

APPLICATION FOR REVIEW OF PROJECTS INVOLVING HUMAN SUBJECTS
INSTITUTIONAL REVIEW BOARD

COVENANT HEALTHCARE SYSTEM
SAGINAW, MICHIGAN

Please note: Handwritten applications will not be accepted

1. **Date:**

2. **Title of Project:**

3. **This proposal is submitted as:**

___ a. Exempt from full review, explain _____

___ b. Expedited review, explain _____

___ c. Chart review

___ c. Full review

4. **Principal Investigator:**

Department

Address

Phone

Fax

Email

5. **Co-Investigator(s):** (List names, titles and departments)

6. **IRB Submission:** Have you submitted this study to another IRB? **No** _____ **Yes** _____

A. What IRB(s)? List name of Institution(s) _____

B. What category of review was the project submitted as? _____

C. Status of review (i.e. approved, not approved, pending). If the project was approved, please attach a copy of the approval letter.

7. **Estimated date to begin data collection:** (pending IRB approval)

8. **Duration of project:** Please remember you **may not** begin data collection without IRB approval

9. **Drug/Device Usage:** (check all that apply)

___ Project uses an approved drug for a **new application**

___ Project uses an **unapproved drug** – IND# _____

- Project uses an approved device for a **new application**
 Project uses an investigational device – IDE# _____
 Letter of **indemnification** attached (letter should include person/firm and date of filing)
 Letter of indemnification **not applicable**

10. Sponsorship:

- Project **does not require funding** from an outside source or a commercial sponsor
 Project **requires funding** from an outside source or a commercial sponsor
(refer to Clinical Research Programs Administrative Policy)
- a. Commercial sponsor clinical contact name _____
 - b. Commercial sponsor clinical contact telephone number _____
 - c. Funding source: _____
 - Funding obtained
 - Funding application pending
 - Funding application to be submitted, deadline _____

11. Please explain the scientific merit of the study:

12. General Outline of Proposed Study:

- A. Describe the research design** – include objectives, procedures and expected results.
(please attach a copy of full protocol or grant application if available)

- B. Describe the involvement of human subjects** - you may use a flow chart to illustrate exactly what will happen to the subjects.

C. Summarize the project in one paragraph in the space below completely in lay terms:

D. Does this project utilize materials of human origin (e.g. blood, tissues)?

No Yes, explain:

13. Description your subject population:

A. Special Subject Groups:	Target Population	Incidental Population
Pregnant Women	_____	_____
Psychiatric Patients	_____	_____
Mentally Disabled Patients	_____	_____
Institutionalized Persons	_____	_____
Low Income Persons	_____	_____
Women of Childbearing Age	_____	_____
Incompetent Persons or those with Diminished Capacity	_____	_____
Prisoners	_____	_____
Pediatric/Minor Patients	_____	_____
HIV/AIDS Patients	_____	_____
Students	_____	_____
Minorities	_____	_____
Other	_____	_____

B. Patients: Yes No and/or **Volunteers** (e.g. healthy controls): Yes No

C. Sex: Male Female

D. Age Range: _____ to _____

E. Estimated Total Number of Subjects: Experimental _____ Controls _____

F. Report the results of the power analysis which determined the adequacy of your sample size:

G. Criteria for inclusion of subjects:

H. Criteria for exclusion of subjects:

I. If you are associated with the subjects (e.g. students, employees, patients), please explain the nature of the association:

J. Will someone receive payment for recruiting subjects? ___ No ___ Yes, explain:

14. Informed Consent:

_____ Please attach a copy of informed consent form, which should include HIPAA requirements. If HIPAA elements are **not included**, please provide a copy of HIPAA authorization form along with the informed consent. **Complete A-C below.**

_____ Informed consent not applicable (Chart review, Expedited, or Exempt study)
Do not complete A-C below. Skip to Number #15

A. Describe how people are identified as potential study subjects (physician referral, record review etc):

- 1. Who will perform the screening of patients to determine eligibility?**
- 2. When does screening occur in relation to the signing of the consent?**

3. Describe how potential subjects will be approached and by whom:

B. Indicate the approximate length of time that potential subjects will be given to consider participation in this study (length of time between study explanation and signing of the consent form):

C. Please describe subject payment information:

1. Subjects will not be paid _____

2. Subjects will be paid (describe as follows)

a. Total compensation _____

b. Payments will be dispersed as follows:

One time payment _____

Multiple payments (please list the frequency and amount of each payment) _____

Other (describe) _____

Subjects will be provided with other compensation, such as gifts or services without charge (please describe) _____

15. **Waiver of Informed Consent:**

Are you requesting a waiver of informed consent?

