Appendix C

Form 1

CENTRA HEALTH - Institutional Review Board

INSTRUCTIONS FOR APPLICATION FOR IRB APPROVAL OF HUMAN SUBJECTS RESEARCH

Version 12, December 19, 2017

The purpose of this application is to seek ***initial*** IRB approval for a research study. The Principal Investigator is the person who will personally conduct or supervise this research study.

There are three levels of IRB Review [**full board, expedited (only applies after initial approval), and exempt *refer to FDA 45****CFR 46 101(b)***], determined by the nature of the project, level of potential risk to human subjects, and the subject population. *The type of review applicable to a particular study is determined by the IRB.*

Submission Instructions

This form is in Word format.

- Click into the highlighted area ( ) requesting an answer and type your answers into the form.
- Save the form and name.
- Send the application and All other pertinent documentation (ie protocol, informed consent, etc.) electronically via email to irb@centrahealth.com. All proposals for investigational activities must be submitted to the IRB at least fourteen (14) days prior to the next meeting in order to be considered in one of the next two meetings.

What parts of this application should you submit?

Answer all questions, or mark "not applicable," when appropriate. Do not alter wording or delete questions from this form.

- For ***all studies***, submit Part A, which consists of these sections:
  Part A.1. Contact Information, Agreements, and Signatures
  Part A.2. Summary Checklist
  Part A.3. Conflict of Interest Questions and Certification
  Part A.4. Questions Common to All Studies
  Part A.5. The Consent Process and Consent Documentation (including Waivers)
- For ***studies that involve direct interaction*** with human subjects (any contact with subjects including questionnaires, interviews, focus groups, observation, treatment interventions, etc), submit:
  Part B. Questions for Studies that Involve Direct Interaction with Human Subjects
- For ***studies*** **that use existing data, records or human biological specimens**, including for use in identifying potential subjects, submit:
  Part C. Questions for Studies using Existing Data, Records or Human Biological Specimens

Note: You should submit Parts B or C only as applicable. If the study involves *both* direct interaction *and* use of existing materials, use both Parts B and C in addition to Part A.

Address for all Applications and Other Correspondence

irb@centrahealth.com electronically or
Centra Health IRB, Administration
1901 Tate Springs Road, Lynchburg, VA 24501

Centra IRB Received (date):

Action:

Part A.1. Contact Information, Agreements, and Signatures

Date:

CHIRB#: (Will be assigned upon receipt)

Title of Study:

Name and degrees of Principal Investigator:
Department: Mailing address:

Phone #: Fax #: Email Address:

Center, institute, or department in which research is based if other than department(s) listed above:

Name of Project Manager or Study Coordinator (if any):
Department: Mailing address/CB #:
Phone #: Fax #: Email Address:

List **all other project personnel** including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. **Include name, location (local site or specific outside location), role and email address for each person who should receive electronic copies of IRB correspondence to PI.**

Name of funding source or sponsor (*please do not abbreviate*):
__ not funded __ Federal __ State __ industry __ foundation __ other (specify):

Name of IRB of Record: Centra Health IRB or Other: _____

For industry sponsored research (if applicable):

Sponsor's master protocol version #: Version date:

Investigator Brochure version #: Version date:

IND (Investigational New Drug) #:

IDE (Investigational Device Exemption #:

For FDA Required Monitoring for:
HUD (Humanitarian Use Device) #:_____
HDE (Humanitarian Device Exemption) # _____
Sponsors determination of risk: Significant Risk Study _____
Non-Significant Risk Study _____

Any other details you need documented on IRB approval:

Checklist of Items to Include with Your Submission

Include the following items with your submission, where applicable.

- Check the relevant items below and either send electronically (by email to irb@centrahealth.com) or include one copy of all checked items 1-9 in the order listed.

Applications will be returned if these instructions are not followed.

Check	Item
□	1. This application electronically (by email to irb@centrahealth.com).
□	2. Consent and assent forms (include DHHS-approved sample, when one exists), fact or information sheets, phone and verbal consent scripts.
□	3. HIPAA authorization (Form 7) and/or PHI: Waiver of Authorization (Form 5) as needed.
□	4. All recruitment materials including final copies of printed advertisements, audio/video taped advertisements, scripts, flyers, letters, and emails.
□	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc.
□	6. Documentation of reviews from any other committees.
□	7. Protocol, grant application or proposal supporting this submission, if any (e.g., extramural grant application to NIH or foundation, industry protocol, student proposal). This must be submitted if an external funding source or sponsor is checked on the previous page.
□	8. Data use agreements (may be required for use of existing data from third parties).
□	9. For drug studies, Investigator Brochure if one exists. If none, include package insert for previously approved uses.

