

**TITLE: SUBMISSION OF RESEARCH PROTOCOL TO THE ST. CLOUD HOSPITAL
INSTITUTIONAL REVIEW BOARD (INTERNAL)**

Original: 5/03 Revised: Replaces
Responsible Person(s): Chairperson, Institutional Review Board
Cross Reference: Nursing Research Proposal Policy

I. POLICY:

It is the policy of the St. Cloud Hospital Institutional Review Board (IRB) that all research protocols submitted for review pass through a preliminary review procedure as outlined in this policy.

The procedure is designed to provide the IRB with information necessary to determine the feasibility of providing study resources and recovering costs incurred by St. Cloud Hospital, CentraCare Pharmacy and CentraCare Laboratory Services.

The investigator is responsible for the completion of the documents and payment of fees as indicated in the IRB Review Application prior to full IRB review unless waived by the IRB Chairperson.

II. PURPOSE

To ensure that the procedure for submission of a research protocol for the St. Cloud Hospital is appropriately followed according to the guidelines noted in this policy.

III. DEFINITIONS

A research study protocol is described as: A formal written document which states the rationale, objectives and statistical design/methodology of the trial, with the conditions under which is performed and managed.

IV. PROCEDURES/GUIDELINES

The investigator contacts the IRB secretary to submit a study for IRB review.

1. IRB secretary provides investigator with the IRB Application packet. Contents include:
 - a. Submission of Research Protocol for Institutional Review Board Review
 - b. IRB Fee Schedule
 - c. IRB Initial Protocol Submission Cover Sheet (includes IRB meeting schedule and required documents for submission of protocols)
 - d. Conflict of Interest Form
 - e. Feasibility Assessment
 - f. Cost/Resource Analysis Checklist
 - g. HIPAA Authorization Document
2. Nursing investigators must contact the Nursing Research Review Board for an IRB and NRRB application. All nursing research protocols must be reviewed by the NRRB prior to IRB review. The IRB secretary provides investigator with the NRRB application packet.
3. The investigator/study coordinator will contact the Care Center Director/Department Director of the St. Cloud Hospital primarily affected by the study for Cost/Resource Analysis and Feasibility Assessment. The Care Center Director/Department Director will have 45-60 days to review/process the feasibility assessment.
 - a. Investigator must settle any Care Center Director/Department preparation fees (if applicable) before proceeding.

4. Following completion of the cost/resource analysis and feasibility assessment, the investigator returns completed application with the following required documents to Linda Chmielewski, IRB Chairperson.
 - a. Required documents include:
 1. Completed Protocol Submission Cover Sheet
 2. Feasibility Assessment
 3. Conflict of Interest Document
 4. Summary Page of Protocol
 5. Informed Consent Document
 6. HIPAA Authorization Form (if not already included in the Informed Consent)
 7. Budget
 8. Research Proposal/Protocol
 9. Investigator's Brochure
 10. Investigators CV
 11. Supporting Documents (questionnaires, abstracts, advertising materials)
5. IRB chairperson reviews application and determines if study will be submitted for IRB review.
 - a. IRB secretary contacts the investigator with decision or request for additional information
 - b. IRB fee must be settled prior to IRB review
 - c. Research studies approved will be scheduled for IRB review at next available meeting.

**St. Cloud Hospital
St. Cloud, Minnesota**

INSTITUTIONAL REVIEW BOARD FEE SCHEDULE

Industry Sponsored Study: \$1,500
• Expedited Review/Amendments additional \$250 each

Non-Industry Funded Study: \$1,000
• Expedited Review/Amendments additional \$250 each

Unfunded Study (Government, Academic, Internal): Fee is Waived

Compassionate Use Study: Fee Waived

The fee for ECOG, NCCTG and RTOG protocols are waived.

The IRB Chairperson reserves the right waive IRB fee any time.

INSTITUTIONAL REVIEW BOARD
FEASIBILITY ASSESSMENT

Principle Investigator or designee to complete for all protocols submitted for IRB review.

Applicant: _____ Phone #: _____ Date: _____

Principle Investigator: _____ Sponsor: _____

Address: _____ Site: _____

Protocol Title: _____

_____ Device IDE#: _____

FEASIBILITY ASSESSMENT (Principal Investigator or designee to complete)

1. Adequacy of patient population:

____ Not applicable (no patients will be enrolled at St. Cloud Hospital). (omit question 2)

Patient recruitment goal: _____ patients

Time period for enrollment _____ months/years

Describe patient pool. Include department or site, approximate number of available patients and recruitment methods. _____

2. Adequacy of Resources:

a. What percentage of time will be needed by the investigator(s) over what time period?

b. Please describe staffing needs (personnel and time commitment):

c. Who is responsible for negotiating the budget?

d. Include the signed and completed attached Department Service Agreement (Attachment A) for each department requesting protocol-related services. i.e., pharmacy, laboratory, imaging services, etc.

e. Preparation fee _____ paid__ /pending __/ not applicable ____

3. Please note location of Investigator's Brochure: _____
(i.e., Primary Investigator's office / Coordinator's Office)

Please attach any comments on the availability and allocation of resources.