NO _____ *If NO skip to #16*

YES _____ **If Yes, complete A-D below**

Each of the following conditions must be true in order for a waiver to be granted. Please discuss and provide rationale for each condition below:

A. The research involves no more than minimal risk to the subjects?

TRUE _____

Please explain:

FALSE _____

If false, does not meet criteria for waiver

B. The waiver will not adversely affect the rights and welfare of the subjects?

TRUE _____

Please explain:

FALSE _____

If false, does not meet criteria for waiver

C. The research could not be practicably be carried out without the waiver?

TRUE _____

Please explain:

FALSE _____

If false, does not meet criteria for waiver

- D. Whenever appropriate the subjects will be provided the additional pertinent information after participation.

TRUE _____

Please explain:

FALSE _____

If false, does not meet criteria for waiver

16. Confidentiality and Privacy Procedures:

A. _____ NO _____ YES Does the project involve **protected health information** as defined by HIPAA? *If NO skip to # 17*

B. _____ NO _____ YES **IF YES to A (above)** Are you requesting a waiver of authorization to use or disclose protected health information? (i.e. using patient protected health information without obtaining patient consent).

C. _____ NO _____ YES **IF NO to B (above)**--*Please attach an authorization form for review, if HIPAA requirements are **not addressed in the submitted informed consent.** Do not complete items 1-11 below. Skip to #18.*

IF YES TO B (above) Please complete items 1-11 below

1. If requesting a waiver of authorization to disclose personal protected health information, please explain why the waiver is needed?
2. Will you record any direct identifiers (names, social security numbers, patient, hospital, laboratory numbers, addresses, telephone numbers, email addresses, locator information etc.)? **No** _____ **Yes** _____
3. Please explain why it is necessary to record findings using these identifiers.
4. Will the data be reported in such a manner that the subjects are not identified directly?
5. Describe the coding system you will use to protect confidentiality of these subject identifiers.
6. Describe how subject identifiers will be maintained and destroyed after the study is completed.
7. Will you retain a link between the study numbers and direct identifiers after the data collection is complete? **No** _____ **Yes** _____

If yes, explain why this is necessary and state how long you will keep this link?

8. Will you provide a link or identifier to anyone outside the research team? **No** ___ **Yes** ___
If yes, please explain why and to whom?

9. How long, where, and in what form (such as paper, digital or electronic media, etc) will data be kept? In addition, describe what security provisions will be taken to protect the data (password protection, locked file etc.).

10. Indicate the length of time research records will be kept before EITHER all identifiers/codes are removed OR the records are destroyed. Please describe the procedures used for destruction.

11. If multi-site projects, how will confidentiality be maintained?

*****Please note: Signature of this application form by the primary investigators provides written assurance that the identifiable individual patient information will not be reused or disclosed improperly.**

17. **Will this research be conducted with subjects who reside in another country or live in a cultural context different from mainstream US society?** ___ No ___ Yes

If yes, will there be corresponding complications in your ability to minimize risks to subjects, maintain their confidentiality, and/or assure their right to voluntary informed consent as individuals?

If yes, explain how you will resolve them.

18. **Procedures for RESEARCH PURPOSES ONLY:**

None _____ *Skip to #19*

YES _____ **complete A-C below**

A. List procedures, which are being performed for RESEARCH PURPOSES ONLY:

- These procedures would not normally be done in the absence of this research protocol

B. Describe rationale for using each noted procedure:

C. How will the procedures that are for RESEARCH PURPOSES ONLY be paid for?

- Who will be responsible for these costs if the patient's insurance will not cover it?

- Will the subjects incur additional cost as a result of participation in this study? If yes, explain:)

19. **Is there utilization of hospital resources needed for research purposes?**

Such as

- Manpower
- Medical record retrieval **please note medical records 3 years or older incur a retrieval, delivery and filing cost*
- Nursing time for documentation

___ **No** *if No, skip to #20*

___ **Yes** **If yes please describe how hospital resource cost will be reimbursed:**

****Residents, Nursing Students, and Medical Students:**

- Have you obtained funding from your institution to help defer the cost of the research study?
NO _____
- *If NO above; you will need to submit your protocol to the Covenant Board Contract Committee for approval or denial if hospital resources are utilized.*
YES _____ *please describe* _____
N/A _____

20. **Describe any ALTERNATE TREATMENTS (as opposed to those for research purposes only) and their relative advantages and disadvantages:**

NONE _____ Skip to # 21

YES _____ Please describe below

21. **RISK VS BENEFITS ANALYSIS:**

A. Describe the anticipated benefits of this research to individual subjects:

B. Please describe the one or both of the following:

- What are the anticipated benefits of this research for society and how do those benefits outweigh the risks? *and/or*

- How does this research contribute to the recent literature available on the topic and how do those benefits outweigh the risks?

