RAMS-IRB Content Guide

Revised 11/10/2015

Virginia Commonwealth University
Office of Research and Innovation
BioTech 1 Building, Suite 3000
800 East Leigh St.
Box 980568
Richmond, VA 23298
(804) 828-0868

TABLE OF CONTENTS

INTRODUCTION

All Virginia Commonwealth University (VCU) IRB submissions are submitted in the RAMS-IRB (Research Administration Management System-IRB) electronic system.

This document is intended to serve as a guide to help you fill out the electronic smart form as well as possible, which may help to decrease the time it takes the IRB to review your proposed project.

- Off-Site Access to RAMS-IRB: If you are connecting to RAMS-IRB at an off-site location, you will need to connect to the VCU network by logging in via a VPN program (available for free through VCU Technology Services).
  For instructions on how to download, install and access the RamsVPN, please click here.
- Log into RAMS-IRB by using your VCU eID and Password at https://irb.research.vcu.edu

Note: The numbering in this document correlates with the smart form question numbers. Not all questions are described in this guide.

General Tips:

- Fill out each question with complete information.
- Use lay language as much as possible. The IRB staff and reviewers may not have background knowledge in your area of study, and they need to be able to understand all of the procedures you will follow.
- Be consistent within your submission.
- The smart form is "smart" because the questions branch depending upon how the form is filled out. Your answer to one question affects what other questions you are asked.
- An * indicates a required question.
- Click the button next to smart form questions for more guidance.
- For templates, please see Study Conduct Toolkit & Forms page.

SECTION 1 – INITIAL SETUP

Study Identification

1. Select Principal Investigator
   - Select the individual at VCU who will be responsible for the overall conduct of the study.
     - If the study is a student project, the student cannot be the PI – the PI needs to be someone who meets the eligibility requirements below.
   - See IRB WPP IX-1: Principal Investigator Eligibility and Signed Statement of Responsibilities for more information on who may be named as PI.

2. Study Title
   - Use the operational title for the study rather than the grant title.
   - The title should be unique to this study, not just the number of the study.

3. Student/ Trainee
   - This should only be marked "yes" if the research is a student-initiated project. If the student is simply assisting in the research, this would be marked "no."
   - Individuals classified as 'student' or 'trainee' include undergraduate students, graduate students, postdoctoral scholars, fellows and residents.

4. Associated VCU IRB Protocols
   - List other protocols that are connected or related to the current study. For example:
     - Pilot studies, previous phases, or previous iterations of the same research that were conducted under a separate submission
     - "Parent" studies that this project will build upon
     - Registries that you will be receiving information from or giving information to
     - Withdrawn, expired, or closed studies that are being reopened in this submission
5. IRB Editors
   - List anyone who needs to be able to edit the study in RAMS-IRB.
   - If a student investigator is filling out the smart form, they should be listed as an editor so that they can continue completing the rest of the submission.
   - The PI does not need to be listed because they already have editing access.

Research Determination

1. Type of Research
   - Most research is going to be "Research Project or Clinical Investigation," but refer to the  to understand other options.

Federal Regulations

1. Clinical Trial
   - **Clinical trials** are "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

2. Applicable Clinical Trial
   - All applicable clinical trials must be registered with clinicaltrials.gov and special language must be in research consent forms.
   - See the Office of Research Policy document "Clinical Trials Protocol Registration" for more information. A flowchart from the NIH is available here.
   - If the study IS a clinical trial, and meets ALL of the following criteria, it is considered an **applicable clinical trial:**
     - Is an intervention
     - Intervention type is drug, biologic, device, radiation, or genetic
     - Is currently in Phase 2, Phase 3, or Phase 4
     - Is located in at least 1 location in the United States OR is an Investigational New Drug (IND) / Investigational Device Exemption (IDE)
     - Recruitment status of IRB Study is not withdrawn

3. FDA Regulated Study
   - FDA regulated research includes all clinical investigations involving a **test article** and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
   - A **test article** means any drug (including a biological product) for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation.

4. Department of Defense (DOD) Supported Study
   - If the DOD provides any support (funding, facilities, equipment, assistance, identifiable information, etc.), read WPP XVII-12.

5. Other funding sources
   - If the Department of Education provides support (funding) read WPP XVII-17.
   - If the Department of Justice provides support (funding) read WPP XVII-18.

