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| **TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION RESEARCH****GENERAL INSTRUCTIONS**This application template is for investigators at Catawba Valley Medical Center who wish to conduct studies in which the *only* involvement of human subjects is research utilizing educational tests, survey procedures, interview procedures, or the observation of public behavior. With this template, create a study protocol for submission to the Catawba Valley Med Cnt Institutional Review Board (IRB) for evaluation and action.Use this template to create a **study protocol** as follows:* **Red** text represents instructions to you – delete all red text from the final version.
* Blue text represents guidance on suggested content – replace with the requested information using black font in the final version.
* Black text represents section headings and is to remain in the final version.
* Green text represents definitions or verbiage examples – delete.

Please make sure to complete the header on this page with your Surname and initials, followed by a colon, and an abbreviated protocol title. Also include the version number, colon, and date. Ensure page numbers remain in the footer, right side. The initial submission to the IRB is Version 1. Once an application is submitted to the IRB, should amendments or future protocol or study personnel changes be necessary, the version numbers of revised applications are indicated by the next ascending number. NOTE: The submitted application is to contain NO red, green, or blue text nor instruction boxes. The abbreviated information in the Protocol Summary will be fleshed out in the subsequent sections of the application. |

**Tests, Surveys, Interviews, or Observation Research IRB Application**

**Protocol Title:** complete

**Protocol Version Number:** 1, 2, etc.; see explanation in general instructions above

**Principal Investigator (PI):** name

 **Phone:** number

 **E-mail:** address

**Co-Investigator(s):** name(s)

 **Phone:** number(s)

 **E-mail:** address(es)

**Research Sponsor:** name

 **Phone:** number

 **E-mail:** address

Investigator and Research Sponsor Responsibility Acknowledgements

I assure this study will be conducted in compliance with the approved protocol, applicable federal regulations, and the policies and procedures of the Catawba Valley Med Cnt IRB. By checking the box and typing my name below, I confirm this to be my electronic signature and the legal equivalent of my manual signature.

[ ]  Investigator Signature: Date:

I assume responsibility for ensuring the Principal Investigator complies with the policies and procedures of the Catawba Valley Med Cnt IRB and federal regulations as applicable in conducting this research and the use of human subjects. By checking the box and typing my name below, I confirm this to be my electronic signature and the legal equivalent of my manual signature.

[ ]  Research Sponsor Signature: Date:

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| **STUDY DESCRIPTION INSTRUCTIONS**To allow the IRB, consisting of scientists and non-scientists, to understand this study completely use non-technical terms to describe the proposed research, i.e., avoid clinical jargon. Detailed information about the use of human subjects is necessary for the IRB to evaluate potential risks to subjects. The following definitions are key to understanding research involving human subjects as defined by 45 CFR 46.102.(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.(3) *Interaction*includes communication or interpersonal contact between investigator and subject.(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).(5) *Identifiable private information*is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.(6) An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.The information in Sections 2 through 9.1 must be provided in complete sentences. Bulleted information is not acceptable. First use of an acronym or abbreviation within Sections 2-9.1 must include its description. Thereafter, the acronym or abbreviation can be used alone. Pay close attention to the instructions for each section providing only the information requested as later sections may request related information. This will preclude duplicity in the application. |
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# List of Acroymns/Abbreviations

Complete this table with all abbreviations/acronyms used herein. Add rows as needed.

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| **Acronym/Abbreviation** | **Definition** |
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# Protocol Summary

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| **Title:** | Study title. |
| **Study Population:** | Describe targeted study participants. Detail any/all vulnerable populations or state no vulnerable individuals will be used. |
| **Study Purpose:** | State the purpose of the research. |
| **Primary Intervention:** | Describe the study intervention(s). |
| **Overall Study Duration:** | Provide the desired start date and the expected end date through data analysis for this study. |

Check the appropriate box relating to the proposed research.

[ ]  This research seeks to collect participant identifiable private information.

[ ]  No participant identifiable private information will be collected.

# Background, Rationale & Purpose

## Study Signifiance and Rationale

Describe the health or working condition the study will address. State the rationale for and potential significance of the research. Provide a concise background based on existing knowledge, published research, evidence-based practice guidelines, and current standard(s) of practice. Include any pertinent unpublished data if existent. Cite all sources numerically in the order of their appearance. Full citations are to be provided in Section 9 of this application.

## Study Purpose

State the purpose of the research. The purpose or primary objective is the reason for performing the study in terms of the scientific question to be answered. State secondary objectives if they exist. Secondary objectives are goals that may provide further information on the topic. Include your hypothesis/hypotheses regarding what the study findings might reveal and/or the practical application(s) of the research.

