TITLE: SUBMISSION OF RESEARCH PROTOCOL TO THE CENTRACARE INSTITUTIONAL REVIEW BOARD

Original: 5/03 Revised: 1/2014; 9/2015; 8/2016; 11/2016, 2/2022 Replaces: 8/2016
Responsible Person(s): Chairperson, Institutional Review Board
Cross Reference: Nursing Research Proposal Policy

I. POLICY:

It is the policy of the CentraCare 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 CentraCare.

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 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 NRRB application. All nursing research protocols must be reviewed by the NRRB prior to IRB review.
3. The investigator/study coordinator will contact the Senior / Executive Director(s) of any CentraCare departments affected by the study for Cost/Resource Analysis and Feasibility Assessment. The Senior / Executive Director(s) will have 45-60 days to review/process the feasibility assessment.

   a. Investigator must settle any Senior / Executive Director(s) 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 the Research Compliance Officer.

   a. Required documents include:
      1. Completed Protocol Submission Cover Sheet
      2. Feasibility Assessment
      3. Conflict of Interest Document
      4. Informed Consent Document
      5. HIPAA Authorization Form (if not already included in the Informed Consent)
      6. Budget (if applicable)
      7. Research Proposal/Protocol
      8. Investigator's Brochure (if applicable)
      9. Investigators CV
      10. Supporting Documents (questionnaires, abstracts, advertising materials)
      11. Documentation of Human Subjects training

5. The Research Compliance Officer reviews application and determines if study will be submitted for IRB review.

   a. The Research Compliance Officer contacts the investigator with requests for additional information.
   b. IRB fee must be settled prior to IRB review.
   c. Proposed research studies will be scheduled for IRB review at the next available meeting.

CentraCare
St. Cloud, Minnesota

INSTITUTIONAL REVIEW BOARD FEE SCHEDULE

Industry Sponsored Study: $1,500

- Expedited Review/Amendments additional $250 each
- Continuing Reviews -- $250 annually

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 to 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#:_____

If this is a Medical Device Study, please indicate if it is Significant Risk or Non-Significant Risk?
_____ Significant Risk _____Non-Significant Risk

Please provide the name of the Data Safety Monitoring Board and how frequently the data will be reviewed.
_____
_____

FEASIBILITY ASSESSMENT (Principal Investigator or designee to complete)

1. Adequacy of patient population:
   ____ Not applicable (no patients will be enrolled at CentraCare). (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: _____
   CentraCare Review:
   Study is __ / is not __ feasible for implementation at CentraCare with current or funded resources.

_____ _____
Senior / Executive Director(s) Signature Date

To Be Returned with IRB Application

ATTACHMENT A
DEPARTMENT SERVICE AGREEMENT

A separate service agreement must be completed for each CentraCare Department providing protocol induced cost items or services outlined on the study timeline. Signatures confirm all departments agree on pricing and discounts. Please contact Research Compliance Officer to determine if a Standardized DSA is available.

Protocol Title		Study Depart	
Study Director		Phone #	
Study start date		Approx lgth of study	

Dept providing Service:	
Department location:	
Estimated # of pts to be seen:	

1. Service or Item	2. Est. # of services expected per patient	3. CPT/HCPC	4. Charge code	5. Technical fee for service	6. Pro fees for service	7. Hospital Services Discount

Senior / Executive Director(s) Signature Date Extension

Clinic Department Director Signature Date Extension

Research Compliance-Officer Date Extension

ATTACHMENT B
Instructions
DEPARTMENT SERVICE AGREEMENT

Study Department:

1. A Department Service Agreement form must be completed for each department providing protocol-related services. Some departments have Standardized Department Service Agreements. Please contact Research Compliance Officer to see if one if available.
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. Attachment C lists the names 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 Research Operations Officer 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(s) 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. Research Compliance Officer Signature
        - Forward completed and signed form to the Research Compliance Officer. Once signed, the Research Compliance Officer 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 Senior/Executive Director(s) 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 to completing the Department Service Agreement Form to the Research Compliance Officer.

Attachment C
Department Service Agreement
Contact list

Department(s)	Phone #/Extension
Magnet Director	251-2700/51756
FBC/NICU/Perinatal Clinic/Women & Children's Center Outreach	656-7103/57103
Emergency Preparedness Emergency Trauma Center	251-2700/23109
Pediatrics Unit/Plaza Child/Adolescent Specialty Clinic	251-2700/73605
Family Health Center/Family Practice Residency Program	251-2700/75014
Mental Health Adult Inpatient/Mental Health Child & Adolescent Inpatient/Outpatient Behavioral Health/Recovery Plus/Behavioral Medicine/Child & Adolescent Services	251-2700/23790
Trauma/Perioperative Care/Perianesthesia Care/Processing Sterilization/Wound Center	251-2700/54248
Non-Invasive Cardiology/CPRU/Electrophysiology/Inpatient Cardiology/Catheterization Lab	251-2700/57461
Rehab Unit & Physical/Occupational/Speech Therapies/Plaza Rehab Unit & Physical/Occupational and Speech Therapies/Neuroscience Spine/Neurodiagnostics/Physiatry	251-2700/55924
Home Care/Hospice/Palliative Care/Care Management/Transitions of Care	251-2700/75018

SCH Pharmacy/Plaza – Infusion Pharmacy	251-2700/71287
Medical Oncology/Sur 1 & 2/ICU/Med 1/Med 2/MPCU/Observation Unit/Respiratory Therapy	251-2700/53546
Bone and Joint	251-2700/54131
Imaging/Interventional Radiology/Plaza – Imagine Breast Center/Outpatient Services	251-2700/55694
Endoscopy/Dialysis/Sleep Center/Dieticians	251-2700/52150
Outpatient Medical Oncology and Chemotherapy Services/Radiation Oncology	251-2700/70644
Internal Medicine/Endocrinology/Diabetes/Rheumatology/Dermatology	251-2700/75019
Ambulatory Pharmacy	251-2700/70979
Laboratory Services	251-2700/57312
Pharmacy Inpatient	251-2700/54084

CONTACT THE RESEARCH COMPLIANCE OFFICER 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.

IRB MEETING SCHEDULE

The CentraCare IRB meets the third Thursday of each month. For questions, please contact the Research Compliance Officer.

REQUIRED DOCUMENTS TO SUBMIT WITH IRB APPLICATION

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

To Be Returned with IRB Application

CentraCare
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 Senior / Executive Director(s) 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				
Section 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.

Senior / Executive Director(s) Signature_____ _____ Date _____

To Be Returned with IRB Application

Progress/Continued Study Review

Date:

Protocol Title:

Primary Investigator:

Study Coordinator:

Name of the Data Safety Monitoring Board and how frequently the data will be reviewed:

Summary:

Number of Subjects:

Withdrawals:

Deaths:

Protocol Amendments / Consent Form Changes:

Changes to Research Staff:

Research Results:

SAEs & Deviations:

Request to Continue or Terminate:

Consent Form Included:

Attachment C

Protocol Deviation

Date:

To:

From:

Re:

Title:

Principle Investigator:

Date of Occurrence: Drug Involved:

Age: Sex:

Summary of Deviation:

Attachment D

Serious Adverse Events Report

Date:

To:

From:

Re:

Title:

Principle Investigator:

Date of Occurrence: Drug Involved:

Age: Sex:

Diagnosis:

Contributing Factors:

Is the event attributed to the study?

Summary of Adverse Event(s):