CentraCare Health

INSTITUTIONAL REVIEW BOARD (IRB)

APPLICATION FOR RETROSPECTIVE CHART/RECORD REVIEW

Study Title:

1) Personnel

All personnel listed (PI, co-investigators and study personnel) must attach a copy of their completed Investigator Financial & Other Personal Interests Disclosure Form

Principal Investigator (PI) (last name, first name, MI, highest degree earned)	
St. Cloud Hospital/CentraCare Paid Faculty	YES or NO
St. Cloud Hospital/CentraCare Staff	YES or NO
Phone	
Pager or Cell	
Fax	
Email	
Required education in human subjects protection completed	YES or NO

Contact person for IRB matters, if other than PI. *This person must be listed under Study Personnel in the box below.*

Name	Phone
E-mail	Fax

STUDY PERSONNEL: All individuals responsible for or working on this study must be listed below for the IRB record. This includes individuals who will have responsibility for the consent process, interactions or interventions with subjects, data collection, etc., or who will have access to identifiable private information for research purposes

Study Personnel (Name/Degree/Title)	Role in Study *Identify as co-investigator or other personnel*	Department	Phone	E-mail	Month/Year of Completion for Human Subjects Protection training

2) Sponsor

Is this study funded? YES or NO

If yes, complete the following:

Name of Funding Agency:

Title of funded study, if different from IRB study application title:

Identification number:_____

Grant/Project number:_____

Dates of funding are/will be from_____ to _____

If funded, attach a complete copy of grant application as submitted to the sponsor. Salary information (not % effort) may be redacted.

3) Subject Population

Age range:_____ to _____

Vulnerable Populations: Check all populations below that might be enrolled, even if not target group:

- ○ Non-English speaking
- ○ Minorities
- ○ Wards of the state or foster children
- ○ Pregnant women
- ○ Fetuses
- ○ Economically or educationally disadvantaged
- ○ Diminished decision-making capacity
- ○ Prisoners

4) Research Plan

a) Purpose of the study (provide a brief description)

b) Provide background information, including references to any prior studies, to support your project.

c) Describe the expected medical, scientific and research benefits of the project.

d) What are the potential risks (including breach of confidentiality) and/or benefits to subjects or society?

e) How will you obtain your list of potential subjects?

f) How will data be obtained? Check all that apply

- ○ Hospital Medical Record
  - ○ Epic
  - ○ Paper
  - ○ Other _____
- ○ Office Records
  - ○ Paper
  - ○ Electronic, specify source:_____

○ Other, specify:

_____

g) How many records will be reviewed?

h) Records will be accessed to review information dating from _____to_____

i) Who will review the records? *List anyone who will have access to the personal identifiers collected for research.*

j) Where will the records be located?

k) What data items will be collected? Provide specific data fields or attach data collection sheet.

l) Describe the plan for data analysis:

Privacy/Confidentiality

Personal Identifiers are any data that can be used to identify a unique individual (e.g. name, medical record number, social security numbers, address).

a) Check all personal identifiers that will be recorded or linked by code to the data, select None if no identifiers will be recorded.
   - ○ None
   - ○ Name
   - ○ Social Security number
   - ○ Medical record number
   - ○ Telephone number
   - ○ Address by street location, city, zip code
   - ○ Dates (unless use of year only), e.g., date of birth, admission/discharge date, date of procedure, date of death
   - ○ Fax number

- ○ E-mail l address
- ○ Web addresses (URL's)
- ○ Internet IP address
- ○ Account number
- ○ Health plan beneficiary number
- ○ Certificate/license number
- ○ Vehicle identification number and serial numbers, including license plate number
- ○ Medical device identifiers and serial numbers
- ○ Biometric identifiers (finger and voice prints)
- ○ Full face photographic image
- ○ Any other unique identifier or combination of identifiers likely to identify the subject

PHI or Protected Health Information is protected by HIPAA and includes information about an individual's physical or mental health, health care or payment for health care so long as that health information is identifiable, i.e., linked to some personal identifier.

PHI includes both personal identifiers and health information and must be protected (i.e., consent must be include the HIPAA Authorization section or the IRB must grant an Authorization Waiver).

Will data collected contain any PHI?

- ○ Yes
- ○ No

b) How long will you keep the link (identifying code) to the personal identifiers? *State in terms which relate to the study timeline, i.e., after data entry is complete, until close of study, six years after study completion, etc. State N/A if no link will be kept. State indefinitely if the link will never be destroyed. If the link will be kept indefinitely, explain why the identifier must be retained, including whether it is needed for a health purpose, legal or institutional requirement or another reason.*

c) How long will you keep the research data? *State in terms which relate to the study timeline, e.g., six years after the closure of the study. State indefinitely if the data will never be destroyed.*

d) Describe how the data will be stored and protected:

i. For paper-based information include the following information: where the data will be stored, who has access to the storage area, and how access will be monitored:

ii. For electronic information include the following information: how electronic security will be maintained, what password protection and virus software are enabled, and how the system will be audited:

e) Is your computer authenticated within the CentraCare Health System?

- ○ Yes
- ○ No

If not, list computer, its use, and location:

f) Is the PI the data steward?

- ○ Yes
- ○ No

(A data steward is any individual who creates, maintains or stores a file, which contains protected health information and is responsible for that database.) *Note that the data must be listed on page 1 of the application under Personnel.*

If not, indicate who will be responsible:

g) Do you have encryption capabilities for transmission of PHI?

- ○ Yes
- ○ No

h) Will your research data be stored in a repository?

- ○ Yes
- ○ No

If yes, is it compliant with NIH regulatory requirements?

i) Will your data be used to create a data repository?

- ○ Yes
- ○ No

If yes, the creation of a date repository requires the submission of a separate protocol to the IRB

Informed Consent and Authorization for Use of PHI

Will informed consent be obtained or data collection and storage?

- Yes
- No

If Yes, attach copies of informed consent

If No, you must request a **Waiver of Informed Consent and Authorization** by supplying the following information):

a) Explain why/how this research involves no more than minimal risk to the subjects or their privacy.

b) Explain why the waiver of alteration will not adversely affect the rights and welfare of the subjects.

c) Explain why the research could not practicably be carried out without the waiver or alteration

d) Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation

e) If personally identifiable information will be collected, describe:

1) The plan in place to protect identifiers from improper use or disclosure

2) When and how identifying information will be destroyed

3) Why the research could not be practicably conducted without access to/use of this identifiable information

Signatures

Investigator Assurance:

- I agree to accept responsibility for the scientific conduct of the protocol and to comply with Federal, State, and St. Cloud Hospital policies relative to the protection of the rights and welfare of human subjects.
- I will submit to the IRB for review any changes in the protocol before their implementation. I also agree to provide the required final progress report at the end of the study and/or progress report for continuing review in time to have this study approved before the expiration date as directed by the IRB.
- I will promptly inform the IRB of any and all protocol deviations/violations or unanticipated problems.
- My signature below also provides written assurance that identifiable information will not be reused or disclosed except as required by law; or for other research only if that research has been reviewed and approved by CentraCare IRB with specific attention to an approval of the issue of access to this identifiable information.

Print Name:_____

Signature:_____ Date: _____