Catawba Valley Med Cnt Institutional Review Board
Application for the Conduct of Research Using Human Subjects

Before applying to the IRB, investigators must consult guidance from the Department for Research & Evidence-Based Practice at research@cvmc.us. Student and novice investigators are required to have Catawba Valley Health System (CVHS) sponsorship. The Department will assign research sponsors. All items must be completed, and the application submitted electronically or in PDF format to irb@cvmc.us.

Title of Proposal:		
Primary Investigator (PI) Name & Credentials:		
PI Status: ☐ CVHS Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Non-CVHS		
PI Department:	PI Work Phone:	PI Mobile:
PI Work Email:	PI Personal Email:	
Co-Investigator Name & Credentials:		
Co-Investigator Email:	Co-PI Work Phone:	
Sponsor Name & Credentials:	Sponsor Dept:	
Sponsor Email:	Sponsor Work Phone:	
Proposed Study Dates: Beginning	Through	
Source of Funding (if applicable):		
Has this study been reviewed by another IRB? ◯ No ◯ Yes		

Indicate Protecting Human Research Participants (PHRP) and HIPAA training completed. **Training is required**.

PI	☐	PHRP & HIPAA
Co-PI	☐	PHRP & HIPAA
Sponsor	☐	PHRP & HIPAA
Key Personnel (name):	☐	PHRP & HIPAA
Key Personnel (name):	☐	PHRP & HIPAA

Undersigned Acknowledgment of Assurance Statements:

This application represents an accurate and complete description of the proposed research. The research will be conducted in compliance with the recommendations of and only after written approval has been received from the CVMC IRB. The rights and welfare of human subjects participating in the research will be protected. Informed consent will be secured unless the IRB has approved a waiver. The confidentiality of the data will be safeguarded. Study records will be maintained according to IRB guidelines. Written IRB approval will be obtained prior to implementing any substantive modifications in the proposal, including changes in procedures, personnel, etc. The PI will promptly report any significant adverse events or unanticipated problems that may occur in the course of this study. All IRB requests to report on the status of the research will be complied with. I (we) understand if these conditions are not met, this research could be suspended or terminated.

Principal Investigator Signature:

Co-Investigator Signature:

As Student or Novice Investigator Sponsor, I assume the responsibility for ensuring that the student or novice investigator complies with CVHS policies and federal regulations in conducting this research and the use of human subjects in research.

Sponsor Signature:

Study Description Instructions. To allow the IRB, consisting of scientists and non-scientists, to fully understand the study, use non-technical terms to describe the proposed research, i.e., avoid clinical jargon. The IRB must have complete and detailed information about what will happen with or to human subjects in order to evaluate or estimate the potential risks. Use complete sentences; bulleted information is NOT acceptable. Define acronyms upon first use followed by the acronym in parentheses. If an item is not applicable, then so indicate by listing **NA**.

Purpose of the Research

Provide a brief background explaining why this research is important, state the purpose of the research and expected hypothesis(es) as appropriate, and whether/how the study results will be used and/or disseminated to others.

Research Procedures

Describe the study design and all study procedures including how the data will be collected and/or accessed. List any/all identifying information (personal identifiers) to be recorded.

Have the data been or will be collected solely for non-research purposes (treatment or diagnosis)? Yes ◯ No ◯

Research Subjects: Will any of the subjects fall under Federal guidelines for vulnerable subjects?

a. Minors: <18 years of age?	◯	Yes	◯	No
b. Prisoners?	◯	Yes	◯	No
c. Pregnant women?	◯	Yes	◯	No
d. Mentally infirmed?	◯	Yes	◯	No
e. Other potentially vulnerable persons (specify)?	◯	Yes	◯	No
Additionally,				
f. Will the subjects be employees of Catawba Valley Health System?	◯	Yes	◯	No
g. Will the subjects be deceived in any way?	◯	Yes	◯	No
h. Will information be requested that subjects might consider to be personal or sensitive?	◯	Yes	◯	No

Target number of subjects:

Describe inclusion and exclusion characteristics.

Explain how subjects will be recruited or selected and enrolled.

Informed Consent: Describe how informed consent will be obtained from subjects.

◯ Consent will be obtained from each subject (written, oral, or parent/guardian w/wo assent)

◯ Waiver of documentation of consent requested

◯ Waiver of consent requested

Privacy/Confidentiality

Explain how confidentiality of the data will be maintained.

Will identifiable data be made available to anyone other than the study investigators (PI, Co-PI(s), Sponsor) and the Director for Research & Evidence-Based Practice? Yes ◯ No ◯

If yes, explain who and why they will have access to the identifiable data?

Describe the data security plan to include how the data will be recorded (electronic, paper), stored (private server, password protection, encryption, locked cabinet) and duration of storage.

Risks and Benefits

State the risks to subjects that may occur because of their participation in this study. Describe the means in place to minimize these risks.

State the benefits that are expected to accrue to subjects as a result of participating in this study. Note: Benefits to society and/or persons in the future may be included, but these are not direct benefits to the study subjects.

Payment to Subjects

Will subjects be paid or receive incentives to participate in the study? Yes ◯ No ◯

If Yes, explain.

Investigator-Subject Relationships

Select the option(s) below describing any relationship that exists between the investigator(s) and potential subjects.

☐	None
☐	Practitioner-Patient
☐	Manager-Subordinate
☐	Co-Workers
☐	Other- specify:

Address how the identified relationship(s) could influence a subject's ability to participate voluntarily.

Attachments

Check all that apply.

☐	PHRP completion certificate(s)	☐	Consent Waiver Request
☐	HIPAA completion certificate(s)	☐	Recruitment materials (flyers, email message text)
☐	Informed Consent Form	☐	Survey or Subject Interview Script
☐	Oral Informed Consent Script	☐	External IRB Application and Decision Notification
☐	Assent Form	☐	Other (specify):