SECTION 2 – PERSONNEL & ROLES

Personnel

1. Engaged VCU/VCUHS Personnel
    - **Engaged** means interacting or intervening with research participants OR having access to identifiable data about research participants.
    - List all individuals, including the PI, who will be engaged in the research.
        i. There can only be ***one*** PI designated.
        ii. The student investigator for the study should have the role "Student/Trainee"
        iii. If project is grant funded, the grant holder is to be listed as PI or as a sub-investigator on this project.
    - Conflict of Interest (COI) Investigator:
        i. Please refer to the "Getting Started Guide" to determine whether someone is a COI investigator.
        ii. The PI and student investigators are automatically COI investigators.
2. All COI investigators following VCU's policy must complete a Financial Interest Report (FIR) using the AIRS system.

3. Engaged Non-VCU personnel who DO NOT have IRB approval from another institution
    - List any independent investigators (see WPP XVII-15)
    - If your project involves any non-VCU sites who will be deferring to VCU for IRB review, list all of the employees from that site who are engaged in the research (see WPP XVII-6).

4. CV/Biosketch
    - Upload a CV, resume, or biosketch for the following individuals to show their qualifications and research experiences:
        i. PI
        ii. Medically Responsible Investigators
        iii. Student/Trainee Investigators

Note: Please ensure that all engaged study personnel are up to date on their CITI training. For more information, click here.

Conflict of Interest

Conflicts of Interest (COIs) are inherent to the nature of the research enterprise. A COI can arise in situations in which there exists discord between a primary duty and a secondary interest. COIs can be either financial or non-financial and can yield conscious or subconscious bias in the conduct and/or interpretation of research, and can adversely impact the safety of human or animal research subjects. Often financial COIs will simply present an appearance of compromising an investigator's professional judgment in conducting or reporting the results of research. Accordingly, and whether real or perceived, all identified conflicts of interests must be addressed.

Institutional Conflicts of Interest in Research Policy
Conflicts of Interest in Research Policy

Communication Plan for Research Team

1. Describe the communication plan for people involved in the study. To ethically conduct a study, everyone should be kept informed about the protocol, their duties, changes, and be able to report problems or adverse events that may arise. Be as detailed as possible, especially if the study involves sites outside of VCU. Some examples include plans for initial trainings, team meetings, and email/phone communications.

SECTION 3 – REVIEW SETUP

IRB Panel Setup

1. Most studies will be submitted to the **VCU IRB**, unless they qualify for one of the following:
    - Western IRB (WIRB) – All industry sponsored research involving human subjects, except:
        - Research conducted by Navy or Marine Corps personnel; involving naval military personnel or Department of Navy employees as subjects; supported by naval activities through an agreement; or using Department of Navy property, facilities, or assets
    - NCI Central IRB – Cooperative Cancer Group sponsored studies that are already approved by the NCI Central IRB (CIRB) are eligible for an IRB deferral to the NCI Central IRB. The Principal Investigator or regulatory coordinator is responsible for determining that a study is eligible.
    - Other IRB - Deferral of IRB review by VCU to another institution may be utilized on a limited basis. The request is carefully considered by ORSP and subject to ORSP approval. If you would like VCU to defer to another institution, please contact ORSP before submitting your study.

Review Setup

1. Decide if any of the research activities are greater than **minimal risk**.
    - **Minimal risk** is defined as "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(i)).
        - This should be compared to the average person, not the population the study is targeting.
    - **If any activity is greater than minimal risk, the study must have full board review!**
2. Review type: Click here to learn about the different levels of IRB oversight and choose which one best fits your research.
    - Full Board review
    - Expedited review - View the Expedited Research Categories
    - Exempt review - View the OHRP Exempt Categories

SECTION 4 – RESEARCH PLAN

Research Description

This section is extremely important because it asks for details about what you will be doing, why, and how you will be conducting the research. IRB reviewers may not have a background in your study's area of research, so describe your project using language that your friends and family would be able to understand. If you have a separate protocol, you may reference it, but still be clear and detailed about any site-specific differences.

1. Hypothesis/Research Questions
    - What question is the research trying to answer?

2. Specific Aims/Goals
    - What objectives, key steps, or short or long-term goals will you meet in order to answer the research question?

3. Study Background
    - Briefly explain what is known about the study topic, your rationale for conducting the study, and/or how it will contribute to the discipline/practice
    - This section could be similar to the background section of a journal article.
    - Include citations or references, or upload a reference list

4. Study Design
    - Describe your study's design and methods including all interactions and interventions with participants, data and materials collected, and data analysis plans.
    - Include step by step procedures of what participants will be asked to do
        - For example, it is not sufficient to simply say that a survey will be administered. The reviewers need to understand the procedure from start to finish – survey invitations, how the survey can be completed, time limits for completion, reminders, etc.
    - Describe what participants will experience.
    - BE CONSISTENT! It is important that the information you provide in this section matches other parts of the smart form, as well as the documents (i.e. consent form)

5. Documents/Tables
    - Upload any relevant documents that support the study's background and procedures.
    - Examples of documents may include, but are not limited to: study procedure flow charts, reference lists, multi-center protocols, etc.
    - Do not upload journal articles. These articles should be summarized in question #3.

