Application Cover Memo

Cover memo prepared by Marie Grubbs on 08/09/2022 at 04:38 PM

1. If the data collected is coming from medical records and meets the criteria for a limited data set, it can still be granted an exemption **unless** the data is coming from Carolina Data Warehouse (CDW).
   It's **their** policy to require a full consent and HIPAA waiver, and we need the Full Form application in order to do that.
2. There are other data sources (such as CMS) that require full consent and HIPAA waivers. If a study team requests this, have them change their application type to "Full Form."
3. If the application doesn't provide enough detail for you to determine whether it needs expedited or exempt review, see the macro "Attachments - Data collection sheet." This asks the investigators to include a list of their variables which should provide you with enough information to make the determination.

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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 Answer Provided

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.

Explain

***Publicly available: This information CAN include identifiers, but the information should be truly publicly available (accessible to anyone). Examples: publicly available social media data (no restricted or private accounts), voter registration, some census data, COVID case or vaccine rates in a given geographical area. ***We typically see the second option. This can be medical records, secondary datasets from other research studies, any other administrative data. It can also include previously collected biospecimens if not able to be linked to individuals. Expedited 5 studies are often hiding in exempt 4 applications so always check A.9 to see if subjects can be individually identified. *** Remember that there are actually 4 subcategories. UNC doesn't use subcategory 3, so we've removed it as an option in IRBIS. This subcategory allows for the use of medical records even with identifiers, as long as it's protected by HIPAA. UNC is a hybrid institution and not all departments are HIPAA covered entities, so we're unable to exempt under this category. These studies can often be exempt at other institutions, but not here. If investigators tell you that their collaborators received an exemption and we're unable to grant one, this is likely the reason.

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.

It's OK for this section to be blank. The regulatory requirements surrounding consent do not apply to exempt studies. Most exempt 4 studies studies do not involve obtaining consent. This is fine, there is no waiver of consent required, and they don't have to provide justification. The data in these studies is either publicly available or not individually identifiable, so there shouldn't be much risk to subjects. Don't stip this section if it's obvious they're not interacting with subjects.

If they **are** obtaining consent to use this data for research purposes (very rare), we'd want the same information here that we always do. Additionally, the screening question (under General Information) should indicate that they're collecting data through direct interaction, even if the data is all secondary data. This will open up section B.1 so they can describe recruitment.

General Information

1. General Information

1. Project Title

   Exempt 4 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.

   What we get a lot here, when the project is analyzing data from another study, is that they explain the original study (e.g. "Interviews were conducted with 30 cancer patients...") Make sure it's clear from this section that they're using existing data.

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

Participants: This section should describe the population and/or the dataset being used. (e.g. "Pediatric Asthma patients seen at ABC clinic in 2019" "Previously collected tumor tissue from the tissue bank" "De-identified data from the XYZ Research study" "Publicly available Twitter data")

Procedures (methods): For these purposes, something brief such as "Retrospective chart review" can be ok. As with the rest of this section, it should be clear that this study is not collecting prospective data.

If the secondary data is coming from a previous UNC study, the answer to question #3 below should be yes.

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).

19-9645

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
	Pastore Rampazzo	Marina	Office of Human Research Ethics	Co-investigator	view
	Cantrell	Celeste	Office of Human Research Ethics	Study Coordinator	view
	Yocum	Dustin	Office of Human Research Ethics	Research Assistant	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?

   No

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

   No

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.

   No

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?

   Yes

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?

   No

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.

Beware: This is where some NHSRs are hiding! If they state something like "Data will be collected for quality improvement purposes" or "Program data will be analyzed to target recruitment efforts for the program" the project may not be intended to contribute to generalizable knowledge.

This is also where FDA regulations can be hiding. Look out for investigations of safety and/or effectiveness of drugs or devices. These will require expedited review, even if the study would otherwise qualify for a category 4 exemption.

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. Often several sites will pool their data on patients with a certain condition, so it's not uncommon to see different numbers.

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

Examples:

- We will pull the records of 100 patients who developed an infection following surgery and 100 patients who did not.
- This is a rare condition so we anticipate enrolling no more than 50.
- We will not know the exact number until we receive access to the dataset, which will occur after IRB approval.

9999 can be ok, depending on how they're collecting their data. If a medical chart review, or data that they have to apply to get access to, they may not know the number until they receive the data. If they're using data from a previous study, they may know how many people originally participated. Use your judgment.

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.

Item #4:

- If the age range includes children (or doesn't exclude children), that item should be selected. If pregnant women are specifically targeted in the chart review, that item should be selected. There are no child or pregnancy findings necessary, because those regulations don't apply to exempt studies.
- Prisoners should not be checked. If the research is focused on prisoners or if prisoner status will be known and included in the research, the study should be expedited. If prisoner inclusion is only incidental, exempt is ok.
- If UNC athletes/coaches is checked, please obtain athletic approval.

Item #5: These items are really related to consent and recruitment. As this typically doesn't apply to secondary data, nothing should be checked her in most cases.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	0
	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 insufficient responses here such as "N/A" or "Retrospective chart review". This section doesn't have to be long, but should at least contain a brief description of what the data is and how they'll be using it in the study.

If the data comes from a previous study, here they *may* provide more detail about how that study was originally conducted, though we don't necessarily need that level of detail. This is fine, as long as it's not too much detail, and as long as it's clear that the data or specimens have already been collected. Sometimes they will describe the previous study and not provide any information on what they're currently doing.

