General Information, Exemptions, Part A

RENEWAL SUBMISSIONS:

If the study has a DSMC, attach report or note in the cover memo if the board has not met or you have not yet received the letter.

If the study is industry sponsored, attach all monitoring follow-up letters, not previously submitted.

Be sure you select the appropriate "Renewal Action Request" in the Progress Report:

- Select, "Continue study as approved", if you are renewing a study that has always involved only analysis of data or specimens; there has never been any direct interaction or contact with subjects.
- Select, "Continue study as approved, including enrollment of new subjects", if you are renewing a study that involves direct interaction or contact with subjects.
- Select, "Enrollment of new subjects closed; interaction/intervention with previously enrolled subjects continues", if your study includes any ongoing interaction with subjects for the purpose of this study, including face-to-face visits during which study procedures or tests will be completed.
- Select, "Subjects have completed all research-related interaction, but study remains open for long-term follow-up", if your study includes ongoing activities that involve no more than minimal risk to subjects (e.g., quality of life surveys) or the collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence (e.g., collection of results from routine labs and radiological studies). NOTE: Research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk are NOT considered long-term follow-up (e.g., monthly collection of 5 mL of blood for research purposes only). If you are uncertain about whether your study is in long-term follow-up, please call the IRB and ask to speak with Coordinator.
- Select "All research-related interaction with subjects is complete, including any contact or follow-up. Renewal is requested for data analysis", if you have completed the study as described in the approved protocol/application and are analyzing data for this study. Once data analysis for this study has been completed and all data/specimens have been destroyed or stored of as described in your application, the study should be closed.

In the progress report section, be sure you update the enrollment numbers to accurately reflect the current numbers (including any changes you may be requesting as part of a modification to the study).

Do not respond to COI stipulations until you have checked and all COIs have been reported and RESOLVED. The IRB cannot approve your application until all COI issues have been resolved.

MODIFICATION SUBMISSIONS:

Make sure that modifications are accurately reflected in the application, consent documents, and recruitment materials.

If the modification is a result of an Unanticipated Problem (UP) report, be sure to indicate the UP Reference ID#.

Summarize all requested changes and list all revised documents in modification section. This information will be included in your approval letter.

For revised consent documents, remember to change version date (including footer, if applicable) and update file name. Conversely, you SHOULD NOT update consent version dates at renewal if you have not made any changes to the consent documents.

When revising consents, DO NOT DELETE the old version; instead REPLACE it with updated version. This allow the IRB reviewer to identify your changes.

General Information

1. General Information

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.

Summary should be BRIEF (50-100 words).

Please do not cut and paste from the protocol, use non-technical language that can be understood by non-scientists who may not be an expert in the field of study.

Please do not delete the headings: Purpose, Participants, and Procedures. The study description will appear in your initial and annual approval letters.

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).

Explain how the previous study is related to the current study (i.e., information that would be useful to the IRB reviewer).

2. Project Personnel

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.

PI and Faculty Advisor cannot be the same person.

Use the directory to select personnel. If the individual is not listed in the directory (i.e., external to UNC), select "person not listed" and enter information manually.

If the information in the directory is not current, it should be updated.

Verify, prior to submission, that all contact information for each person listed is correct.

Also see: NC TraCS Community Academic Exchange, a one-stop shop for anyone interested in engaging communities, faculty and healthcare providers in translational research at UNC-CH and across the state of North Carolina.

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?

If externally funded, be sure to enter funding source. If any materials (study drugs, incentives, etc.) are provided by a third party, they should be listed here.

Funding Source(s) and/or Sponsor(s)

More than one funding source can be added. If not in the drop down list, at the bottom, click not found and enter it manually.

If this information is not available when you submit your application, please update with your next modification or renewal.

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

If not externally funded and your study includes tests or procedures or if subjects are paid, you must indicate funding source (typically departmental).

Internal UNC Chapel Hill funding

Be sure to enter UNC funding if applicable. If this information is not available when you submit your application, please update with your next modification or renewal.

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

Most studies are NOT classified. Do not check 'YES' here unless you are certain this applies to you.

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

Attach associated document(s) in the as ATTACHMENT(S) at the end of the application.

4. Screening Questions

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.)

If yes, this application will require additional review by the Oncology Protocol Review Committee (PRC). A PRC Addendum will be generated for your completion.

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See guidance.

You should respond YES to this question if:

1.Research is being conducted at more than one site or facility.

2.Research personnel external to UNC-CH are part of the research team.

3.Organizations external to UNC-CH are "engaged" in the research.

4.Your are requesting a reliance agreement (where UNC will rely on an external IRB OR if you are requesting that UNC provide oversight for individuals or sites external to UNC-CH.)

Click on "See guidance" to access guidance document for detailed information about how to complete this section if you are requesting a reliance agreement.

5. Multi-site Study Information

2. Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH (e.g., as lead site, study headquarters or IRB of record for other sites)?

For additional guidance and examples, see the Office for Human Research Protections website (www.hhs.gov/ohrp). Please be clear as to whether UNC has oversight or if UNC is relying on another site.

When the collaborating site is a **GROUP or ORGANIZATION** outside of UNC-CH, complete the following information for each site:

Please be sure to contact the external institution to identify the correct signatory official. This is usually a high-ranking institutional official (not an IRB Chair) who has the authority to legally commit on behalf of the institution.

Exemptions

Request Exemption

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

If you are not familiar with the requirements for an exemption, read the guidance for exemption (guidance provides definitions and examples) before requesting exemption. If you select YES in error, you will be instructed to change your response to NO and complete the full application.

Part A. Questions Common to All Studies

A.1. Background and Rationale

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.

If you copy and paste from the protocol, you should edit the information for relevance, clarity, and length. Do not include text that is beyond the scope of the question.

State the research question(s) (i.e., specific study aims and/or hypotheses).

If you paste from protocol or consent, you should edit the information for relevance, clarity, and length. Do not include text that is beyond scope of the question.

A.2. Subjects

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

This is the total number of subjects for all sites. If UNC is the only site, your response will be the same as A.2.2. This is projected number to be enrolled; not the number of subjects to be screened.

If there is no upper limit on enrollment (e.g. prospective records review, bio-repository), enter "9999".

A.2.2. Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number; if unlimited, enter 9999):

Enter the total number of subjects to be studied at UNC or affiliated sites (e.g., Rex). This is projected number to be enrolled does not include the number to be screened. Be sure that your response here matches the information in the consent form.