C. Describe the likelihood of the risk of harm (including stress, discomfort, invasion of privacy, potential loss of confidentiality, etc.) from study procedures, drugs, devices etc.

D. Please indicate projected incidence, severity and duration of side effects. If the study compares an experimental drug to a marketed drug, include information on side effects of marketed drug also. If there is a washout period or a placebo-only period during this study, indicate any potential risks to subjects without medication during this time. Include physical, psychological, social, economic or other risks or discomforts.

Side Effects

Projected Incidence

Severity

Duration/Reversibility

E. Other Potential Risks:

F. Precautionary measures to be taken to eliminate or reduce the risks and/or discomforts:

22. Conflict of Interest:

A. _____ NO _____ YES Have you or will you or a member of you immediate family receive from the sponsor of the research financial or other forms of compensation?

B. _____ NO _____ YES Do or will you or a member of your immediate family have a vested interest in the company/agency/firm that is to sponsor the research (answer no if there is no sponsor for the research)

C. _____ NO _____ YES Are you submitting FDA form 3454 or 3455 (Conflict of Interest)? **If yes,** please attach a copy.

If yes to either 22a. or 22b. complete 1 and 2

1. Describe the relationship between you or a member or your immediate family and the sponsor of the research.

2. Include a statement in the consent form addressing potential conflicts of interest or state below why you believe such a statement is not necessary for the protection of human subjects.

23. Attachments:

- ____ **Copy of principal investigator's curriculum vitae attached**
- ____ **Copy of CV on file with IRB** (Submitted with previous protocol in the last 2 years)
- ____ **Copy of Data Collection Form attached**
- ____ **Copy of Survey attached**

24. Assurance of Principal Investigator:

I will promptly report **proposed changes in the activity** or **unanticipated problems** involving risk to subjects or others including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices to the IRB and, in case of DHEW supported activities, to the Department of Health, Education and Welfare (through the respective granting office).

As the Principal Investigator on this project, I certify by my signature below that the information provided in this application is accurate and fully describes any and all procedures regarding human subjects under which I will conduct this research.

I, the undersigned, agree to accept responsibility for my co-investigators and other personnel involved on this project, in regards to their compliance with the above stated policies.

I will retain the documentary evidence of informed consent for at least three years after the proposed activity has been completed or discontinued.

The IRB is obligated to continually review this activity. Therefore, I agree to furnish progress reports to the committee when requested.

*****Please note: Signature of this application form by the primary investigators provides written assurance that the identifiable individual patient information will not be reused or disclosed improperly.**

Principal Investigator or Project Director

Date

For faculty or staff supervisor approval, if applicable.

I believe that the research can be safely completed without endangering human subjects. Further, I have read the enclosed proposal and I am willing to supervise the investigators.

Faculty or Staff Supervisor

Date

*****Your presence is required at a scheduled Institutional Review Board Committee meeting to present this new protocol to the members. Please call (989) 583-6098 for a schedule of meetings.**

- **Residents and medical students:** Prior to Covenant HealthCare IRB submission and review, your project must first be reviewed and approved by the Synergy Medical Education Alliance IRB. Include a copy of the signed and dated approval letter from the Synergy IRB. If your project is a retrospective chart review, ensure that the Synergy IRB has completed the boxed section on the first page of the retrospective chart review application.
- **Nurses and nursing students:** Prior to Covenant HealthCare IRB submission and review, your project must first be reviewed and approved by the Covenant HealthCare Nursing Research Committee. Include a copy of the signed and dated approval letter from the Covenant HealthCare Nursing Research Committee. The chairperson for the committee is Sue Garpiel, RN, CNS. She can be contacted at (989) 583-4495, (989) 258-0513 pager, or sgarpiel@chs-mi.com.
- **Undergraduate and graduate students in *any* curriculum:** Prior to Covenant HealthCare IRB submission and review, your project must first be reviewed and approved your college or university IRB. Include a copy of the signed and dated approval letter from the college or university IRB.

If you have any questions or concerns please call the IRB Specialist, Pam Bonds RN, E-Mail Address: pbonds@chs-mi.com, telephone: (989) 583-6098.