# Study Design, Endpoints and Population

4.1 Study Design

The scientific integrity of the study and the credibility of the data collected depend substantially on the study design and procedures. Describe the design/type of study (e.g., comparative, descriptive, etc.) and include the target study population (e.g., inpatient/outpatient, employee, subject groups if comparative). State the methodological approach (e.g., observational, phenomenological, etc.) and the study interaction or intervention or means of observation. Interactions may include surveys, interviews, or focus groups. Interventions may include staging scenarios or manipulating the environment to evaluate behavior.

4.2 Endpoint(s)

Describe the primary study endpoint, event, or outcome to be evaluated or observed. Describe any secondary endpoints, events, or outcomes to be evaluated or observed if any.

4.3 Study Population

4.3.1 Inclusion and Exclusion Criteria

Describe the criteria that define who will be included in the study. If this research includes any persons considered to be a Vulnerable Population, then complete the Vulnerable Populations Form and include it in the application appendix. Next, describe the criteria that define who will be excluded from the study.

Exclusion criteria may include vulnerable populations (e.g., pregnancy, dementia, mentally challenged or psychiatric patients, incarcerated persons, etc.). Also, anything that would exclude a potential subject even if they met all inclusion criteria (e.g., incomplete survey responses, failure to show for a focus group, etc.). Do not include antithesis of inclusion criteria (e.g., minors, participants not members of the targeted population, etc.).

4.3.2 Select the applicable option as it pertains to this research:

[ ]  This research does not require access to individual private health information. Therefore, HIPAA does not apply.

[ ]  I am requesting IRB waiver of research subject authorization for study participation.

[ ]  The study will only collect information provided voluntarily by the participants.

4.3.3 Population Size

State the number of participants you plan to enroll and how this sample size was determined. Include the lowest number of participants sufficient for data analysis and the maximum number estimated to voluntarily participate. Address the feasibility of enrolling a sufficient sample.

# Study Methods

## Procedures

Provide a description of all research procedures to be performed and when they are to be performed. Describe the data to be collected and the source(s) to be utilized for collection. Provide surveys, scripts, and/or other pertinent instruments in the application appendices.

## Participant Identification and Recruitment

Describe the methods that will be used to identify and subsequently recruit potential participants. When, where, and how will potential participants be recruited. For example, will recruitment advertisements be sent to potential participants or will advertisements be posted publicly? Will potential participants self-identify in response to posters, mailings, emails, etc., or will they be actively recruited, i.e., verbally propositioned. If the latter, identify who will make initial contact with potential participants.

If the basis for participant identification is a potential participant’s employment status, delineate the particulars. If participant identification is based on information contained in private/protected records, e.g., employment records, student records, etc., explain your legitimate access to these records.

## Recruitment Materials

Append any and all recruitment materials to this application. For advertisements, attach the final copy of printed advertisements. When advertisements are recorded for broadcast, attach the final audio recording script and for video recordings provide a URL link. Alternatively, the wording or script for recorded advertisements may be submitted instead of final recording scripts, i.e., prior to recording them to preclude the necessity of re-recording due to wording changes (omissions, deletions, revised verbiage, etc.). In such cases, the IRB must review the final audio/video recording after approving the initial wording or script.

## Participant Compensation

If study participation includes a financial benefit, describe the type (payment, reimbursement, gift, extra credit, etc.), amount, and timing of the compensation, i.e., when it will be provided to the study participants. If not applicable, state no compensation will be provided to study participants.

## Withdrawal of Participants

Describe aniticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures to be followed when participants chose to withdraw from the study with regards to data already collected.

## Data Analysis

Detail the data analysis plan. Include statistical methods for organizing the data and those for determining statistical significance. Describe how missing data will be handled and the justification for the proposed method.

## Data Handling and Confidentiality

Explain how the data will be recorded, whether entered electronically or on hardcopy data collection forms. State the procedures for maintaining subject confidentiality of the data.

Example confidentiality verbiage: 1) Electronic data will be stored under two levels of password protection on a facility private server, 2) Collected surveys will be kept in a locked cabinet in a secure location. If the study interaction, intervention and/or observation will include identification of the participant, explain the means for de-identifying the data prior to analysis. State that study findings will be reported in aggregate only. If the research data will be collected anonymously, state if waiver of documentation of informed consent will be requested. If the research seeks to collect data anonymously by observation, state that waiver of informed consent will be requested.