If there is no upper limit on enrollment (e.g. prospective records review, bio-repository), enter "9999".

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:

Be sure to answer question. If not applicable, respond "n/a".

Example #1: Total # subjects = 4: "2 subjects in Arm I, 2 subjects in Arm II"

Example#2: Total # subjects = 8, subjects will be randomized to study drug or placebo: "Subjects will be randomized to study drug or placebo. The exact number of subjects in each group is unknown as this is a multi-site study."

A.2.4. Do you have specific plans to enroll subjects from these vulnerable or select populations?

> Do not check if status in that group is purely coincidental and has no bearing on the research. For example, do not check 'UNC-CH Employees' for a cancer treatment study or survey of the general public that is not aimed at employees.
>
> >>LIST<<

Check only those you are specifically targeting for enrollment. This is about prospective intention.

Do not check "UNC employees" because a UNC employee might enroll (even if you are utilizing the University mass email as a means of recruitment advertising); check only if you are specifically targeting UNC employees.

A.2.5. If any of the above populations are checked, describe how you plan to confirm status in one or more of those groups (e.g., pregnancy, psychological or HIV testing)

Be sure to answer for each group checked.

Examples:

Children Recruitment will be done in Orange County elementary schools; medical records will be used to identify subjects based on date of birth.

HIV positive Individuals being treated in the ID clinic, having HIV diagnosis documented in medical record; HIV status is self-reported by responding to recruitment flyer and will be confirmed by testing upon consent.

A.2.6. If any of the above populations are checked, please describe your plans to provide additional protections for these subjects

Be sure to answer for each group checked.

See OHRE SOP 32: Special Topics: Research Subject Groups.

A.3. Inclusion/exclusion criteria

A.3.1. List required characteristics of potential subjects (i.e., inclusion and exclusion criteria). If not covered, list also characteristics that would preclude their involvement.

If you copy and paste from protocol, include only information that is directly related to inclusion/ exclusion criteria.

You should avoid copying and pasting from the consent form as all inclusion/exclusion criteria may not be included.

A.3.2. Justify any exclusion based on race, gender or ethnicity

If excluding individuals based on race, gender or ethnicity, you must justify their exclusion. If not applicable, state that.

A.3.3. Will pregnant women or women who become pregnant be excluded?
If yes, provide justification and describe the type and timing of pregnancy testing to be used:

Provide justification for excluding pregnant women.

Both here and in the consent form, describe the method of pregnancy testing (e.g., urine, serum) to be used and frequency of urine pregnancy testing during the study.

A.4. Study design, methods and procedures

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)?

If the study includes treatment, exams (e.g. physical exam, range of motion assessment), testing (e.g., psychological assessments, x-rays), labs, sample collection, etc., you should respond 'YES'.

You should respond 'YES' even if your study is not considered a clinical trial if the study includes any procedures or tests.

You should always respond 'YES' if your study is a clinical trial.

A 'YES' response to this question triggers the biomedical portion of the application. (Failure to answer 'YES' when appropriate will result in you missing a necessary part of the application--description of study design.)

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.

You must complete this section; do not respond "see attached protocol".

Including a Schedule of Events table may be helpful.

If you copy and paste from protocol, you should edit the information for relevance, clarity, and length. Do not include unrelated information.

A.4.3. If subjects are assigned or randomized to study "arms" or groups, describe how they are assigned.

- Describe the methods of computing the randomization schedule (if any) and maintaining blinding (if any).
- Who will perform these computations?
- How will you verify each subject's eligibility prior to randomization?

Respond to all parts of the question.

If not applicable, state that.

A.4.4. Describe any follow up procedures.

This question applies to procedures that are planned as part of this research following the intervention portion of the study (e.g., annual physical exam or phone calls).

This does NOT apply to potential to recontact for future research projects.

A.4.5. Once this study has been approved by the IRB, for how many months or years will this study be active (you are collecting data or have access to identifiers)?

Provide the anticipated time (number of months or years) the study will be active. This includes data collection and/or time you will have access to identifiers.

A.4.6. Will this study use any of the following methods?

>>LIST<<

Check all that apply.

If you are pre-screening via telephone, you must include a telephone script.

All surveys, questionnaires, telephone scripts, and interview scripts must be uploaded with the application. If not yet available, state that in the cover memo.

A.4.7. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

If the research team already has the necessary specialized training please state that here.

If you will be training additional study members please explain how they will be trained.

If you have training materials, please attach to your application.

Examples: The investigator and all co-investigators are MDs who are proficient in reading/interpreting ECGs. The study coordinator has been training in phlebotomy. All study procedures will be completed by CTRC nursing staff.

A.4.8. Are there cultural issues, concerns or implications for the methods to be used with this study population?

Cultural concerns are often raised for international studies or studies involving non-English speaking subjects.

Respond 'YES' to this question and provide details below.

If not applicable, state that.

Please explain

You should provide details documenting your awareness of cultural concerns and what special protections are already in place or those you plan to put in place, to protect subjects.

Example: Cultural issues surrounding blood draws in sub-Saharan Africa. The investigators should be aware of the concerns of blood stealing and sorcery among the local population and have a plan in place to address it.

For more information see: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4125237/

For international studies, a local ethics review committee may be a more appropriate source for guidance regarding local context. See: http://ohrp.cit.nih.gov/irbresearch.aspx?styp=bsc. for to locate international IRB's.

Additionally, information can be obtained from appropriate consultant(s), e.g. an in-country expert with direct knowledge of the local context. In some cases, investigators or their on-site collaborators may be able to provide sufficient insight to the IRB. For further information see SOP 31.0 International Research. Additional guidance is available from the Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/international/index.html.

A.4.A. Biomedical methods and procedures

A.4.A.1. Is this an interventional study that involves treatment, evaluation or diagnosis of a medical disease or condition?
If yes, distinguish what is being done specifically for this research from procedures that would be done anyway for clinical care:

Differentiate between what would be done to/for the participant even if they were not in the study, Standard of Care (SOC) (i.e., routine clinical care) versus study-specific research procedures (things that would not be done if the individual was not participating in the study).

Be aware that a device, procedure, drug, etc. commonly used in clinical care, even if part of SOC/routine clinical care, may NOT be FDA-approved for that indication (i.e., off-label use). Healthcare providers often use 'off-label', 'combination', or 'modified' devices, procedures, drugs, etc., but when these 'SOC' devices, procedures, drugs, etc. are used for 'research purposes only', they are considered Investigational.