Study Activities

1. Study type- you may only choose one. This section asks about your methodology, not your topic.
   - **Biomedical** - Research that involves medical interventions/observations and/or FDA-regulated products.
     - Examples: health interventions, clinical trials, testing a drug, etc.
     - If the study involves questionnaires, interviews, or surveys, it is "Mixed Method."

   - **Social/ Behavioral / Education (SBE)** - Social, behavioral, or educational research that does NOT involve medical interventions/observations or FDA-regulated products.
     a. Qualitative studies are those that utilize non-numerical data to search for patterns and themes.
        - Examples: Interviews, focus groups, oral histories

     b. Quantitative studies are those that utilize numerical data to identify statistical relationships between variables.
        - Examples: Secondary data, surveys that collect numerical data

   - **Mixed Method Studies (Social/Behavioral or Biomedical)** include both qualitative and quantitative analysis about either biomedical or SBE fields of research.

2. Study Procedures
   - This is a branching question that will influence subsequent pages of the smart form. You should check all appropriate answers.
     - **Interactions**: Gathering information through communications or interpersonal contacts, such as using surveys, interviews, field studies, focus groups, educational tests, deception, psycho-physiological testing, and any other similar data collection methods.

     - **Secondary Data**: Procedures such as analysis of information collected for non-research purposes (includes both retrospective and prospectively collected information), or analysis of data previously collected for a prior research study.
       - Collecting data from medical records are included in this category

     - **Medical Procedures/Interventions**: Physical or medical procedures, or manipulations of the subject or their environment, such as using drugs, devices, experimental interventions, biohazards, radiation, and any other medical or surgical procedures.
       - Sample collections (blood, urine, etc.) are included in this category

SECTION 5 – PROJECT DETAILS

Biomedical Project Details

1. Most of the checkboxes are branching questions that will influence subsequent pages of the smart form. You should check all appropriate answers.
    - Research involving biohazards or non-clinical radiation may require approval from an ancillary committee.
        - Radiation Safety Committee: http://oehs.vcu.edu/radiation/radiation.html
        - Institutional Biosafety Committee: http://oehs.vcu.edu/chemical/index.html
    - If your study involves a VCU faculty-held Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), please review the information at http://www.research.vcu.edu/IND_IDE/
    - "Other medical/surgical procedure" should be checked if the research includes sample collection or other clinical tests or procedures.
    - "Protected Health Information (PHI)" should be checked if the research involves identifiable health information.

Social / Behavioral Project Details

1. Several checkboxes are branching questions that will influence subsequent pages of the smart form. You should check all appropriate answers.
    - "Analysis of Information Originally Collected for Non-Research Purposes" needs to be checked if the researcher is collecting secondary data, such as from medical charts.
    - "Oral History" refers to collecting historical information about past events using interviews with people who had direct experiences.

4. Documents
    - Upload the final versions of all instruments/guides/scripts/other measures. The reviewer will be considering the layout as well as the content and needs to see the documents as the participants will see them.

SECTION 6 – DATA COLLECTION

Data Collection Details

1. These checkboxes are branching questions that will influence subsequent pages of the smart form. You should check all appropriate answers.
    - **Specimen/Biologic Sample Collection**: Check this box if you will be collecting specimens or biologic samples specifically for this study (not getting secondary samples)
        - On the Sample Collection page, describe the following items in detail
            - Who – who will be collecting the sample,
            - What - the volume/size of the each type of sample,
            - When – the frequency/schedule of collection,
            - Where – where sample collection will take place, and
            - How – the sample collection procedures
        - If your research involves genetic or DNA testing, please read WPP XVII-5.
    - **Protected Health Information (PHI)**: Check this box if medical records are used during the research or if your research data will contain identifiable health information.
        - Please be sure to read WPP XII-3.
    - **Audio/Video**: Check this box if your research involves audio or video recordings or photographs that could identify an individual
    - **Existing Data or Specimens not from a Registry or Repository**: Check this box if you will receive secondary data from a source other than a registry, repository, or medical records. (Examples: Data from another research study, data from a national survey, specimens from TDAAC).
    - **Use of Internet for Data Collection**: Check this box if you will use the internet to collect data. (Examples: Web surveys, observing chat rooms, participating in online communities).
        - Please be sure to read WPP XVII-9.
        - Passive Data Collection includes data mining from online sources and other passive observations of online behavior.
        - Active Data Collection involves using the internet to interact or intervene directly with research participants, such as through the use of online surveys, avatar worlds, computer games, etc. The use of REDCap is encouraged; however, other online survey tools may be used.

