|  |
| --- |
| **Residents and Medical Students**: Prior to Covenant Medical Center IRB submission and review, your project must first be reviewed by the Director of Research, CMU College of Medicine. **Approval for submission will be indicated by their electronic signature in IRBNet or wet ink signature on this application.****Nurses and Nursing Students**: Prior to Covenant Medical Center 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 Robin Begick RN, MSN. She can be contacted at (989) 583-4893 or RJBegick@chs-mi.com**Undergraduate and Graduate Students in *any* curriculum**: Prior to Covenant Medical Center IRB submission and review, your project must first be reviewed and approved by your college or university IRB. Include a copy of the signed and dated approval letter from the college or university IRB.IRB Contact InformationIRB Administrator: Pam Bonds, RN CIM CIPCovenant Medical Center IRB700 Cooper Saginaw, MI 48602Phone; 989-583-6486Email: pbonds@chs-mi.comFax: 989-583-1097 |

Directions to fill in the check boxes on this document;

1. Hover over checkbox
2. Double click—A window will open that is called “Check Box Field Options”
3. Go to second category called “Default Value”
4. Click “Checked” to mark the box, or “Uncheck” to unmark the box

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |   |
|  | **IF MEDICAL STUDENT OR RESIDENT (*this box must me checked for submission to be accepted by Covenant Medical Center IRB)*****[ ]  Director of Research, CMU College of Medicine had reviewed and signed this submission** |
|  |  |

1. **TITLE OF PROJECT**:
2. **RESEARCH TEAM**: (please add more rows as needed)

**Principal Investigator:**

**Department:**

**Email:**

UPLOAD IN IRBNET

[ ]  CV

[ ]  CITI training completion certificate

[ ]  Conflict of Interest Disclosure form

**Sub-Investigator #1:**

**Department:**

**Email:**

UPLOAD IN IRBNET

[ ]  CV

[ ]  CITI training completion certificate

[ ]  Conflict of Interest Disclosure form

**Sub-Investigator #2:**

**Department:**

**Email:**

UPLOAD IN IRBNET

[ ]  CV

[ ]  CITI training completion certificate

[ ]  Conflict of Interest Disclosure form

**Sub-Investigator #3:**

**Department:**

**Email:**

UPLOAD IN IRBNET

[ ]  CV

[ ]  CITI training completion certificate

[ ]  Conflict of Interest Disclosure form

1. **CATEGORY OF REVIEW:** **[ ]  Expedited** **[ ]  Full Board**
2. If “Expedited” please indicate the sub category: *(see IRB Policy #7-2 “Expedited Review for full category descriptions)*

[ ]  Category 1 Clinical studies of drugs and medical devices when neither an IND and IDE is required.

[ ]  Category 2 Collection of blood samples from healthy, non-pregnant or other adults.

[ ]  Category 3 Prospective collection of biological specimens for research purposes routinely employed in clinical practice.

[ ]  Category 4 Collection of data through noninvasive procedures routinely employed in clinical practice.

[ ]  Category 5 Research involving materials that have been collected, or will be collected for non-research purposes

[ ]  Category 6 Collection of data from voice, video, digital or image recordings made for research purposes.

[ ]  Category 7 Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation or quality assurance methodologies.

1. **SUBMISSION**
2. [ ] No [ ] Yes Have you ever submitted this study to another IRB?

If yes to a;

* + - 1. Name of Institution/IRB
			2. What is the status of review?

[ ]  Approved *(upload a copy of IRB approval letter)*

[ ]  Not approved

[ ]  Pending review

1. **RESOURCES AND FUNDING**
2. [ ] No [ ] Yes Are their funding sources for this project?
3. **List Funding sources**
4. Contact Information of Funding Source

**Name:**

**Email:**

**Phone number:**

1. [ ] No [ ] Yes Funding has been obtained
2. [ ] No [ ] Yes Funding Application pending

a. Funding application will be submitted by (date)

4. Unique Site Number (if provided by sponsor)

5. List the “short name” or acronym that you are using for the study, if any

1. List all Covenant Resources that will be utilized for research purposes;

[ ]  Nursing staff

[ ]  Health Info Systems (HIM) staff

[ ]  Information systems staff

[ ]  Lab staff

[ ]  Diagnostic Imaging staff

[ ]  Other (please explain)

1. If any above are checked, please describe how hospital resources will be reimbursed:
2. Residents, Nursing Students, Medial Students, Graduate or Undergraduate Students;
3. [ ] No [ ] Yes The project includes the use of Covenant Resources
4. [ ] No [ ] Yes The University or Institution that I am attending has provided funding to help defer the cost of the study
5. [ ] No [ ] Yes **ONLY COMPLETE** **IF YES TO (c-i) and NO to (c-ii)—**the Covenant Board Contract Committee has seen and approved the project