Consent documents should clearly indicate which procedures, treatments, devices, etc. are not FDA-approved as being used in the study. (Example: Drug X is approved to treat depression however, we are using Drug X in this study to see if is an effective treatment for weight loss. Its use in this study is considered experimental; it has not been FDA-approved for to treat weight loss.)

A.4.A.2. Is this a Clinical Study? Will this clinical trial be listed in ClinicalTrials.gov, either by you or the sponsor?

A 'YES' response to this question will automatically insert the required clinicaltrials.gov language into the consent documents. See guidance on clinical trial embedded in the question above.

If you have questions about clinicaltrials.gov. contact Monica Courdurier via email at m.coudurier@unc.edu or phone: 919-843-2333.

Choose the appropriate Phase designation for this clinical trial.

>>LIST<<

If other, explain.

A.4.A.3. If the study involves the use of placebo control, provide justification

Provide justification on why placebo is an integral part of the study. Include references to support your response.

A.4.A.4.Will this study involve drugs, biologics or other substances (such as a botanical or dietary supplement)?

For guidance on dietary supplements, see Section VI, C FDA guidance document UCM229175.pdf

Please respond “yes” if ANY drugs/biologics/substances are being given as part of the study, this includes approved and investigational drugs/biologics/substances.

Be aware that dietary supplements and herbal preparations may be considered "drugs". Please review FDA guidance document provided via link in the question.

Please list all drugs/biologics or other substances to be administered. Provide separate entries for combination drugs and describe in procedures. For complicated dosing schedules (e.g., dose escalation studies), provide range below and detailed information in procedures.

List ALL Drugs being given for research purposes - include both investigational and approved drugs/biologics/substances.

Drugs/biologics/substances being administered as part of the study that are not the focus of the study should also be listed (e.g., pre-medications such as Tylenol or Benadryl).

Example: If the focus of the study is an ophthalmological device, but use of the device requires eyes to be dilated, then the dilation drops should be listed as a study medication.

Investigational drugs include drugs that may be approved by the FDA for one indication, but will be used in the study for an indication that has NOT been FDA approved should be listed.

This 'off-label' use of drug(s) is common in clinical practice, but the off-label use makes the drug(s) 'investigational' when being used in Research. In these situations, an IND may be needed. If exempt from IND requirements, complete the IND Exemption worksheet (found on the IRB website) and upload as an attachment to your application.

A.4.A.5. Is there an Investigational New Drug application (IND) for this study?

If you have questions regarding an IND, contact Amy Franklin, email: Amy_Franklin@med.unc.edu, phone: 919-843-9514.

If you select IND exempt, complete the IND exemption worksheet (found on the IRB website) or provide correspondence from the FDA.

IND # for this specific study, if available (Note: Not the IND# associated with the DRUG):

List the IND number here.

Name of the party holding the IND (as listed on FDA Form 1571)

Specify who holds the IND (e.g., Sponsor, PI).

Where is the IND# documented?

Specify where the IND is documented. (Be specific: Master Protocol, page 4).

A.4.A.6. Will this study involve investigational devices, instruments, machines or software?

Questions regarding IND and IDE should be directed to Amy Franklin, email: Amy_Franklin@med.unc.edu; phone: 919-843-9514.

If you respond "yes", you must attach the device description and any other documentation describing the device and its approved use, including diagrams.

Is there an Investigational Device Exemption (IDE) for this study?

If you have an IDE, respond 'YES' and attach correspondence from the FDA.

Where is the IDE# documented?

Specify where the IDE# is documented. (Be specific: Master Protocol, page 4).

Name of the party holding the IDE (sponsor, investigator or other)

Provide name of the party holding the IDE. This might be an individual or organization (i.e., drug company).

If yes, provide rationale to support this determination or attach documentation from the FDA at the end of the application.

In order for the IRB to determine device risk, rationale to support a non-significant risk determination must be provided. Unless the FDA has already made this determination you must provide documentation from the Sponsor indicating that the device does not meet the definition of a significant risk device (and therefore is considered a non-significant risk device AS USED IN THE CONTEXT OF THIS STUDY).

Under 21 CFR 812.3(m), an SR device means an investigational device that:

- **Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;**

• Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

• Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

• Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Please refer to this FDA guidance for additional information: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

A.4.A.7. Does your study involve any of the following? (check all that apply)

>>LIST<<

Checking these will involve additional information, and often determines template language in consent forms.

Genetic testing: GINA and GWAS language will be automatically inserted into the consent form templates.

Testing for communicable diseases: Information regarding mandatory State reporting requirements must be included in the consent form.

Radiation: Approval letter from Radiation Safety Committee must be uploaded to the application and approved language inserted into the consent documents.

Gadolinium: Mandatory risk language will be automatically inserted into the consent form templates.

Gene therapy: Institutional Biosafety Committee (IBC) must also approve and a copy of the approval letter must be uploaded to the application.

A.4.A.8. Will your study involve storage of specimens for future unspecified research?

Samples are often kept for various lengths of time during the duration of the study, for example, they may be stored and shipped in batches to labs running study specific assays.

Respond 'YES' only if samples being collected will be stored and used for research unrelated to this particular study (i.e., future unspecified research). Responding "yes" to this question will prompt the system to generate a separate stored samples consent for study subjects.

Please explain:

Describe why specimens are being collected and stored. Include information about how long samples will be stored, where they will be stored, who will have access to the specimens, if they will be stored with identifiers, etc.

A.4.A.8 (2nd question) Will any personal identifiers or codes be retained with the specimens that would allow anyone to link the specimen back to an individual subject?

You should answer 'YES' even if there is a linkage code that is controlled by a 3rd party (e.g., honest broker).

Examples of identifiers, would include names, social security numbers, medical record numbers, or pathology accession numbers, or any other code that permits specimens or data to be linked to individually identifiable living individuals and perhaps also to associated medical information.

Coding means assigning a unique identifier to an individual's specimen or data. Ideally, the code or linkage file is stored separate from the data/specimens. Unless the code or linkage has been destroyed, the data/ specimens are considered identifiable.

A.5. Benefits to subjects and/or society

A.5.1.Describe how this study will contribute to generalizable knowledge that will benefit society.

If your study will contribute to generalizable knowledge that provides societal benefit, describe here.

Potential benefit to individual subjects should be described in below in A.5.2.