- **Registries/Repositories**: Check this box if you will create a new registry, contribute your data/samples to an existing registry, access data/samples from an existing registry, and/or submit data to the NIH GWAS Registry
  - A "human subjects/ research registry" is an organized collection of ***identifiable*** information that is ***intentionally maintained*** for use as a ***prospective*** instrument for the conduct of research.
    - Collection of data or specimens for a specific study DOES NOT constitute a registry IF the data or specimens will not be saved for future unspecified research purposes.
    - Similarly, if data/specimens will be maintained without identifiers or a code enabling re-identification, the maintenance does not involve a registry or repository.
  - On the next Registry pages, read each question carefully and explain in detail the procedures that will be followed.

2. Identifiers
   - Select all identifiers that will be used or collected throughout the **ENTIRE** study, not just the identifiers that will be included in the data set.
     - If you will use direct identifiers, have plans in place to protect confidentiality and to minimize the risks of having identifiable data.
   - If Social Security Numbers and other identifiers will be collected for payment purposes, these identifiers should be checked.
   - "Other unique identifier" might refer to a database number (e.g. pathology number), a student ID number, a military ID number, etc.

4. Withdrawing Data
   - If participants will be allowed to withdraw their data, describe the steps participants must take to do so. This option and withdrawal process must be included in the consent form.

Data Confidentiality and Storage

Confidentiality and privacy are often confused. The main difference is that confidentiality relates to information and data, and privacy is about people.

- Confidentiality – the way private, identifiable information about a research participant or defined community is maintained and shared (See another definition here)
- Privacy – how much control someone has about what is known about them (See another definition here)

1. Be detailed about precautions used to maintain confidentiality of data. The  button provides examples, but you will need to describe how you plan to implement each security measure. For example, the help text recommends using access controls, so your response could describe specifically how your study will use passwords to protect your data.
   - For information about VCU's security policies, see the Policy Library

2. Include all persons and groups who will have access to the study data. This includes groups beyond the study team, such as sponsors, governmental agencies, data monitoring committees, etc.

3. Coding data refers to removing all direct identifiers from the study data and inserting a subject code. The subject code is linked with the subject's name in a separate document (the key to the code). This key (electronic or paper) is kept separate from the data and the consent document.
   - If you will code your data and keep a key to the code, describe in detail:
     - whether there will be a key linking identifiable information to the data
     - the method by which codes will be assigned
     - the location where the key will be stored
     - who will have access to the key
     - when the key will be destroyed

4. Certificate of Confidentiality (CoC)
   - Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect sensitive identifiable research information from forced disclosure. Certificates are study specific, so to learn more, click here.

6. Storing Records
   - VCU requires records be stored for 5 years minimum, after publication.
   - Records from studies involving PHI/HIPAA information must be retained for a minimum of 6 years post study closure.
   - Be sure to review VCU's policy about Research Data Ownership, Retention and Access.

SECTION 7 – STUDY LOCATIONS

Types of Sites

- **Multicenter studies**
  - A multicenter study typically involves the same protocol being implemented at multiple sites.
    - For example, in multi-center oncology trials, multiple independent hospital systems/ organizations each carry out the same protocol at their own site, and then the data from all sites is combined for analysis.
    - Collaborating with other institutions or sites ***does not*** necessarily make the research multi-center, such as when the institutions are implementing different parts of a single protocol.
    - The lead site is typically the site where the multi-site protocol originates or the PI overseeing the entire project resides.

- **VCU Site Details**
  - Be specific about what VCU clinics/facilities will be used throughout the entire study. Include the places where participant interactions and interventions occur as well as the locations of where other activities like administrative tasks, sample/data storage, and/or data analysis will be done.
  - For research conducted in VCUHS, refer to the VCUHS policy Conduct of Clinical Research In VCU Health System Patient Care Areas

- **Non-VCU Site Details**
  - Non-VCU sites can be part of VCU based research. On this page, you will be asked to provide details on what research activities happen at the other sites – recruitment, procedures, use of the facility etc. You will also want to think about the logistics of how both sites will communicate about study conduct, dealing with unexpected problems, modification, results, and local rules/regulations.