**FDA INFORMATION: Questions 6-7 pertain to clinical trials that are FDA regulated (i.e. drugs, devices, or biologics). If your project does not involve those, skip to question 8.**

1. [ ]  No [ ]  Yes Are you using an **FDA approved** drug/device/biologic/diagnostic test ? *If YES (answer a)*

a. [ ] No [ ] Yes Are you using the **FDA approved** drug/device/diagnostic test/biologic for a **non-approved** **FDA** indication? *IF YES (answer b)*

b. [ ]  No [ ]  Yes Has an IND/IDE or will and IND/IDE be submitted to the FDA?

7. Select appropriate option that is involved in research study(s)

 [ ]  Drugs

 [ ]  Biological products for human use

 [ ]  Medical Device

 [ ]  Nutritional Supplements

 [ ]  Foods, including dietary supplements that bear a nutrient or a health claim

 [ ]  Color additives

 [ ]  Food additives

 [ ]  Infant formulas

Section a; **DRUGS and BIOLOGICS (if Medical Device only, go to section b)**

* + 1. Name(s) of Drug (s) or Biologic(s). Include brand names, generic names or other synonyms. *If multiple drugs, clearly differentiate*:
		2. Name firm(s) or organization(s) who manufactures the drug(s) or biologic(s):
		3. [ ]  No [ ]  Yes Is the drug a controlled substance?
		4. [ ]  No [ ]  Yes Is the drug a biological product?
		5. Describe the procedures and plan for storage and control of the drug or biologic:

Section b; **MEDICAL DEVICES (if Drug or Biologic, skip and go to c)**

1. Name the device(s) name(s). Include brand names, generic names or any other synonyms. *If multiple devices, clearly differentiate:*
2. Name firm(s) or organization(s) who manufacture the device(s)?
3. [ ]  No [ ]  Yes Is the research being done to determine the safety or effectiveness of the device? Provide and explanation:

**HUMANITARIAN USE DEVICE SUB SECTION**

1. [ ]  No [ ]  Yes Is the device a Humanitarian Use Device (HUD)
2. FDA assigned HDE#
3. [ ]  No [ ]  Yes Are you collecting safety and effectivenss to support a Pre

 Market (PMA) for the **HDE-approved** indication?

1. [ ]  No [ ]  Yes Will you use the HUD **beyond its approved** indication (e.g.

 for a broader or different indication)?

1. Describe the procedure and plan for storage of the device?

 Section c; **MARKETING STATUS**

* + 1. [ ]  No [ ]  Yes Is this a clinical investigation to support applications for research or marketing permits for products regulated by the

 Food and Drug Administration (e.g. foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products) (21 CFR 50.1 (a)?

* + 1. [ ]  No [ ]  Yes Is this a post marketing study/clinical trial *(if yes, answer 1-2)*
			1. Explain why the postmarketing study/clinical trial is being conducted:
			2. [ ]  No [ ]  Yes Is the FDA requiring the postmarketing trial? *If yes, check reason below?*
				1. [ ]  To assess a KNOWN serious risk related to the use of the drug
				2. [ ]  To assess SIGNALS of serous risk related to the use of the drug
				3. [ ]  To identify an UNEXPECTED serious risk when available data indicates the potential for a serious risk

 Section d: **NEW IND OR IDE Information**

[ ]  No [ ]  Yes Has the protocol been submitted to the FDA or are there plans to submit it to the FDA? *(if yes complete a-b)*

1. [ ]  No [ ]  Yes Is there an IND# or IDE# (*if yes, complete i-ii)*

Name of institution, organization or individual submitting the IND or IDE:

* 1. List IND# or IDE# (please include the FDA approval letter as well)
	2. Select Phase: [ ]  Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4 [ ]  other *explain;*