Completed by: _____ Date: _____

Reviewed by: _____ (Principal Investigator) Date: _____

St Cloud Hospital Review:

Study is __ / is not __ feasible for implementation at St Cloud Hospital with current or funded resources.

Care Center/Department Director Signature's Date

To Be Returned with IRB Application

St. Cloud Hospital

DEPARTMENT SERVICE AGREEMENT**Study Department:**

1. A Department Service Agreement form must be completed for each department providing protocol-related services.
2. Please allow the service department adequate time to complete the form. The service department should receive the service agreement at least 4 weeks prior to the scheduled IRB meeting.
3. Attachments C lists of individuals for each department, who may sign off on participation in a clinical trial.
4. The service agreement form will also need to be signed off by the Managed Care Research Compliance designee prior to submission to the IRB.
5. Study department will complete the following fields on the Department Service Agreement:
 - a. **Protocol Title**
 - b. **Study Department**
 - c. **Study Director**
 - d. **Phone #**
 - Study director's extension
 - e. **Study start date**
 - Approximate date study will begin enrolling patients if approved by the IRB.
 - f. **Approximate length of the study**
 - Time frame the study will continue to enroll patients.
 - g. **Department providing service**
 - List the department that will perform the protocol specific service (e.g. lab, radiology, etc.)
 - h. **Department Locations**
 - Enter the location of the department providing protocol specific services (e.g. Plaza Lab, River Campus Lab, etc.)
 - i. **Estimated number of patients to be seen**
 - The number of patients anticipated to receive the service outlined in the protocol
 - j. **Service or Item (#1)**
 - A brief description of the service outlined in the protocol (e.g. TSH, MRI breast unil wo & w contrast)
 - Attach the pertinent pages from the protocol to assist the department in accurately evaluating the service(s) to be performed and accurately quote a price.
 - k. **Estimated Number of services expected per patient (#2)**
 - e.g. Protocol specifies patient will receive 3 DEXA scans throughout the course of the study...3 would be entered in this field.
 - l. **Hospital Service Discount (#7)**
 - A 30% discount will automatically be applied to St. Cloud Hospital services.
 - If the study department and service department agree upon a discount (either less than or great than) other than the 30%, it must be outlined on the form with both department director signatures.
 - Managed Care has the authority to deny any discount which is larger than the 30%.
 - The hospital discount is for hospital services, provided to hospital departments enrolled in studies.
 - m. **Signature**

- After you have received the form back from the Ancillary Department, and agree with the price listed and acceptance or denial of the 30% discount, please sign and date.

n. **Managed Care Signature**

- Forward completed and signed form to the Managed Care Clinical Research Compliance Designee. Once signed, the Managed Care designee will return the form to the study department for submission with the IRB packet.

Ancillary Department Providing Study Related Services

1. Each department providing protocol-related services must complete a Department Service Agreement form.
2. Please return the service agreement to the study department listed no later than 10 days of its receipt.
3. Study department will supply the ancillary department with pertinent pages from the protocol to assist in accurately evaluating the service(s) to be performed and accurately quote a price.
 - a. If the protocol page(s) are not attached, please contact the Department Director listed on the form.
- b. Ancillary department will complete the following fields on the Department Service Agreement:
 - a. **CPT/HCPC (#3)**
 - b. **Charge Code (#4)**
 - c. **Technical Fee for Service (#5)**
 - d. **Professional Fee for Service (#6)**
 - Please forward the form to the individual that can supply the correct professional fee (Clinic Administrators are listed below as well as their departments) and their signature. (e.g. reading of MRI from radiologist, ICD analysis, etc.)
 - e. **Hospital Service Discount (#7)**
 - Hospital services will automatically receive a 30 % discount, unless deemed otherwise, which will be outlined on the signed form.
 - f. **Signature**
 - Please sign below with the date and your extension, which signifies you agree to perform the service(s) requested at the price and discount listed.

Please forward any questions in regards to completing the Department Service Agreement Form to Sherri Liebl ext. 54536, St. Cloud Hospital Managed Care and Clinical Research Compliance.