Principal Investigator: 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 Centra Health's 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 within five (5) business days 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.

_____ _____

Signature of Principal Investigator Date

Typing my name on the line above constitutes an electronic signature.

Part A.2. Summary Checklist

	Yes	No
A.2.1 Is the study to be conducted at a Centra facility?		
A.2.2. Will you be requesting a central IRB waiver? The Centra IRB may require an annual renewal/update and notification of any **local** Serious Adverse Events or Unanticipated problems.		
A.2.3 If so, which central IRB? _____ What is the agreement regarding costs?_____		
A.2.4. Does the study utilize existing data, research records, patient records, and/or human biological specimens?		
A.2.5. Does the study utilize surveys, questionnaires, interviews, or focus groups with subjects?		
A.2.6. Does the study require videotaping, audiotaping, filming of subjects, or analysis of existing tapes?		
A.2.7.1 Do you have specific plans to enroll subjects from these vulnerable or select populations: a. Centra Health's employees? If this is a survey of Centra employees, it is mandatory the study has been approved by Human Resources? *If **yes**, please include documentation of approval.*		
b. Non-English-speaking?		
c. Decisionally impaired?		
d. Centra patients?		
e. Prisoners, others involuntarily detained or incarcerated, or parolees?		
f. Pregnant women?		
g. Minors (less than 18 years)? ***If yes***, give age range: to years		
h. Handicap?		
A.2.472 If b., c., e., f., or g. are checked yes, are there additional safeguards in place and what are they?		
A.2.8. a. Are sites outside Centra Health engaged in the research?		
b. Is Centra Health the sponsor or lead coordinating center multi-site study?		
If yes, include the ***Addendum for Multi-site Studies***.		
If yes, will any of these sites be outside the United States?		
If yes, is there a local ethics review committee agency with jurisdiction? (provide contact information)		
c. If the study is eligible for IRB or equivalent approval by the Institution of higher education, approval shall be obtained prior to submission to Centra IRB.		
A.2.9. Will this study use a data and safety monitoring board or committee?		
If yes: Specify:		
A.2.10. a. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?		
b. Do you plan to obtain a federal Certificate of Confidentiality for this study?		
c. Is this research classified (e.g., requires security clearance)?		
A.2.11 Does the study utilize: a. Investigational drugs? (provide **IND #**)		
b. Approved drugs for "non-FDA-approved" conditions?		
c. Are the investigational drugs/devices stored securely under the conditions recommended by the protocol/manufacturer?		
A.2.12. Does the study utilize placebo(s)?		
A.2.13.Investigational devices, instruments, machines, software? (provide **IDE #**) If yes, is it categorized as Significant Risk or Nonsignificant Risk? (Circle one)		

Devices FDA requires monitoring: (provide HUD#) (provide HDE# ____)		
A.2.14. Fetal tissue?		
A.2.15. Genetic studies on subjects' specimens?		
A.2.16. Storage of subjects' specimens for future research? ***If yes**, complete **Consent for Stored Samples***		
A.2.17 Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive if not enrolled in the investigation?		
a. If yes, does the dose that research subjects will receive from undergoing a procedures or series of procedures exceed a total effective cumulative dose of 100 mSv (0.1Sv, 10rem, 10,000 mrem)? *If yes, the study must be referred to the **Radiation Safety and Medical Isotopes Committee**by the Chairman of the IRB and the RSC must make a recommendation to the IRB before the IRB can review the study.*		
b. Will the patient be subject to deterministic effects from radiation exposure such as skin erythema, epilation, desquamation, or cataracts as a result of receiving doses above 2 Gy (200 rad)? If yes, the study must be referred to the Radiation Safety Committee (RSC) by the Chairman of the IRB and the RSC must make a recommendation to the IRB before the IRB can review the study. Note: a dose estimation tool can be found at http://www.doseinfo-radar.com/RADARDoseRiskCalc.html		
A.2.18. Recombinant DNA or gene transfer to human subjects?		
A.2.19. Will gadolinium be administered as a contrast agent?		
A.2.20. Will subjects' Social Security Number (SSN) be collected for: a. processing payments greater than $200 per year, to support IRS reporting (see also B.6)?		
b. processing payments of any amount through Centra Health Accounts Payable?		
c. use as a unique identifier for study tracking purposes for national registry or database?		
A.2.21 Has the level of risk to the subject been described in the application?		
A.2.22 What is the level of risk to the subject? Circle one: a. None b. Minimal risk c. Greater than minimal risk but potential direct benefit d. Greater than minimal risk and no direct benefit, but has potential to yield generalized knowledge about the subject's disorder or condition.		
A.2.23 If the risk is greater than minimal, are the risks reasonable in relation to the potential benefit in the investigator's opinion?		
A.2.24 Are the potential benefits to subjects adequately described in the application?		
A.2.25 Are the study groups clearly described in the protocol?		
A.2.26 Are the objectives and outcome measures consistent with the rationale?		
A.2.27 Are experimental procedures distinguished from the standard of care or treatment?		