 Section e: **BIOLOGICS, RADIATION, and OTHER CONSIDERATIONS:**

1. **[ ]** No [ ]  Yes Does this project involve the use of materials of human

origin (e.g. human blood, tissue, or cells)? *(If yes, answer i)*

1. What you are collecting and why?
2. [ ]  No [ ]  Yes Will there be any use of radioactive materials and/or use of radiation producing machines? *(If yes, answer i)*
3. What will you be using and why?
4. **RESEARCH CATEGORY *(check all that apply)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **[ ]**  | Survey/Interview | **[ ]**  | Stem Cell Research |  | *If Clinical Trial, check Type* |
| **[ ]**  | Audio/Video Recording | **[ ]**  | Medical Imaging | **[ ]**  | **Surgical** |
| **[ ]**  | Analysis of Existing Data | **[ ]**  | Oncology | **[ ]**  | **Therapeutic** |
| **[ ]**  | Medical Records | **[ ]**  | Investigator Initiated | **[ ]**  | **Prevention** |
| **[ ]**  | Other | **[ ]**  | Clinical Trial  | **[ ]**  | **Other**  |
|  |  |  | *If clinical trial, go to* |  | *If Clinical Trial, check phase* |
|  |  |  | *next column*  | **[ ]**  | **Phase 1** |
|  |  |  |  | **[ ]**  | **Phase 2** |
|  |  |  |  | **[ ]**  | **Phase 3** |
|  |  |  |  | **[ ]**  | **Phase 4** |
|  |  |  |  |  |  |

1. **TIMELINE-\* you may not begin the project without Covenant IRB approval**

a. Anticipated Project Start Date(mm/dd/yyyy):

 b. Estimated duration of project (includes identifiable data analysis):

**10**. **PROJECT DESCRIPTION (abstract**): Please respond to the project description questions below.

 a. Purpose of the Research Study;

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| --- |
|  |

 b. Hypotheses:

|  |
| --- |
|  |

 c. Describe General Design:

|  |
| --- |
|  |

 d. Describe Scientific Merit:

|  |
| --- |
|  |

e. Describe any ALTERNATE TREATMENTS (if applicable) and their relative advantages and disadvantages:

|  |
| --- |
|  |

f. Are you obtaining informed consent?

 [ ]  Yes (please upload a copy with your project submission)

 [ ]  No (please explain why it is not practicable to obtain informed consent)

|  |
| --- |
|  |

g. Briefly summarize the project in one paragraph completely in lay terms;

|  |
| --- |
|  |

**11.** **PROCEDURES**: Describe any procedures, measures and analysis you will use in collecting data from human subjects. If procedures are listed, indicate whether they are being performed for RESEARCH PURPOSES ONLY.

|  |
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**12.** **SUBJECT POPULATION:**

 a. Describe your subject population *(e.g. women with breast cancer, adults 18 and older with coronary artery disease.)*

|  |
| --- |
|  |

b. **AGE RANGE OF SUBJECTS:** Minimum Years:       Maximum Years:

c. **VULNERABLE POPULATIONS:**

 i. Please indicate if any of the below vulnerable populations will be purposefully included in the research (which populations are targeted?)

*To select--Double click on check box, then click default value “checked”*

|  |  |
| --- | --- |
| [ ]  | Minors (age 0-17) |
| [ ]  | Incompetent Persons |
| [ ]  | Students |
| [ ]  | Low Income persons |
| [ ]  | Minorities |
| [ ]  | Psychiatric patients |
| [ ]  | Covenant employees |
| [ ]  | Other |
| [ ]  | None of these |

 ii. [ ]  No [ ]  Yes Will some or all the subjects likely be vulnerable to coercion or undue influence?  *(if yes- answer i below)*

 1. Describe the additional safeguards included in the protocol to protect subject’s rights and welfare;

|  |
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|  |

 d. **ENROLLMENT:** Total number of subjects (including controls) expected to be enrolled for the entire project period;

i. Provide rationale for your sample size (e.g. acceptable parameters for your research design, statistical power, power analysis, etc.)

|  |
| --- |
|  |

 ii. **INCLUSION CRITERIA**; please describe

|  |
| --- |
|  |

 iii. **EXCLUSION CRITERIA**: please describe

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|  |

 e. **RECRUITMENT:**

 i. Who will make initial contact with the subjects:

|  |
| --- |
|  |

 ii. Who will recruit the subjects:

|  |
| --- |
|  |

 iii. Who will enroll subjects:

|  |
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|  |

1. Does the research project have a strategy for the enrollment of racial or ethnic minority subjects? [ ]  No [ ]  Yes

If yes, please describe below:

|  |
| --- |
|  |

 f. **ADVERTISMENT:**

i. Will any of the following be used:

 [ ]  letters

 [ ]  flyers

 [ ]  posters

 [ ]  other (please list)

 ii. Please describe the advertisement *(checked above)*

|  |
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 g. **ASSOCIATION WITH SUBJECTS:**

i. [ ]  No [ ]  Yes Are you associated with the subjects (if yes, answer ii)

 ii. Describe the nature of the association;

|  |
| --- |
|  |

 ii. What measures are you taking to protect the subjects’ rights, including safeguards against any coercion.

|  |
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|  |

 h. **PAYMENTS for RECRUITMENT:**

i. [ ]  No [ ]  Yes Will someone receive payment for recruiting subjects’?