**Attachment C
Department Service Agreement
Contact list**

NAME	DEPARTMENT(S)	PHONE #/EXTENSION
PENNY BEATTIE	FBC/CHILDREN'S CENTER/PERINATOLOGY/OUT REACH PCW	656-7103 / 57103
PHIL LUITJENS	SURGERY/ANESTHESIA/CSC/ POH/PACU/ & CPD	54248
ROBERTA BASOL	SURGICAL CARE UNIT & ICU	54110
GAIL OLSON	HOME CARE/HOSPICE	259-9375 / 23280
MARY PHIPPS	PHARMACY	251-2700 / 54083
JIM MAHOWALD	PHARMACY INPATIENT	251-2700 / 54084
MICHELE OLMSCHIED	PHARMACY INFUSION	251-2700 / 70979
CINDY JOHNSON	LABORATORY SERVICES	251-2700 / 57312
JIM FORSTING	BEHAVIORAL HEALTH SERVICES	251-2700 / 23790
MARY SUPER	IMAGING SERVICES	251-2700 / 55694
SANDY JOHNSON (1st point of contact)	COBORN CANCER CENTER	251-2700 / 70855
JO ZWILLING (Only if Sandy not available)	COBORN CANCER CENTER	229-4952 / 74952
TIM DALTON	NON-INVASIVE HEART CENTER PROCEDURES	251-2700/57462
PHIL MARTIN	INVASIVE HEART CENTER PROCEDURES	251-2700/57461
AARON FISTER	EKG, ECHOS, HOLTERS, HEART CENTER	251-2700/57499
<i>CLINIC SERVICES</i>	<i>PROFESSIONAL COMPONENTS</i>	
JIM GWOST	CARDIOLOGY, GASTROENTEROLOGY, NEONATOLOGY	240-7845 / 57845
MICHELE FISCHER	FAMILY PRACTICE SITES (Heartland, Plaza, St. Joe, Becker, Melrose, Little Falls, Long Prairie),	240-2154 / 57845
PAT FAUST	WOMEN'S & CHILDREN'S CLINIC	654-3605 /73605
GREG CAMPBELL	RIVER CAMPUS	240-2150 / 52150
RYAN BJERKE	GENERAL SURGERY, NEPHROLOGY, PULMONOLOGY	240-7835 / 57835

OR CONTACT SHERRI LIEBL 320-251-2700 EXT. 54536 TO ASSIST IN PRICING.

**Institutional Review Board
INITIAL PROTOCOL SUBMISSION COVER SHEET**

To Be Completed By the Investigator

Please complete for all protocols submitted for IRB review.

Applicant: _____ Phone #: _____ Date: _____

Principle Investigator: (If different than applicant): _____

Address: _____ Site: _____

Protocol Title: _____

GENERAL INFORMATION (Incomplete applications will be returned)

_____ Internally or Collaboratively Generated

_____ Externally Generated

_____ Compassionate Use

Complete budget information for all applications:

Budgeting assistance is requested? _____ Yes _____ No

Is funding requested? _____ Yes _____ No*

If yes:

_____ Funding request is attached

Will this study be supported by any other resources?

Yes _____ Attach Documentation _____ No*

Has external funding been requested or secured? _____ Yes _____ No*

_____ Budget proposal attached

_____ Budget proposal is pending

_____ Enter name of proposed funding agency.

*If this study is not funded, and you are not requesting funds, please include explanation detailing the allocation of resources.

ST. CLOUD HOSPITAL IRB MEETING SCHEDULE

The St. Cloud Hospital IRB meets the third Thursday of each month from 7:30 – 9:00 a.m. in the Spruce Room of the St. Cloud Hospital Conference Center. For questions, please contact Brenda Ackerman in the Administration Office at ext. 55723.

REQUIRED DOCUMENTS TO SUBMIT WITH IRB APPLICATION

- | | |
|---|--|
| 1. Completed Protocol Submission Cover Sheet | 9. Investigator's Brochure (do not need to include in packet, but need to know where it is located) |
| 2. Feasibility Assessment | 10. Investigator's CV |
| 3. Conflict of Interest Document | 11. Supporting Documents (questionnaires, abstracts, patient teachings, advertising materials) |
| 4. Summary Page of Protocol | 12. Department Service Agreement |
| 5. Informed Consent Document | 13. Industry Sponsored Studies: Initial contract between Facility and Vendor must be submitted to the Managed Care Coordinator for review. |
| 6. HIPAA Authorization Form (if not already included in the Informed Consent) | 14. A copy of the Certificate of Human Subjects Training |
| 7. Budget | |
| 8. Research Proposal/Protocol | |

To Be Returned with IRB Application

**St. Cloud Hospital
St. Cloud, Minnesota**

CONFLICT OF INTEREST DISCLOSURE

_____ I have no actual or potential conflict of interest in relation to this study.

_____ I have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject and/or funding of this study.

A significant conflict of interest is considered:

- \$10,000 per year income
- Equity interests over \$10,000 or 5% ownership to the company

Attach explanation for each:

_____ Consultant at/for _____
_____ Speaker for _____
_____ Stock shareholder in _____
_____ Proprietary interest in _____ Value: _____
_____ Other financial or material support (\$) _____

Principal Investigator's Signature

Date

To Be Returned with IRB Application

Cost/Resource Analysis Checklist

(To Be completed by Care Center Director/Department Director and Investigator)

Study Title:

Investigator/Sponsor: _____

Administrative Pre-trial costs				
Item	Estimated hours	Base Cost	Total (hours x base cost)	Comments
Assessment of protocol feasibility				
Budget preparation & negotiation				
IRB submission preparation				
Coordination of Services				
Pharmacy				
Radiology				
Laboratory				
Other Ex: Managed Care				
Care Center Activities				
Staff training				
Participation • RN • Case Coordinator • Other				
Other				
Admin./Pretrial Costs		Subtotal		
		25% institutional overhead		
		Total		

This is a guide, please attach any additional supporting financial documents.

Care Center Director/Department Director _____ Date _____

To Be Returned with IRB Application