  - If you are working with another site, there will be additional IRB requirements, so please read the relevant WPP(s):
    - Involving Non-VCU Institutions in VCU Human Subjects Research
    - Involving Foreign Institutions/Sites in VCU Human Subjects Research
    - Involving Independent Investigators in VCU Human Research
    - Research Conducted Within the Federal Bureau of Prisons

- Site Engagement
  - Non-VCU sites become engaged in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d)-(f)]. For examples, click here.
- IRB Review for Engaged Sites:
  - If a non-VCU site is engaged in the research, that site will need to obtain IRB review for the project.
  - Sometimes the site is an institution that has its own IRB, so the site could obtain its own IRB review. Alternatively, other sites can request that the VCU IRB provide the IRB review for them (they defer to the VCU IRB).
  - For more information, about IRB Reliance Agreements, read Involving Non-VCU Institutions in VCU Human Subjects Research as well as the guidance available here.

- Federal Wide Assurance (FWA) Number:
  - This is a registration number that the government assigns to institutions who commit to complying with the requirements of the Department of Health and Human Services (HHS) Protection of Human Subjects regulations, 45 CFR part 46. Information about VCU's FWA can be found here.
  - Institutions (both domestic and foreign) must have an FWA number in order to receive federal funding for research involving human subjects.
  - You can click here to look up FWA numbers or they can often be found on IRB websites.

- **Community Partners**
  - A community partner is more than just a community location or non-VCU site. In the smart form, this term refers to community engaged research in which a community organization or group will be collaborating with a researcher in a project that that will be beneficial to that organization. Partners might provide access to study subjects or project sites, offer guidance to the researcher, or participate equally in the design and conduct of the study.
  - If you are conducting Community Engaged Research, see the information available here and at http://www.community.vcu.edu/research/

SECTION 8 – SPONSOR DATA

Study Funding

If your study is funded, you will be asked to provide information about the sources of the funding because certain funding sources have IRB requirements that must be followed. Common types of funding include:

- **Direct Federal** funding is funding from a federal source (NIH, DOD, DOE, NSF, etc.) that is granted directly to VCU.
    - If you have funding from any of the following agencies, there will be additional IRB requirements, so please read the relevant WPP(s):
        - Department of Defense (DoD) - Department of the Navy (DoN)
        - Department of Education (DoEd) and National Institute on Disability and Rehabilitation Research Requirements (NIDRR)
        - Department of Justice (DoJ) including the National Institute of Justice
- **Indirect Federal** funding is funding from a federal source (NIH, DOD, DOE, NSF, etc.) which is granted to another institution and VCU receives a subaward/subcontract (flow through money).
- **Internal Grant** funding is funding from a grant source internal to VCU (CCTR Endowment Fund, VCU Presidential Research Quest Fund, etc.)
- **Other:** If you select "other," describe the source of funding on the Research Description page.

Grant Congruency Review: Grant funders (and particularly funders of HHS-supported research) may require that the IRB conduct a congruency review before they will give an award or release funds. The following three instances are the times when congruency review is usually necessary:

(1) A new grant application,
(2) A resubmission of a grant application, or
(3) A competing continuation of a grant application.

During congruency review, the IRB will review a grant proposal to make sure that the research project described in the grant application and IRB submission are generally the same. For more information, click here.

SECTION 9 – PARTICIPANTS

Study Population

1. Total Expected Enrolled Participants
    - This is the total number of people whom you expect could participate in the study.
        - Anyone who consents to participate in some or all of the study activities, including anyone who consents to participate in screening procedures, would be considered enrolled.
        - Be sure to account for all groups and all phases of the project, including the screening process.
    - For studies that work with secondary data or specimens, the enrollment goal would be the total number of people who will be represented in your data.
    - Be as accurate as possible, but you might need to over-estimate in order to account for screen failures, dropouts, withdrawals, loss to follow-up, etc.

3. Justification of sample size
    - Explain to the best of your ability how you calculated or arrived at the enrollment goal listed in question 1.

4/5. Eligibility criteria
- The inclusion and exclusion criteria define who can participate in your study.
- If your project has different people participating in different study activities (for example, one group takes a survey and another does a focus group), you will need to list inclusion and exclusion criteria for each independent group of participants.
- Be specific about whether children, pregnant women, and prisoners are eligible to participate.