A.5.2. Does this study have the potential for direct benefit to individual subjects in this study?

If your study will have the potential for direct benefit individual subjects, describe here.

If specific benefits to minor subjects, describe here.

Explain

Describe known or anticipated benefits to subjects.

This is especially important to address for studies involving children and pregnant women (distinguish difference between possible benefits to mother or fetus).

If there is no direct benefit to the individual subject, state that.

Monetary payment or other compensation is not a benefit.

Benefit language must be added to the consent form as well.

A.5.3. Are there plans to communicate the results of the research back to the subjects?

Answer 'YES' if you plan to provide information to subjects about the outcome of the research, following completion of the study.

Do not answer 'YES' simply because you may be providing results of lab tests that were completed during the study.

If 'YES', describe below.

A.6. Risks and measures to minimize risks

1. Psychological

2. Describe any items checked above and what will be done to minimize these risks

The IRB is designated to protect the rights, safety and well-being of humans involved in research. Provide information here that will help the IRB understand how the PI and study team manage potential risks. If applicable, address risk of suicide.

A potential risk of breach of confidentiality exists whenever identifiers are being collected. Please check this item only once on this page and describe only once, what will done to minimize the risk.

3. Social

4. Describe any items checked above and what will be done to minimize these risks

For each checked, please describe risk and how it will be minimized.

5. Economic

6. Describe any items checked above and what will be done to minimize these risks.

For each checked, please describe risk and how it will be minimized.

7. Legal

8. Describe any items checked above and what will be done to minimize these risks

For each checked, please describe risk and how it will be minimized.

9. Physical

10. Describe any items checked above, including the category of likelihood 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%)
- Likely (approximate incidence of 10-25%)
- Infrequent (approximate incidence of 1-10%)
- Rare (approximate incidence < 1%)

Describe any items checked above, include category of likelihood 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%), likely (approximate incidence of 10-25%), infrequent (approximate incidence of 1-10%), rare (approximate incidence < 1%). AND include a description of what will be done to minimize these risks.

If withdrawal or tapering of a drug, include a description of potential associated risks AND include a description of what will be done to minimize these risks.

DO NOT describe who will cover the costs associated with study-related injury. This information should be described in Section B.5.1 (and in the consent document(s).)

When copying and pasting this information from a protocol, please include only information that addresses the question and edit to remove any macros, references, etc.

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

If not described elsewhere, describe how subjects will be provided medical care if needed.

If subjects will be evaluated for depression or suicide, describe your plan for assessing subjects, determining the need for follow-up, referral and/or counseling. Describe who will be responsible, including their qualifications.

12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study? If yes, explain

Describe here and in the consent form, your plans to follow subjects or partners who become pregnant. Describe if pregnant partner will be contacted or followed. If so, you will need a pregnant partner consent form.

A.7. Data and safety monitoring

A.7.1. When appropriate, describe the plan for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based data and safety monitoring board or committee (DSMB, DSMC, DMC), depending on the study. For studies that do not raise obvious safety concerns, you may still describe your plans for monitoring the study as it progresses.

Include information here describing your data monitoring plan. If you copy and paste from the protocol, edit to include only information that directly relates to this question.

A.7.2. If not already addressed above, describe the plans for aggregate review of unanticipated problems (including but not limited to adverse events) across all sites, in order to monitor subject safety.

This question is about AGGREGATE data analysis, not individual subject data.

If addressed above, state that.

A.7.3. What are the criteria that will be used to withdraw an INDIVIDUAL SUBJECT from this study or halt the research intervention (e.g., abnormal lab tests, allergic reactions, failure or inability to comply with study procedures, etc.)?

List criteria for withdrawal of INDIVIDUAL SUBJECTS from the study. Do not list criteria for stopping the study. If not applicable, state that.

A.7.4. Are there criteria that will be used to stop the ENTIRE STUDY prematurely (e.g., safety, efficacy, unexpected adverse events, inability to recruit sufficient number of subjects, etc.)?

Respond 'YES' if there are criteria for stopping the ENTIRE STUDY (not for withdrawal of individual subjects).

Please explain

List STUDY STOPPING RULES even if described in the DSMC Charter.

5. Will this study involve a data and safety monitoring board or committee?

>>LIST<<

If external or other, please identify here. You will be asked to attach charter and stopping rules later in the process. (limited to 200 characters)

If other, provide the name of the DSMB or DMC here.

A.8. Data analysis

A.8.1. Summarize the statistical analysis strategy for each specific aim.

Include discussion of the following when research proposal is a CLINICAL TRIAL:

For each aim, describe your statistical analysis plans in terms of:

- **key variables with well-defined scales (e.g. ,viral load in log10 RNA cA.opies/mL)**
- **the parameters to be estimated (e.g., mean differences)**
- **the null hypotheses to be tested (if any)**
- **and appropriate statistical methods.**

If any interim analyses will be conducted, please describe them.

What are your plans for computing confidence intervals?

What is your strategy for controlling the probability of false discoveries or type I errors?

Who will perform the statistical computations for these analyses?

A.8.2. What are the practical objectives of the study? Examples: pilot study to obtain data for a grant proposal, train junior investigators, create a registry, develop new assay methods, pilot-test procedures, evaluate feasibility, generate hypotheses, estimate parameters, test hypotheses.

Examples: pilot study to obtain data for a grant proposal, train junior investigators, create a registry, develop new assay methods, pilot-test procedures, evaluate feasibility, generate hypotheses, estimate parameters, test hypotheses.

A.8.3. If this is a pilot study, please describe the future study and say how its study design, aims, sample size, and methods differ from the pilot study you are proposing.

For example, in most pilot studies the primary aims do not involve hypothesis testing. (Note: A well-designed pilot study is preparatory for an envisioned future study).

If not applicable, state that.

A.8.4. Provide a compelling justification for the proposed sample size in terms of the likelihood of achieving each aim.

Include discussion of the following when proposal is a CLINICAL TRIAL:

- **State in simple language why you believe the proposed sample size is a good choice. Any claim made should be supported by discussion of related data (or information) previously published together with realistic conjectures that are thoughtfully developed for the new study.**
- **Describe the considerations that guided your choice of sample size.**
- **Discuss the anticipated precision of statistical estimates (e.g., expected widths of confidence intervals)**
- **If hypotheses will be tested in this study, discuss the anticipated levels of power of the hypothesis tests.**
- **How likely is it that each aim will be achieved? (Are some aims more risky than others?)**

For investigator-initiated studies, ensure this section has been reviewed by a statistician.