A.2.28 Are provisions in place to maintain the confidentiality of the data and subject information?		
A.2.29 Are the costs to be borne by subjects accurately described?		
A.2.30 If there are complications, who will bear the financial responsibility for these?		
A.2.31 Are all the procedures in the protocol stated in the consent?		
A.2.32 Does the consent contain the notice provisions dealing with the description of the trial being on line at http://www.Clinical Trials.gov? (Required for all drug and device trials regulated by the FDA. Also required for publication of research results generated by a clinical trial. Please indicate page number on ICF: _____.		
A.2.33 Are the data monitoring provisions adequate for subject safety?		
A.2.34 Are all of the consent provisions in place?		
A.2.35 Is there any information that is not contained in the study protocol or information that the I RB should know about? If yes, attach full explanation.		
A.2.36 Include Curriculum Vitae (CV)/Resume of the Principal Investigator.		
A.2.37 Studies that involve surveying employees require Human Resource approval which must be obtained prior to application submission to the IRB. The contact for the Human Resources Department is HR Director at 434-200-5342		

Part A.3. Centra Institutional Review Board
Conflict of Interest Questions and Certification

The following questions apply to **all IRB Principal Investigators and/or Study Doctors and Study Coordinators** engaged in the design, conduct, or reporting results of this project **and/or Related Party.**

Definitions:

Related Party is the Principal Investigator's and/or Study Doctor and Study Coordinator's spouse, domestic partner, or dependent children, siblings, parents or equivalents by marriage, or other individuals residing in the PI/Study Coordinator's household.

Financial Interest: Anything of monetary value received from a financially interested company, including but not limited to: director's fees; consulting fees; honoraria; gifts; other emoluments or "in kind" compensation such as travel and entertainment (including those from a third party if the original source is a financially interested company), for any services not directly related to the reasonable costs of conducting the research as specified in the research agreement; equity interest (*e.g.*, stocks, stock options, convertible notes, other ownership interests); and intellectual property rights (*e.g.*, license fees, current and future royalties from patents and copyrights).
The term "Financial Interest" does not include:

i. Salary or other remuneration received from [Hospital];

ii. Holdings in mutual funds;

iii. De minimus gifts whose aggregate value does not exceed $100 per annum; or reasonable business expenses, including travel and meals provided in the regular course of business.

Conflict of Interest: means any situation or circumstance in which an IRB Member or a Related Party has a financial, personal, or other interest (including, but not limited to, an Individual Interest, Financial Interest, or Institutional Interest) which conflicts with, compromises, or has the appearance of conflicting with or compromising the individual's independent judgment and objectively rendering the member incapable of making an unbiased and objective decision regarding the research.

A.3.1. Currently or during the term of this research study, does any member of the research team or a Related Party have or expect to have:		
(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? Explain: _____ _____ _____	__ yes	__ no
(b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no
(c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? Explain: _____ _____ _____	__ yes	__ no

(d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no
A.3.2. Has Centra Health or has Centra Health-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team? Explain: _____ _____ _____	__ yes	__ no
A.3.3. Has Centra Health or has a Centra Health-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no

If the answer to ANY of the questions above is *yes*, list name(s) of all research team members for whom any answer to the questions above is *yes*:

_____

<u>Certification by Principal Investigator/Study Doctor/Study Coordinator</u>. By submitting this IRB application, I (the PI/Study Doctor/Study Coordinator) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every Centra Health employee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered "yes" to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential Conflicts of Interest that exist in relation to my study are reported as required by IRB policy.