6. Participant groups
    - Although the smart form says, "If it is possible that a regulated vulnerable population (children, pregnant women, prisoners) COULD BE involved in the study, be sure to check them," **only check the populations that you can specifically identify in your data or interactions.**
        - Select any participant groups that describe your subject population, that you will be targeting in the study, OR that you will be able to identify in a data set (such as in chart reviews).
    - Most of these checkboxes are branching questions, so the smart form will open new pages for you to fill out based on the populations selected in this question.

- For many vulnerable populations, there will be additional IRB requirements, so it is important for you to read the relevant WPP(s):
  - Children
    - Permissible Categories
    - Assent and Parental/Guardian Permission Considerations
    - Children in Court-Appointed or State Custody and Emancipated Minors
  - Pregnant Women, Fetuses, Neonates, and Fetal Materials
  - Prisoners – for this population also read this Guidance Form
  - Decisionally Impaired Adults / Persons with Limited Decision-making Capacity
  - Cancer research
    - All cancer related studies must be approved by Massey Protocol Review and Monitoring Committee. Please refer to the PRMC's website for more information.
  - VCU/VCUHS Students or Trainees
    - Family Educational Rights and Privacy Act (FERPA) and/or Protection of Pupil Rights Amendment (PPRA) regulations may apply
  - Individuals with Limited English Proficiency – also read this Guidance
  - Active Military Personnel
  - Research in a K-12 Environment
    - You will need to get school/district approval prior to submitting to the IRB.
    - Family Educational Rights and Privacy Act (FERPA) and/or Protection of Pupil Rights Amendment (PPRA) regulations may apply

8. Make sure that the age ranges you choose match with the inclusion criteria and will cover all participants in all aspects of the research.

Potential Subject Identification and Recruitment

1. Recruitment Methods
   - These recruitment methods are a way of categorizing how you will initially approach potential participants to let them know about the study.
   - Each of the methods that you select here should be described in question #5.
   - The IRB will need to approve all recruitment materials, so be sure to upload all posted or mailed materials, scripts, and texts that will be used.
     - For example, if you will use a mass email to recruit participants, you would select "Email Campaign" in question #1. You would then describe the procedures you will follow when sending the email in question #5 (who will send it, to whom, how many reminders, how interested individuals can respond, etc.). The email text that you will use (and the text of any reminder emails) would be uploaded in question #7.

3. Obtaining Names and Contact Information for Potential Subjects
    - These identification methods are a way of categorizing how you will initially find potentially eligible participants to recruit into the study.
        - If you are accessing data or obtaining contact information from a research registry, you must select "Registries/Repositories" on the Data Collection Details page and complete the Accessing a Registry section.
        - If you are obtaining contact information from the VCUHS medical records, you must select "PHI" on the Data Collection Details page and request a Partial Waiver of Authorization for recruitment on the HIPAA page.

5. Identification and Recruitment Process
    - Provide a detailed explanation about the systematic procedures you will follow to identify and recruit potential participants. Discuss who will be identified and how, when and where recruitment will occur, and how a member of the study team will approach or respond to interested individuals.
    - For studies using secondary data or specimens, you may not be having direct contact with participants, so you can just describe how you will identify which individuals' samples/data you wish to use.

8. Screening:
    - **If the screening activities of your project meet the definition of being research involving human subjects, informed consent is required.**
        - "Research" is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."
        - "Human subject" is defined as "a living individual about whom an investigator conducting research obtains:
            - data through an intervention or interaction with the individual OR
            - identifiable private information."
        - For more detailed information about how to determine whether an activity is human subject research, see WPP II-2 and this flowchart.
    - You may choose to use a separate, minimalist, informed consent document specific to the screening activity, or the main study consent could cover screening activities as well as the main study's research activities.
    - In order to minimize the burden on participants when obtaining consent for screening, it is possible to request a waiver of certain elements of consent, which would allow you to either omit or alter some of the elements of informed consent.
        - Federal regulations require that 8 basic elements of informed consent be included in all consent forms to ensure participants are educated about the research. In order to omit or alter any of these 8 basic elements of consent, the IRB must approve a Waiver of Some or All Elements of Consent (requested on the Consent Groups page of the smart form).

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. One way to remember the difference between privacy and confidentiality is that privacy is about people (both start with the letter *p*), and confidentiality is about data.

Here are a few examples of privacy protections:

- Physical protections like using private rooms or providing a cover sheet for surveys so responses are not immediately visible to others;
- Interpersonal protections like giving the participant a choice about who is around when the research is being discussed or the researcher being in a private area when making study-related phone calls;
- Electronic protections like only collecting the minimum amount of sensitive information necessary for the study or verifying that you are emailing the correct individual when sending study-related communications.
    - [Note that the concern here is about how the person would feel about their sensitive information being disclosed, which is different from confidentiality concerns about coding or limiting access to sensitive data.]