A.8.5. Summarize the plans for data management.

Include a discussion of the following when proposal is a CLINICAL TRIAL:

What is your plan for verifying that the data have been entered into the database correctly?

What software will be used?

Who will perform the computations for data management?

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."

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

Check one and then provide details below about how your data will be stored.

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.)

Do NOT check "YES' if you are only collecting SSN for the purpose of reimbursement only.

Please justify

If you are collecting SSN as identifiers, provide justification on why this is necessary.

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.).

This question is about maintaining CONFIDENTIALITY OF THE DATA (not about protecting the privacy of subjects).

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

Describe how data will be transmitted (i.e., shared among members of the research team). For example, with or without identifiers, encrypted email, FTP, password protected, etc.

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.?

Under North Carolina law, confidentiality does not extend to information about abuse or neglect of a child or disabled adult. If the researchers become aware of such information, they are required to report it to state authorities. If applicable, you should state this in the consent documents.

If yes, describe the sensitive data being collected

For example, sexual behavior, HIV status, recreational drug use, underage tobacco/alcohol purchase and use, immigration status, child abuse, pregnancy testing for youth, etc.

In NC, there is mandatory reporting for communicable disease and child/elder abuse. If applicable to your study, reporting information must be included in the consent documents.

In NC, youth pregnancy does not have to be disclosed to parents, however, if pregnancy were an exclusion criteria, parents would find out about pregnancy by default.

If you are enrolling minors and pregnancy testing will be conducted, include a statement in both the parental permission form and minor assent forms whether or not the results of pregnancy testing will be share with parents.

A.10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study?

You should consider obtaining a Certificate of Confidentiality from NIH to protect sensitive data from unwanted disclosures or requests. Your study does not have to be sponsored by NIH to obtain a COC (see link embedded in question for more information).

Process for requesting a Certificate of Confidentiality (CoC)

Part 1 - Request CoC:

1. Submit a modification to request a review of the CoC application. CoC requests require a previously approved protocol.

2. Respond "yes" to Question A.10.4.

3. Attach the completed CoC application and sample consent document(s) in the same file (do NOT upload the consent document(s) separately). Include the following language in the sample consent document(s):

What is a Certificate of Confidentiality?

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The researchers should include language such as the following if they intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.] The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. [The researchers should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.]

Part 2. - Following approval of CoC:

1. Submit modification.

2. Attach a copy of the approved CoC.

3. Upload consent document(s) that includes the CoC language (see above).

A.10.5. If relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

If there is a potential for subjects to be identified based on a combination of indirect identifiers (date of birth and diagnoses without name), discuss the potential for deductive disclosure here.

If this does not apply to your study, state that.

A.10.6. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?
Describe these groupings and sample sizes projected.

When responding to this question, consider a population that is so small or unique that subjects could be identified without direct identifiers.

Examples: A rare disease or disorder that might have been covered in the news, small group of school principals from one county, a very distinct ethnic group.

A.11. Data sharing and transmission

A.11.1. Check all of the following who will receive identifiable data (contains any of the 18 identifiers listed above) outside the immediate research team (i.e., not listed as personnel on this application)?

>>LIST<<

Check only if you will be sharing identifiers with individuals outside of the immediate research team.

Example: Check "external labs for additional testing" if date of birth will be documented on the laboratory request form.

A.11.2. For any recipients checked above, explain the confidentiality measures to be taken

Detail confidentiality measures for sharing identifiable data, for example data encryption, secure server, secure email.

For example given above (laboratory requisition), confidentiality measure would be that unique subject identifiers, not names, will be documented on the requisition. Combination of subject ID and date of birth necessary to confirm accuracy of specimen.

A.12. Post-study disposition of identifiable data or human biological materials

A.12.1. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

When study ends, what will you do with the identifiable data (paper, electronic, recordings) and or samples (including the linkage information?

Describe how you will destroy all forms of data and specimens individually.

Example: Specimens will be disposed of in trash, paper records will be shredded, linkage files will be deleted from computers.

If you do not plan to destroy or de-identify data, provide justification for maintaining and describe long-term storage plans.

Part B. Direct Interaction

B.1. Methods of recruiting

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

>>LIST<<

Upload all recruitment materials as attachments.

Recruitment advertisements should state clearly that the project is a research study and may include, where appropriate:

• Purpose of the research
• Summary of the eligibility criteria
• Clear description of the incentives (i.e., payment)
• Time and other commitment
• Location of the research
• Person to contact for further information

Provide SUBJECT LINE for email recruitment advertisements.

Advertisements should not:

• State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
• Include exculpatory language
• Emphasize the payment or the amount to be paid, by such means as larger or bold type.

2. Describe how subjects will be identified.

How will you initially identify potential subjects (before they are approached)?

This question is not about how you will recruit subjects; recruitment is addressed in question B.1.3.

Examples: Review of existing of medical records, review of census data, re-contact of former subjects, obtaining names from registry, self-identification in response to an advertisement (mass email, flyers, etc.)

3. 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.

Answer both parts of the question.

How and where subjects will be recruited?

Examples: Approach subjects during clinic or in class, recruit via telephone, via advertisements (include where will they be posted), via email or internet.

What is likelihood you will be able to get adequate number of subjects?

Examples: You have access to a number of patients seen with certain condition, you have previous experience with similar populations, school principal has already agreed to allow students to participate, you have completed a feasibility study.

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

Describe methods for protecting privacy of potential subjects while recruiting (before enrolling). This question is not about confidentiality of the data.

Examples: Taking potential subject to private area to discuss the study, making recruitment calls from private areas, using discretion when contacting subjects (not identifying the department on the envelope), sending mailing to home address only (i.e., not to place of employment).

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

Suggested Language to use in Recruitment Letters and Telephone Scripts if you are contacting subjects whose names were obtained from the Carolina Data Warehouse for Health (CDW-H)

The below examples include suggested language for Investigators use when contacting potential research participants whose names were obtained from the Carolina Data Warehouse for Health (CDW-H). Please note that any recruitment letters or telephone scripts must be reviewed and approved by the Institutional Review Board (IRB) prior to use with participants. The IRB may have additional suggestions or request changes to the language in these documents.

Recruitment letters should begin with any one of the following:

• We are contacting you because you were seen by UNC Health Care since 2004.