## Study Records Retention

Summarize the record retention plan applicable to the study. Take into consideration any Departmental requirements, if applicable. The Catawba Valley Med Cnt IRB requires that study records be retained for at least three years after completion of the study. Please note that research records will be made available to regulatory bodies (OHRP, FDA) when requested.

# Risk(s) to Participants and Incomplete Disclosure or Deception

## Foreseeable Risk(s) & Mitigation Strategy

List foreseeable risks, discomforts, hazards, or inconveniences related to an individual’s participation in the research. Consider psychological, social, legal, employment, and economic risks. Include, as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. If identifiable data is collected and then de-identified prior to analysis, the possibility of an inadvertent breach of confidentiality prior to the time of de-identification exists. Address the mitigation strategy for all associated risks.

## Incomplete Disclosure or Deception

If the research involves incomplete disclosure or deception, provide the rationale. Indicate if participants will be informed that the study involves deception and given the opportunity to authorize the deception through a prospective agreement. Attach the agreement in the application appendices. If participants will have no prior knowledge of the incomplete disclosure or deception, provide a description of the debriefing process, how it will be documented including a participant’s right to withdraw any record of their participation.

# Potential Benefit(s) to Participants

Describe the potential benefits that individual participants may experience as a result of taking part in the research. Indicate if no direct benefits to individual participants are applicable. Benefits to future students, employees, patients, or to society as a whole may be included after addressing potential benefits to or not to study participants.

# Sharing and Dissemination of Study Results

## Sharing Study Results with Participants and Research Team Members

Indicate whether results (aggregate study results or individual participant results, such as survey results) will be shared with participants or others (organizational leadership, education administrators, etc.) and state the means by which results will be shared. Describe how the research data will be shared among research team members and across multiple sites if applicable.

## Dissemination of Study Findings

Indicate dissemination intentions for the study findings. Include the proposed dissemination type and the audience or setting. For example, poster and/or podium presentation at a departmental meeting and/or a professional organization conference. thesis, manuscript, etc.

# Informed Consent

## Consent Process

Describe the consent process, including: 1) where the consent process will take place; 2) who and how will it be determined that a potential participant understands the information; and if applicable 3) the process to ensure ongoing consent in the case of long-term participant follow-up. Submit the Informed Consent Form as an appended document to this application. If IRB waiver of informed consent is being requested, state and complete Section 9.3.

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## Waiver of Written/Signed Documentation of Consent

When the only identification of a research participant would be the signed Informed Consent form, the researcher may request a waiver of written/signed consent [45 CFR 46.117(c)]. This does not preclude the researcher from obtaining prospective participants’ consent - only that there is no requirement for the study volunteer to sign the consent form.

[ ]  The research involves no more than minimal risk to the participant;

[ ]  The ONLY identification of the participant would be signed consent. The researcher wishes to conduct the study anonymously. Informed Consent will be obtained from the participant without the participant’s signature.

9.3 Request for Waiver of Informed Consent

Informed consent can be waived or altered under 45 CFR 46.116(f)(3) if an IRB finds all of the following conditions have been met. Check all items that apply to this research.

[ ]  The research involves no more than minimal risk to the subjects;

[ ]  The research could not practicably be carried out without the requested waiver or alteration;

[ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

[ ]  The waiver of alteration will not adversely affect the right and welfare of the subjects; and

[ ]  Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

# Researcher Assurance of Ethical Conduction of Proposed Research

# This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines). This protocol and any amendments will be submitted to the Catawba Valley Med Cnt Institutional Review Board for formal approval. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. Commencement of the study cannot begin until written notification of approval or exemption has been received. A copy of the IRB letter will be provided to the research sponsor.

I have read and understand the statements above and ensure that I will abide by them. By checking the box and typing my name below, I affirm this to be my electronic signature and the legal equivalent of my manual signature.

[ ]  Investigator Signature: Date:

# Literature References

Provide a listing of all literature references cited in numerical format in Sections 3-6. Example formats for various types of sources: <http://www.nlm.nih.gov/bsd/uniform_requirements.html>.

# Appendices

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| **Yes** | **Y** | Good Clinical Practice Education Completion Certificate(s) |
| **Yes** | **Y** | HIPAA Education Completion Certificate(s) |
| **Yes/No:** | **Y/N** | Study Design Schematic  |
| **Yes/No:** | **Y/N** | Standard of Practice or EBP Guideline Document(s) |
| **Yes/No:** | **Y/N** | Vulnerable Populations Form |
| **Yes/No:** | **Y/N** | Informed Consent Waiver or Alteration Form |
| **Yes/No:** | **Y/N** | External IRB Decision Notification |
| **Yes/No:** | **Y/N** | Other: describe |