_____ _____

Signature of Principal Investigator Date

Typing my name on the line above constitutes an electronic signature.

_____ _____

Signature of Study Coordinator Date

Typing my name on the line above constitutes an electronic signature.

Part A.4. Questions Common to All Studies

For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.

Complete answers must be provided. While you may reference other documents with supporting information, do not respond solely by stating "see attached."

A.4.1. **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.*

Purpose:
What is the expected duration of the research?
Participants:
Procedures (methods):

A.4.2. **Purpose and Rationale**. Provide a summary of the background information, state the research question(s), and tell why the study is needed. If a complete rationale 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 rationale and literature review, including references.

A.4.3. **Subjects.** *You should describe the subject population even if your study does not involve direct interaction (e.g., existing records).* Specify number, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified. Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subjects (e.g., school principals, facility directors, hospital or healthcare system administrators).

A.4.4. **Inclusion/exclusion criteria.** List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

A.4.5. **Full description of the study design, methods and procedures.** Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

A.4.6. **Benefits to subjects and/or society.** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

A.4.7. **Full description of risks and measures to minimize risks.** Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

A.4.8. **Data monitoring and analysis.** Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies). Describe the provisions 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 DSMB, depending on the study.

A.4.9. **Will you collect or receive any of the following identifiers?** Does not apply to consent forms.

__ No __ Yes *If yes, check all that apply*:

a. __ Names
b. __ Telephone numbers
c. __ 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
d. __ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
e. __ Fax numbers
f. __ Electronic mail addresses
g. __ Social security numbers
h. __ Medical record numbers
i. __ Health plan beneficiary numbers
j. __ Account numbers
k. __ Certificate/license numbers
l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers
m. __ Device identifiers and serial numbers (e.g., implanted medical device)
n. __ Web universal resource locators (URLs)
o. __ Internet protocol (IP) address numbers
p. __ Biometric identifiers, including finger and voice prints
q. __ Full face photographic images and any comparable images
r. __ 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

A.4.10. **Identifiers in research data**. Are the identifiers in A.4.9 above linked or maintained with the research data?

__ yes __ no

A.4.11. **Confidentiality of the data**. Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

A.4.12. **Data sharing.** With whom will *identifiable* (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

__ No one
__ Coordinating Center**:**
__ Statisticians**:**
__ Consultants**:**
__ Other researchers**:**
__ Registries**:**
__ Sponsors:
__ External labs for additional testing:
__ Journals:
__ Publicly available dataset:
__ Other:

A.4.13. **Data security for storage and transmission**. Please check all that apply.

For electronic data stored on a desk top computer:
__ Secure network __ Password access __ Data encryption__ Password protected file(s)
__ Other comparable safeguard (describe):

For portable computing devices/external storage devices (e.g. laptop computer, hand held devices, CDs, memory sticks):
__ Power-on password __ Automatic log-off __ Data encryption __ Password protected file(s)
__ Other comparable safeguard (describe):

For hardcopy data (including human biological specimens, CDs, tapes, etc.):
__ Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above)
__ Locked suite or office __ Locked cabinet
__ Data coded by research team with a master list secured and kept separately
__ Other (describe):

A.4.14. **Post-study disposition of identifiable data or human biological materials**. 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. Describe your plan to destroy identifiers, if you will do so.

Part A.5. The Consent Process and Consent Documentation (including Waivers)

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.

- If you will obtain consent in any manner, complete **section A.5.1**.
- If you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete **section A.5.2**.
- If you are requesting a waiver of any or all of the elements of consent, complete **section A.5.3**.
- If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *waiver of HIPAA authorization*. This is addressed in section B.2.

You may need to complete more than one section. For example, if you are conducting a phone survey with verbal consent, complete sections A.5.1, A.5.2, and possibly A.5.3.

A.5.1. **Describe the process of obtaining informed consent from subjects**.
Describe who will be obtaining consent (or permission) and from whom. Include discussion, as relevant, any waiting period between the initial consent discussion and obtaining consent, and steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain 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 LAR. *After you have completed this part A.5.1, if you are not requesting a waiver of any type, you are done with Part A.5.; proceed to Part B.* For additional information on informed consent, including a checklist of all required elements, please visit: http://www.hhs.gov/ohrp/policy/consent/index.html.