• Your records in the UNC Health Care System indicate you may be eligible to participate in our research study entitled "xxxxxxxxxx". We are contacting people who have either an xxxx (lab value) or xxxxx (specific inclusion criteria) …….

• You were seen by UNC Health Care in the past year. We are contacting people who are in the xx to xx age range who have been seen by UNC Health Care in the past year in order to tell them about a research program that we are doing.

• Based on your medical history, you may be eligible to participate in this study.

Telephone scripts should begin with something similar to the recruitment letters:

• Hello, my name is _____. I am a (student/faculty member/staff member) from the University of North Carolina at Chapel Hill conducting a research study entitled XXXXXXXXX. This study will test xxxxx in xxxxx patients. Your records in the UNC Health Care System indicate you may be eligible to participate in our research study OR based on your medical history, you may be eligible to participate in our study

• If participant asks for an explanation as to how investigator has access to his/her name and contact information: Answer: We received IRB approval to access medical records of patients in the UNC Health Care System who meet our research study criteria. Based on your medical history, you may be eligible to participate in this study.

Notes about the CDW-H patient database:

• Subjects do NOT actually sign up for the Carolina Data Warehouse for Health (CDW-H). The names of potential research participants are in the CDW-H by virtue of them having been seen by UNC Health Care in last few years.

• One should NEVER say "We are contacting you because you signed up with the Carolina Data Warehouse for Health (CDW-H)."

• Recruitment letters / telephone scripts should NOT make a reference or describe that patient data or records were provided by the Carolina Data Warehouse for Health. Recruitment documents should only reference or describe records in the UNC Health Care system.

6. Describe who will do the recruiting

Personnel who will do recruiting (names not needed).

Examples: Study coordinator, research assistant, treating physician, teachers, call center, subjects recruiting/referring other potential subjects.

7. Describe efforts to ensure equal access to participation among women and minorities

Examples: Oversampling to ensure adequate representation, translating study materials to non-English speakers.

It is also appropriate to justify exclusion of certain groups when warranted (e.g., women excluded from prostate cancer studies.)

B.2. Protected Health Information (PHI)

B.2.1. Are you requesting a limited waiver of HIPAA authorization?
If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a limited waiver of HIPAA authorization (see SOP 29.3). This does not apply to situations where you will never contact subjects directly (e.g., retrospective chart review), in which case you should request a full waiver under section D.

You will need a limited waiver of HIPAA to identify potential subjects who you will then approach to elicit their interest in the study.

Do not confuse this limited waiver of HIPAA with a complete HIPAA waiver which is needed for retrospective chart review studies (i.e., you will never contact or interact with subjects).

• If you are a healthcare provider, you may access the records of your own patients without a limited waiver of HIPAA Authorization.

• If you are a healthcare provider, your access to medical records does not extend to patients other than your own.

• If you are a healthcare provider, your access to medical records does not extend to members of your research team.

In all cases, subjects who agree to participate must sign a HIPAA authorization form.

You must destroy all data for subjects who do not agreed to participate in your study.

Please provide a response to each of the following questions:

Under this limited waiver, you are allowed to access and **use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects**. Describe the information you are planning to collect for this purpose

Describe how confidentiality/privacy will be **protected prior to ascertaining the patient's willingness to participate**

Describe when and how you will destroy the contact information if an individual declines participation

Describe the specific data elements you will need to identify potential subjects. This should be limited to the amount necessary to identify eligible subjects, based on study inclusion criteria. For example, name, diagnosis, date of treatment, age, results of last blood tests.

How will the data be protected? For example, storing recruitment list on a secure, password protected server.

If potential participant says no or can't be contacted, when and how will you destroy the data?

B.2.2. Will you need ongoing access to PHI (e.g., medical records) to conduct the study, beyond the identification of potential subjects as addressed above? In this case you will need to obtain a signed HIPAA Authorization from each subject.

A 'YES' response to this question activates the HIPAA Authorization Form template which must be signed by study subjects who agree to participate in the study if you plan to access medical records for the research.

Note: You will still need to edit sections of the HIPAA Authorization Form.

B.3. Subject Contact, Duration and Privacy

B.3.1. Number of contacts per subject

Total # of contacts per subject - including any phone calls, screening visits, follow-ups. This information should be the same information contained in the consent form.

For example: 6 clinic visits (including screening visit) and 4 follow-up telephone calls.

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

Here and in the consent form state how long will each contact last. Description should be given for EACH contact.

Example: Visit 1: 2-3 hours, Visits 2-4: 4-5 hours each, Telephone follow-up contacts at weeks 24 and 48: 30-45 minutes each.

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

Here and in the consent form state the total duration the subject will be participating/being followed.

For example, the study is expected to last a total of 24 months, including a final (follow-up) study visit. Subjects who withdraw from the study prematurely will be asked to return for a final (follow-up) study visit.

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

Non-healthcare setting
Healthcare setting

Check all that apply:

<<LIST>>

B.3.5. Provide more information about the location(s) where research will be conducted (e.g., if UNC Medical Center is checked in #4 above and study visits will be conducted in the CTRC, enter “CTRC” here.)

Locations subject will be seen/studied:

Examples: If you checked UNC Medical Center, you would add here: "Visits will be conducted in the CTRC and ACC clinics."

If you checked UNC Physician's Network, you would list the specific physician offices at which you are conducting your research.

B.3.6. 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)

How will subject's privacy be ensured during contact/study procedures; focus your answer on privacy of subjects following enrollment.

B.4. Incentives for participation

B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate or are you reimbursing subjects for study-related costs (e.g., travel, parking, hotel accommodations or childcare)?

You should respond 'YES' if you are providing either INCENTIVES OR REIMBURSEMENT for study-related costs.

A. Please describe any incentives and/or reimbursements for study-related costs separately below.

Separately describe both incentives and reimbursements for study-related costs. These also needs to be detailed in the consent documents.

Although reimbursements for travel, accommodations, etc. are not considered incentives, they should also be listed in the consent documents.

Be specific. Don't write: "Funds may be available to pay for travel expenses". Instead, explain who how eligibility for travel reimbursement is determined and what information will be provided to subjects. This information should also be reflected in the consent documents.

B. Specify the schedule for incentives and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.

Here and in the consent document(s), describe when subjects will be paid and payment per visit. Explain whether subjects get paid if they withdraw. List the possible total payment for completion of all study-related activities.