When responding to this question, describe how participants' privacy will be protected during the entirety of the study. Take into consideration all aspects of the research, and explain the precautions taken at each stage of the project.

Costs to Participants

When describing the costs to participants, you must explain in detail the costs incurred to the participant or their insurance companies. If study related procedures would be done as part of the individual's standard care (and thus billed to the participant), you will be asked to describe what those standard procedures are on the next page.

Compensation

Compensation should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred. In most cases involving continued participation, compensation should be given on a reasonable prorated basis to avoid the impression that the investigator is coercing the subject to continue in a study or is punishing the subject for non-compliance. In your response, be sure to address each point of the question.

For the IRB's compensation policy, click here. For more information about VCU Procurement office's policies and procedures for the payment of research subjects, click here.

SECTION 10 – RISKS & BENEFITS

Risks, Discomforts, Potential Harms, and Benefits

There are always risks involved with any research, even in minimal risk research, because research asks people to do things that they might not otherwise do in that particular manner. Therefore, it is not acceptable to say a study has no risks.

From the IRB's perspective, studies can only be approved if the risks have been minimized and are reasonable in relation to the anticipated benefits. The IRB relies on you (as an expert in your area of study) to identify the risks and discomforts that each research activity may cause and to help the IRB understand how serious, as well as how likely, those risks are to occur during your study.

From a researcher's perspective, risk identification is important because if something unexpected occurs during the study, the Principal Investigator is responsible for promptly reporting to the IRB any unanticipated problems posing risks to participants or others (WPP VII-6). An unanticipated problem is one that "1) was not anticipated or foreseen; 2) involves risk or harm to participants or others; AND 3) was probably or definitely related to, or caused by, the research activity in the judgment of the investigator." The risks that you identify in the IRB submission are the ones that you have already anticipated or foreseen. However, adverse events that were not previously described in the IRB submission may be unanticipated problems that would then need to be reported.

1. When responding, think systematically through each study activity and their associated risks:
    - Physical risks or discomforts
    - Psychological risks or discomforts
    - Social risks or discomforts
    - Legal risks or discomforts
    - Financial risks or discomforts
    - Reputational risks or discomforts
    - Employment risks
    - Loss of privacy or confidentiality

2. Part of the responsibility of the study team is to minimize the risks. Explain how you will minimize ***each*** of the risks identified in question #1.

3. This question is asking about the possibility of loss of confidentiality and the harms that could result. If this question is applicable, your response could be similar to those on the Confidentiality page.

4. VCU employees are mandated reporters because they are state employees. If you could discover information about child/elder abuse or neglect, you must disclose to participants in the consent form that you will be required to report that information to the appropriate authorities.

5. This question is asking about whether it is likely that you could discover any incidental findings (information about a person that they may not already know about themselves), unknown conditions, or information that a participant is engaging in illegal activities.

6. If you answered "Yes" to question #5, explain how the study team will handle the discovery of previously unknown information. This information should be relayed to all members of the study team.

7. This question asks you to think about community-wide risks based upon the results of your project. Could the research produce outcomes that could harm a population or community (such as by being stigmatizing or derogatory)?
    - For an example, see this article: "The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples"
      Michelle M. Mello, J.D., Ph.D., and Leslie E. Wolf, J.D., M.P.H.
      N Engl J Med 2010; 363:204-207. July 15, 2010. DOI: 10.1056/NEJMp1005203

Questions #8-10 may be non-applicable for minimal risk studies.

8. This question asks about how the study team will decide whether a participant should continue in the study. Participants always have the option to choose to withdraw, but sometimes, the researcher may need to decide to withdraw a participant without their consent. Under what conditions/criteria would it no longer be safe/appropriate for a participant to stay in the study?

9. What criteria will indicate that the entire study should be stopped or changed due to safety concerns? This question assumes that the study team will monitor the collected data throughout the course of the study and will make decisions about whether the study should be changed or stopped, based on this information.

10. What kind of care or referrals will you provide if/when adverse events occur?

11. What potential direct benefits could the participants reasonably expect to experience in this study? If there are no direct benefits, please state that, do not simply say "N/A." If different participant groups may have different expected benefits explain what each group may receive.

12. In general, what are the scientific benefits to be gained by doing this research?

13. If potential participants decide not to participate, discuss alternatives (if applicable).

14. All research protocols proposing to involve human subjects that may involve greater than minimal risk must contain a plan for monitoring data in order to assure the safety of participants, as outlined in 45 CFR 46.111. Monitoring could be done by a formal monitoring board (DSMB) or by an individual or informal monitoring group (DSMP). See the IRB's Data Safety Monitoring WPP for more detail.