A.5.2. **Justification for a waiver of *written* (i.e., signed) consent**. *The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true. *Choose only one:*

a. 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 (e.g., study topic is sensitive so that public knowledge of participation could be damaging). *Participants should be asked whether they want documentation linking them with the research and the participants' wishes will govern whether they sign the form.* Note: This justification cannot be used in FDA-regulated research. __ yes __ no

__ yes __ no

Explain.

b. 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 (e.g., phone survey).

Explain.

If you checked "yes" to either (and you are not requesting a waiver in section A.5.3) consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

→ If you have justified a waiver of written (signed) consent (A.5.2), you should complete A.5.3 *only* if your consent process will not include all the other elements of consent

A.5.3. **Justification for a full or partial waiver of consent.** *The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biological specimens (see also Part C). More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

__ Requesting **waiver of some elements**
__ Requesting **waiver of consent entirely**
If you check either of the boxes above, answer items a-f.. To justify a full waiver of the requirement for informed consent, you must be able to answer "yes" (or "not applicable" for question c) to items a-f. **Insert brief explanations that support your answers.**

a. Will the research involve no greater than minimal risk to subjects or to their privacy? __ yes __ no
Explain.

b. Is it true that the waiver will *not* adversely affect the rights and welfare of subjects? *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)* __ yes __ no
Explain.

c. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? *(e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)* __ yes __ not applicable
Explain.

d. Would the research be impracticable without the waiver? *(If you checked "yes," explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* __ yes __ no
Explain.

e. Is the risk to privacy reasonable in relation to benefits to be gained or the importance of the knowledge to be gained? __ yes __ no
Explain.

If you are accessing patient records for this research, you must also be able to answer "yes" to item f to justify a waiver of HIPAA authorization from the subjects.

f. Would the research be impracticable if you could not record (or use) Protected __ yes __ no

Health Information (PHI)? *(If you checked "yes," explain how* not *recording or using PHI would make the research impracticable).* **Explain.**

Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

→ ***If this does not apply to your study, do not submit this section.***

B.1. **Methods of recruiting.** Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. *For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects' circumstances. Ideally, the individual with such knowledge should seek prospective subjects' permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator.* Provide the IRB with a copy of any document or script that will be used to obtain the patients' permission for release of names or to introduce the study. Check with the IRB for further guidance.

B.2. **Protected Health Information (PHI).** If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *waiver of HIPAA authorization*. If this applies to your study, please complete Form 5.

B.3. **Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

B.4. **Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the Centra Health campus

B.5. **Privacy.** 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).

B.7. **Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

Part C. Questions for Studies using Existing Data, Records or Human Biological Specimens

→ ***This section may apply even if records are used to identify potential subjects.***

→ ***If your study does not use existing data, records or specimens for any purpose, do not submit this section.***

C.1. What records, data or human biological specimens will you be using? *(check all that apply)*:

__ Data already collected for another research study
If applicant was involved in the original collection, please explain role:

__ Data already collected for administrative purposes (e.g., Medicare data, hospital discharge data)
__ Medical records
__ Electronic information from clinical database (custodian may also require form)
__ Patient specimens (tissues, blood, serum, surgical discards, etc.)
__ Other (specify):

C.2. Protected Health Information (PHI). If any of the above checked items constitute Protected Health Information, you need a HIPAA Authorization from each subject (see Form 7), unless the requirements for a waiver of HIPAA authorization are satisfied (see Form 5).

C.3. For each of the boxes checked in 1, how were the original data, records, or human biological specimens collected? Describe the process of data collection including consent, if applicable.

C.4. For each of the boxes checked in 1, where do these data, records or human biological specimens currently reside?

C.5. For each of the boxes checked in 1, do you have permission from the custodians of the data, records or human biological specimens (e.g., pathology dept, tissue bank, original researcher)? Include data use agreements, if required by the custodian of data that are not publicly available.

C.6. If the research involves human biological specimens, has the purpose for which they were collected been met before removal of any excess? For example, has the pathologist in charge or the clinical laboratory director certified that the original clinical purpose has been satisfied? Explain if necessary.

__ yes __ no __ not applicable (explain)

C.7. Do *all* of these data, records or specimens exist at the time of this application? If not, explain how prospective data collection will occur.

__ yes __ no If no, explain