Example: Subjects will be paid upon completion of each study visit as follows: Visit 1 $25; Visit 2-8 $20 each; completion bonus $75. Subjects who complete the entire study will total payment of $240. If subject withdraws or is withdrawn, they will be paid for visits completed to that point.

C. For compensation in foreign currency, provide a US dollar equivalent.

If applicable, provide conversion in US dollars. If not applicable, state that.

D. Discuss the potential for coercion, given factors like the amount of the incentive, the age of the subjects, the purchasing power in foreign countries, the time involved and complexity of procedures, etc.

Consider if the incentive amount is appropriate. Discuss how/if the incentive could influene the decision to participate or the subject's willingness to take on risk. For poor countries, what is the relative value of the amount of incentive?

Example: Is the relative value equivalent to a cup of coffee or a week's wages?

State if the amount of compensation mandated or recommended by the Sponsor, network or consortium.

E. If the subjects are children who will receive the compensation, i.e., the child, the parents or both?

Be sure to make it clear and consistent between the application and the consent/assent/permission forms, who will receive compensation (parent, child, both?).

Example: $50 gift certificate to parent for completion of surveys about child and a small toy valued at approximately $10 to child for play observation visit.

If no compensation will be provided, state that.

B.4.2. Are you collecting Social Security Numbers for payment and/or tax-related purposes?
Check all that apply

Checking either selection generates a SSN Collection Form.

B.5. Costs to be borne by subjects

B.5.1. Will there be any costs that subjects will incur related to participation in the study? Do not include costs for standard care for which patients would be billed if they were not in this study. Also do not include the time spent participating in the study.

Especially for clinical studies, clearly describe research costs (paid for by the study) vs costs covered by subject or their insurance. Describe who will pay for costs associated with injuries incurred while participating in the study.

The consent document should include clearly describe the any costs or potential costs associated with the study.

When applicable, will the research team assist subjects in contacting their insurance provider to explore whether costs will be covered? If so, describe this here.

If yes, please check all that apply:

>>LIST<<

Include a response for EACH item checked in the space provided below.

Example: Childcare: The study has not set aside funds to pay for childcare. Childcare costs, if applicable, are the responsibility of the subjects.

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'): *

This question needs to be answered. Choose one of more sources of existing data or specimens. If "none", check "None of the above" (last item on the check list).

Please note that research involving student records (ex., course assignment, class rankings, diagnostic testing, course grades, PIDs, health records of students, etc.) protected under FERPA must satisfy University review requirements which may include review and approval by the Provost's Office.

Note that personnel who create records, (e.g., medical records created by treating physicians, academic records created by instructors, personnel records created by employers/administrators) do not automatically have permission to access these records for research purposes.

Data collected for administrative purposes include University records such as employment, public safety, performance, and HR.

Be sure to provide a response for each item checked. Describe data, proposed use, how collected and where stored.

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):

Although research personnel may have created the data to be used, they are not necessarily the custodians of the data. Examples: Student records requires permission from registrar, student medical records require permission from student health service, hospital medical records requires permission from Healthcare Information Management (HIM), public school records requires permission from the school district/ school principal, data from previously conducted research requires permission from the PI of the original study.

Some publicly available datasets require permission to access the records.

C.3.3. Do the custodians of the data, records or specimens require a data use agreement?

Many custodians will require a data use agreement of some form before they release records. Even when they do not, the IRB may request an agreement to support certain determinations. If a Data Use Agreement is contingent on UNC IRB approval of the study, please note this is in the cover memo.

UNC guidance on Data Use Agreements: http://research.unc.edu/files/2013/04/CCM3_039360.pdf

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."

If any member of the research team will be receiving coded data, check '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?

If any member of the research team will have access to a key that enables the linkage of data or specimens to individuals, check 'YES'.

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

This may be accomplished by a separate, independent intermediary (e.g., honest broker) who is not involved with the research.

If your response is "other", please explain.

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

You should answer 'NO' to this question if your study involves data/samples that will be collected prospectively and do not exist at the time of this application.

Data that was created during the calendar year, even if collected at the end of the calendar year, is NOT considered "existing" data.

Part D. The Consent Process

D.1. Obtaining informed consent from subjects

D.1.1. Will children under the age of majority in their locale (18 years in NC) be enrolled?

Note: For research purposes, children are defined by Federal Regulations as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Because there are very few laws that define research consent, applying this definition should focus on the age of consent for the procedures to be used in the research and whether there is an age of consent for this procedure outside of research. For example, there is an age of consent for most medical care circumstances, however if a person could agree to a procedure or activity outside the research context, that same principal may apply for research (e.g., a 17 year old can access contraceptive or pregnancy services without parental permission, minors can answer simple surveys without parental permission.)

D.1.1. (second question) Please explain the process for obtaining parental permission (unless waiver of permission will be requested later)

Explain the process for obtaining parental permission. It is generally required that parents give permission for child to participate in research, unless parental permission is waived by the IRB.

Examples where a waiver of parental permission may be considered include: Studies on child abuse and neglect, minimal risk surveys of college studies (some who may be < 18 years old), studies of older adolescents presenting to STD clinics, studies of legally emancipated minors.

Remember, informed consent is an ongoing process; it does not end with a signed consent document. If your study extends over a long period of time or includes complicated procedures, you should describe your plans for an ongoing informed consent process. This include reviewing contraindicated medications or study medication administration at monthly study visits to ensure the subject compliance and safety and documenting this in your study notes.

Check the characteristics of children to be enrolled: * (0-6 years, 7-14 years, 15-17 years)

D.1.1 (3rd question) Explain the process for obtaining the assent of the child (unless waiver of assent will be requested, in which case you should provide justification here).

Explain how assent will be obtained or if applicable, request a waiver of written minor assent below (Explain the process...)

You should request (and provide rationale) for a waiver of written minor assent. The IRB may waiver the requirement for written if it finds that all of the following are true:

1. The research holds out the prospect of benefit to the child,
2. The benefit is important for the child's health and
3. The benefit is only available in the context of research

The most frequent use of this waiver is for clinical trials of an investigational drug or device for life-threatening conditions (e.g., cancer treatment).

IMPORTANT: Unless consent is waived, minors should provide written assent upon reaching the age of majority.

D.1.2 (second question) Explain the process for obtaining consent from the subject or the subject's legally authorized representative, if relevant

Describe the consent process including who, what, when, where, and how.

This might include, providing the potential subjects with a copy of the consent form for their review prior to the sitting down to discuss the study with the subject, having potential subjects watch videos about the research project, "quizzing" potential subjects to ensure their understanding of the important aspects of the study.