The macro below can be used to gather additional information as needed:

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.

Expedited 5 studies are often hiding in Exempt 4 applications. This is one place they may hide statements about receiving identifiers.

If they describe using assays on biospecimens, check to see if they're evaluating a medical device. If it's an established/approved assay or they're using it for research purposes without collecting any information about the assay itself, no action needed.

Nothing in A.4.3 should be checked, as those are prospective data collection methods.

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.

This typically doesn't apply, but occasionally this will be filled out for analysis of secondary specimens, which is fine.

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

No

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 <u>always</u> 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.

The risks in A.6 should describe the risks of the current study (secondary data analysis) rather than the risks of participation in the original study. Typically nothing other than "Consequences of breach of confidentiality" is checked.

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.

If any other risks are checked, such as economic or legal risks, consider how likely it is that subjects could be identified through this data (even if there are no direct identifiers). If the data is sensitive and re-identification seems possible without much difficulty, we can consider bumping up to expedited 5 to offer some additional protection.

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

No Answer Provided

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 shouldn't be any physical risks. If the data includes biospecimens, they will been collected outside of this research and the risks associated with their collection shouldn't be listed here.

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

No Answer Provided

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:
***In general, the identifiers selected should not allow for direct identification of individuals*. Date of birth wouldn't be considered a direct identifier in most cases (as many people share the same birthdate). City of residence is not a direct identifier, but street address is. These indirect identifiers may be stored with the research data, as they often are part of the research data. *** This is where most of the Expedited 5 studies are hiding! If Medical Record Numbers are checked, it's expedited. When dealing with medical records, if the identifiers contain any more than what's allowed in a HIPAA limited data set (https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/limited-data-set/index.html) it must be expedited. Limited Data Sets qualify for exemption BUT if they're coming from CDW, they need a full HIPAA waiver and must be submitted as "Full form" for expedited review. ***When medical records are used, investigators don't need to check every item that might be present in the medical records. Investigators should only check the items they will be extracting from the medical records, or the items they will be receiving. For instance, if CDW is providing them with a list of MRNs for eligible subjects, this must be expedited because the list of MRNs exists outside of the medical record. If they will initially receive data with direct identifiers and will delete them upon extraction, this must be expedited. There should be no way to link data back to a subject, even temporarily. ***If "de-identified" videos are used, but they contain subjects' full face, this likely needs expedited review. ***Remember that if data is publicly available, direct identifiers are ok!

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.).

Investigators will often write something like "Data contains no identifiers." That doesn't mean that the data doesn't need to be kept confidential (even in instances when publicly available data is used). While someone's tweets may be publicly available, a convenient list of them divided into categories and tagged for analysis is not.

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.). There is a macro for this.

A.10.2. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

Yes

Describe these groupings and sample sizes projected.

#2 above should typically be "no." If it's yes, consider the sensitivity of the data and whether expedited review may be appropriate.

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.

****What is selected here should be consistent with the rest of the application. "None of the above" should not be selected, as Exempt 4 studies are dependent on existing data or specimens. It should contain more information than "medical records" or "data from 19-9374" [See macro: C.1.1. Data description] ***If the data is publicly available (such as a publicly available dataset) you can ask for documentation that it's publicly available (such as a link to where the data can be found.) ***If you don't have enough information about the data to make a determination, there is a macro in the attachments section that you can use to ask for a list of variables that they will collect (Attachment Files - Data Collection Sheet). This isn't needed for every submission, but can be useful for determining whether or not something contains direct identifiers and should be expedited.

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):

There are likely other gatekeepers associated with accessing the data and they should describe how they will obtain permission here. Often, access to the data will be granted once the investigators receive IRB approval, so don't ask them for documentation of approval they may not have yet.

An exception is if the data is covered by FERPA. If they're not obtaining consent, you should ask for documentation from the university registrar that they're allowed to use this data for research purposes.

Data use agreements (DUA) are outside of our purview and don't require our review or approval. Even if they check that item below, we don't need to see it.

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

Yes

C.2. Coding and Data Use Agreements

C.2.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."

Yes

Will any of the personnel involved in this study (this includes collaborators providing data or specimens, personnel listed on grants, co-authors, and faculty advisors) have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples?

No

Answer the questions below to identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:

Data use agreement with custodian of data (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	Yes
Note: For Data Use Agreements, Non-Clinical Agreements, or Clinical Agreement Amendments, please submit the New OIC RRF and draft materials via email to OIC@unc.edu	--
Data are publicly available?	--
Honest broker (centralized custodian who controls data and will not release codes or IDs)?	--
Other	--

If other, please explain:

***If the data is coded and they won't have access to the key, they should complete this section to explain the mechanism keeping them from accessing the key, such as an honest broker (like CDW) or a data use agreement. Note that a member of the study team cannot serve as an honest broker. ***If the data is coded and the investigators WILL have access to the key (because they were/are involved in the original study) this can still be exempt if they clearly state in the application that they will create a separate database without identifiers and won't access any identifiers for this study.

Do ALL of these data, records or specimens exist at the time of this application?

No

If no, explain how prospective data collection will occur.

The study team shouldn't be involved in prospective data collection.

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 3 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 3 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: _____