per subject (contacts includes in-person, telephone, email, mailings, etc.)

Should include recruitment, consent and data collection

B.3.2. Duration of each contact. If multiple contacts, provide the range or average time for each contact.

Check 2 & 3 to make sure they're consistent (e.g. 3 contacts of 20 minutes each doesn't lead to 20 total minutes of participation.

B.3.3. Total duration of individual subject's participation, including follow up evaluation, if applicable

20 minutes

B.3.4. Where are you studying subjects or obtaining their data?

✘ Non-healthcare setting
✔ Healthcare setting

B.3.5. Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope)

For sure, B.3 only opens up if subcategory 3 (identifiers) is selected in Category 2/3. This section is relevant to the limited IRB review.

Part C. Existing Data, Records, Specimens

C.1. Data Sources

C.1.1. What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'):

✘ Medical records in any format.

ALERT: You must check both boxes: 1) Medical records in any format and 2) Electronic medical record using Epic, or you/your study team will not be granted access to Epic for research purposes.

✘ Electronic medical records using Epic, WebCIS or other electronic system
✘ Carolina Data Warehouse for Health (CDW-H) (for UNC and its affiliates only)
✘ Carolinas Collaborative Data Request and Review Committee (DRRC)
✘ Paper medical records

If you access the medical records of fewer than 50 patients under a full or limited waiver of HIPAA, submit a copy of your IRB approval letter and a completed Research Disclosure Form to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at : 919-595-5591 or 919-966-1225 or 919-595-5580.

❌ Data already collected from another research study

Were the investigators for the current application involved in the original collection?	--

❌ Patient specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess?	--

❌ Data already collected for administrative purposes

❌ Student records (You will need to satisfy FERPA requirements: see SOP 3101, section 3.1 for guidance)

❌ UNC Dental Records

❌ Data coming directly from a health plan, health care clearinghouse, or health care provider?

❌ Publicly available data

❌ Other

✅ None of the above

For EACH data source checked above, provide a description of the data, proposed use, how data were collected (including consent procedures), and where data currently reside.

Sometimes we get the description of where they are getting their recruitment information. If that is elsewhere, this part can remain "None of the Above." If "Medical Records" are selected need to consider if expedited review and HIPAA Authorization are needed. Sometimes investigators want to access Medical Records to obtain the contact information of potential subjects who will be invited to participate in the survey/interview/BBI. This may still fit exemption. The analyst should send a stipulation with the Limited HIPAA Waiver (LHW) questions. See Macro: Exempt -Section C.1 Limited HIPAA If this is done, make sure they're not retaining any of the collected information as part of the research record. If they are, expedited review is needed.

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., pathology dept, tissue bank, original researcher):

Some odd answer we get are "we will ask the IRB", "we will get consent". Those are fine, but what we are really looking for is how are they getting permission from whoever is authorized to allow them to use it.

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

No

Attachments

This submission requires the following attachments

Document Type
Grant Application

International Research Guidance and Worksheet
Recruitment Ad for Participant Pool
Script for Class Recruitment
Flyer for Recruitment
Website for Recruitment
Other Materials for Recruitment

This submission includes the following attachments

File Name	Document Type

view attachments

Addenda

Data Security Requirements

view addenda

If Principal Investigator of this study is a Student or Trainee Investigator, the Faculty Advisor certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 2 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

Certifying Signatures:

Signature: ______________________ **Date:** ______________

Marie Grubbs

The expectation is that this approval is being given on behalf of the head of the Department, Division, or Center. If the chair or director is an investigator on this project or otherwise conflicted in approving it, the Vice-Chair or Chair's designee should review it. By approving, you are certifying the following on behalf of your department, division or center:

- This research is appropriate for this Investigator and our department
- The investigator(s) are qualified to conduct the research
- There are adequate resources (including financial, support and facilities) available
- For units that have a local review committee for pre-IRB review, this requirement has been satisfied
- I support this application, and hereby submit it for further review

This study proposes research that has been determined to include Security Level 2 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

- If you are approving for other purposes (e.g., CTRC, DSMB, IBC, PRC, RSC, or other review committees), you affirm the following: The proposed submission is approved and may be forwarded for IRB review.

Department Approval Signatures:

By signing in the appropriate space, the Department Chairperson(s) is indicating only that he/she has seen and reviewed this submission

Department: Office of Human Research Ethics

Signature: ______________________ **Date:** ______________

Name & Title: ______________________