D.1.3. Will decisionally-impaired subjects be enrolled in your study? (includes unconscious patients, some psychiatric disorders, others who lack the capacity to give consent)

If you answer 'YES' to this question, be sure you also checked decisionally impaired subjects in A.2.4.

Describe the process for obtaining surrogate consent from a legally authorized representative (LAR).

Describe how the LAR will provide consent. The LAR is defined legally and is not necessarily the relative who happens to be accompanying the subject. See SOP 28.11 surrogate consent for subjects who are decisionally impaired.

D.1.4. Are you planning to obtain consent from any Non-English speaking subjects?

If you answer "YES' to this question, you should also check non-English speaking in A.2.4.

Describe how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their legally authorized representative (LAR).

In answering this question, address written translation and oral interpretation. You must attach signed translation verification form. This form can be found on the IRB website: ohre.unc.edu

See OHRE SOP 28.12, Obtaining consent from non-English speaking and SOP 28.13, Translation and Informed Consent.

D.1.5. Describe who (by role) will be obtaining consent or parental permission.

Describe the role or position (e.g., study coordinator, PI, interpreter) of the person who will obtain.

Anyone involved in the consent process must listed as study personnel.

D.1.6 Discuss the potential for influencing the subject's decision to participate. Describe steps that will be taken to minimize undue influence during the consent process. These might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician).

If applicable, address the potential for a patient/student to feel obligated if their treating physician/ instructor is also the person obtaining consent. Also describe steps to minimize this risk.

For example, the MD/researcher might explain the details of the study with the potential subject, after which he/she will leave the room and informed consent will be obtained by the study coordinator.

D.2. Waiver of written documentation of informed consent

D.2.1. Are you requesting a waiver of any aspect of written (signed) documentation?

The IRB may provide a waiver of written consent for some or all subjects if it finds either:

•That the only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality.

OR

•That the research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

This would apply to studies where a signed consent will never be obtained because the entire study is not done in person (e.g., by phone, internet)

This may also apply to portions of your study. For example, where there is an initial phone/internet screening and those who qualify will later provide written (signed) consent.

D.2.1 (2nd question) Choose which one of the following justifies the waiver of written documentation: *

>>LIST<<

Explain/justify waiver of written consent:

Examples:

If the signed consent form would be the only record linking the subject in a study of illegal drug users, this waiver would be justified to avoid possible legal repercussions.

If the study entails having blood pressure measured at the local pharmacy, waiver of signed consent is justified as this is routinely done without written consent.

D.3. Full or partial waiver of consent

D.3.1. Are you requesting any of the following:
a full waiver of informed consent

a waiver of one or more of the elements of informed consent
a full waiver of HIPAA authorization

Use this section to request one of the following:

1) a full waiver of informed consent

2) a waiver of one or more of the elements of informed consent--See SOP Appendix B (45 CFR 46) or,

3) a full waiver of HIPAA authorization--See SOP 29.2.

Do not check to request a limited waiver of HIPAA to identify potential subjects. This should be requested in Section B.2.1.

Do not check if you are requesting a waiver of written consent. This should be requested in Section D.2.1.

D.3.1 (2nd question) Describe which elements you wish to waive or alter

The IRB may approve a consent procedure that leaves out or alters some or all of the elements of informed consent, if all of the following four criteria are met:

1. the research involves no more than minimal risk to the subjects;

2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. the research could not practicably be carried out without the waiver or alteration; and,

4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Example of alteration of element of consent: A study that includes deception, the entire purpose of the study may not be included in the consent form because doing so would not allow for data to be collected in way that is meaningful. Subjects are debriefed and informed about the true purpose of the research following their completion of the study.

Example of waiver of consent in its entirety: A single finger stick for blood glucose monitoring is being completed as part of a health fair. The results are being collected for research. Subjects are provided with a study information sheet.

Will you access the records of 50 or more patients under this waiver?

If you are accessing the records of < 50 patients, you must provide a list of the patients to Healthcare Information Management (HIM). Do not submit this list to the IRB.

To justify a waiver of the requirement for informed consent, you must affirm, by checking each of the following items that apply to this study. Provide a brief explanation.

The IRB may provide a waiver of informed consent in its entirety providing that ALL of the following four criteria are met:

• the research involves no more than minimal risk to the subjects;

• the waiver or alteration will not adversely affect the rights and welfare of the subjects;

• the research could not practicably be carried out without the waiver or alteration; and,

• whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In this section, you must check and explain how each of the statement applies to your study.

Note: *Impracticable* means that it would not be feasible to carry out the plan in an effective way. It does not mean inconvenience.

D.3.2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

If not applicable, state this.

Data Security Requirements

Data Security

1. Please provide contact information for the individuals or groups who will provide IT expertise and/or consultation for your study and/or will manage the devices where your study data is stored (IT support within your department or school, research staff with appropriate IT expertise, etc). If unsure, you should consult your department administrator.

Please provide the name and contact information for the UNC-Chapel Hill IT staff member designated by your department (generally not study personnel) who will provide data security oversight for this study.

Consent Forms

System-generated consent form templates should be used.

Please review consent forms closely and edit to assure that the information included in the consent form(s) matches information provided in the application (e.g., number of study participants, inclusion/exclusion criteria, and incentive payments, FDA vs. non-FDA-approved drugs).

Verify that all contact numbers provided in the consent form(s) are current and in working order.

Confirm that any Conflict of interest (COI) disclosure language provided by the COI office (if applicable) and subject injury language confirmed as accurate by the Office of Clinical Trials (for industry-sponsored studies) are incorporated into the consent forms.

Submit consent forms in MS WORD only.

Attachments

Attach all required documents here.

All recruiting materials (letters and flyers) must include specific study language (see SOP 25, Recruitment) including:

The purpose of the research, and, in summary form, the eligibility criteria that will be used to admit subjects into the study, a straightforward and truthful description of the incentives to the subject for participation in the study (e.g., payment), the location of the research and the person to contact for further information. The time or other commitment required of the participants.

Advertisements should not: State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol, include exculpatory language, or emphasize the payment or the amount to be paid, by such means as larger or bold type.

If you are required to attach an approval letter, please attach the approval letter, not application or request for approval.

Select the most applicable "document type" and name your document using a unique file name (e.g. Document type=electronic questionnaire, File name=QoL_ver1)