SECTION 11 – CONSENT PLAN

Consent Qualifiers

If you are submitting for expedited or full board review, respond "No" to question #1.

Exempt studies do not have a regulatory requirement to obtain informed consent. However, at VCU, consent is expected because this shows respect for participants.

At a minimum, the consent document should include the following information:

1. A description of the project as research,
2. An explanation of research procedures,
3. A statement that participation is voluntary, and
4. Name and contact information of the researcher.

You are encouraged to include other elements of informed consent in your consent document. It is best if participants can keep this information sheet for their records.

Consent Groups

"Consent groups" are used to differentiate the various consent processes that are used during a study. A study may only use one consent process, and thus might only have one consent group. Or, consent processes may vary and require separate consent groups. For example, obtaining assent from children is a different process than obtaining consent from an adult; therefore, these could be separate consent groups.

Some examples of different groups are given below:

- Child assent vs. parental permission (separated by subject population)
- Survey vs. interview consent processes (separated by research methodology)
- Consent processes for phase 1 vs. phase 2 of a project (separated by phase)
- A waiver for the initial chart review to identify potential participants vs. the written main study consent (separated by study activity)
- Telephone screening vs. main study consent (separated by study activity)

In each consent group, here is some help with specific questions:

3. To learn more about the types of waivers, see the "Getting Started" guide here.
    - Selecting any of these waivers will cause the smart form to branch and you will have more pages to fill out to justify the selected waiver. These are difficult questions to answer, so read each question carefully and do the best you can.

6. You will be asked to describe how consent will be obtained. Be descriptive in terms of where, when, and how the consent discussion will be conducted.

7. "Coercion" refers to unfairly persuading or influencing a person to participate. Sometimes a researcher may have a pre-existing relationship with participants that could set up the potential for coercion (student-teacher, patient-physician, supervisor-employee, etc.), so in these situations, it is important to recognize that coercion could occur and have a plan for minimizing the potential for coercion.

9. Throughout the course of the study, some children (under 18) or those who are decisionally impaired initially may enter adulthood or become no longer decisionally impaired. If you are able to re-consent, how will you do this?

Consent Documents

Federal regulations require that 8 basic elements of informed consent be included in all consent documents to ensure participants are educated about the research. In addition, VCU requires that additional elements must be included if they are applicable.

- To ensure all of these elements, HIPAA authorization language, and necessary signature lines are part of the consent form, you are encouraged to use the consent/assent templates provided by the IRB.
- If you choose to write your own consent form, be sure to include all of the required elements of informed consent and required signature lines.

If your study involves children (or participants who are decisionally impaired), an assent process as well as parental/legally authorized representative (LAR) permission is required. To view these requirements, click here.

Limited English Proficiency Subjects: Click here to review the requirements for interpretation during the consent process and translated documents.

SECTION 12 – DOCUMENTS

This section gives you a place to upload any other relevant documents that were not already uploaded in earlier parts of the form. Below is a list of possible documents that may need to be included **as applicable**:

Personnel Information:

- CV for the PI, Medical Responsible Individual, Student/Trainee Investigator, Translator/Interpreter or Cultural Consultant
- Training Documentation (CITI completion certificates, translator qualifications, device-specific training certificates, etc.)

Protocol Documents

- Protocol
- Reference List/Citations
- Supporting Tables and/or Figures

Research Measures and Recruitment Materials

- Screening scripts and forms
- Instruments, guides, surveys, scripts, questionnaires, interviews, forms, etc.
- Recruitment flyers, emails, ads, letters, TelegRAM texts, TV/radio spots, reminders, etc.

Ancillary Documents

- Grant Proposals and the OSP Internal Approval Form
- Certificate of Confidentiality (if obtained by the VCU PI)
- Ancillary Committee Approvals (PRMC, Radiation Safety, Biosafety, etc.)

FDA Documentation and Drug or Device Information

- FDA Correspondence or Justifications for IND or IDE exemption
- Drug Brochures or Package Inserts / Device User Manuals
- Investigational Drug Pharmacy Management Plans

Consent and HIPAA Documents

- Stand Alone HIPAA Authorization Form (only if using this particular pathway)
- HIPAA Data Use Agreements (only if using the Limited Data Set pathway)
- Informed Consent Forms or Information Sheets
- Assent Forms and Parental Permission Forms