 **IF YES ABOVE:**

 1. What is the amount of the payment?

 2. Who will make the payment?

 3. Who will receive the payment?

 i. **COMPENSATION of SUBJECTS:**

 i. [ ]  No [ ]  Yes Will subjects be compensated? (**If yes**, the following information **must be explained in the informed consent**)

 1. Total compensation:

 2. Payments will be dispersed as follows;

 [ ]  One-time payment: LIST AMOUNT:

 [ ]  Multiple payments: Frequency      Amount

 [ ]  Other: Describe

 [ ]  Other type of compensation (gifts, services-please describe

|  |
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|  |

 j. **COST TO SUBJECTS:**

 i. [ ]  No [ ]  Yes Will the subjects incur additional financial costs because of their participation in the study?

 **IF YES TO ABOVE:**

 1. Explain *(this information must be included in the informed consent document)*

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ii. [ ]  No [ ]  Yes Will the subject’s insurance be billed as part of this project?

 **IF YES TO ABOVE:**

 1. How and when will the insurance be billed? *(this information must be included in the informed consent document)*

|  |
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|   |

 2. Explain what will happen if the insurance WILL NOT cover the cost or if the subject does not have insurance. Will the subject be responsible for costs? *(this information must be included in the informed consent document)*

|  |
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 k. **CULTURAL CONSIDERATION:**

i. [ ]  No [ ]  Yes Will the research be conducted with subjects from another country*? (****if NO, skip to question 11)***

ii. [ ]  No [ ]  Yes Will the research be conducted with subjects in the U.S. from an ethnic group, subgroup, or other non-mainstream minority (including non-English speakers)?

 **IF YES TO #k (ii) ABOVE:**

 1. [ ]  NO [ ]  YES Does the different cultural context present any problems or risks that need to be addressed?

 **IF YES TO ABOVE:**

 a. Describe how they will be addressed below

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 **13.** **RISK TO SUBJECTS:**

|  |
| --- |
| *Definition of Risk; The probability of harm or injury (physical, psychological, social, or economic) occurring because of participation in the study.* *Definition of Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, then those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**Definition of Benefit: A valued or desired outcome, an advantage* |

* 1. Select all types of potential risks that are possible related to subject’s participation in this study? If selected, please comment about the likelihood and seriousness of the selected risk?

[ ]  Physical

|  |
| --- |
| *Comments:* |

[ ]  Social

|  |
| --- |
| *Comments:* |

[ ]  Economic

|  |
| --- |
| *Comments:* |

[ ]  Psychological

|  |
| --- |
| *Comments:* |

[ ]  Legal

|  |
| --- |
| *Comments:* |

[ ]  Data Privacy

|  |
| --- |
| *Comments:* |

 b. Describe the procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness?

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|  |

 c. List other potential risks or deviations of Standard of Care?

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**14. BENEFITS TO SUBJECTS**:

 a. Describe and assess any potential benefits to be gained by the subject’s participation in the research study, as well as benefits that may accrue to society in general because of the research?

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**15. PRIVACY OF SUBJECTS:**

 a. List all individuals who will be interacting with the subjects related to the research project (e.g. resident, nursing, research coordinator?)

 b. List all individuals who will be accessing and abstracting data from subject’s medical records ((e.g. resident, nursing, research coordinator?)

 c. Where will the study take place?

 d. [ ]  No [ ]  Yes Is there a possibility that individuals not associated with the research study will be present during the consent process and the conduct of the study? (if yes, explain below)

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**16. CONFIDENTIALITY OF SUBJECT DATA:**

 a. Where or how will the confidential data be stored? (encrypted devices, password protected computer, paper format in locked cabinet)

|  |
| --- |
|  |

 b. [ ] No [ ]  Yes Will the identifiable information be stored with the data collected?

 **IF YES TO ABOVE:**

 Explain:

|  |
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|  |

 c. [ ]  No [ ]  Yes Will you record any direct identifiers? (see HIPAA info below)

 d. [ ]  No [ ]  Yes Will the data be reported in such a manner that the subjects **are not** directly identified?

 e. [ ]  No [ ]  Yes Will you **retain a link** between the study numbers and direct identifiers after the data collection is complete?

**IF YES TO ABOVE:**

i. Why this is necessary?

|  |
| --- |
|  |

 ii. How long you will keep this link?

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|  |

 f. How long will the data be stored?

 g. Who will have access to the confidential data?

 h. [ ]  No [ ]  Yes Is it appropriate for your research to have a monitoring plan to periodically assess the data to ensure the safety of subjects or to ensure negative outcomes do not occur (e.g. clinical trial, full board project)? *(if yes, complete 1-2)*

i. Describe the steps that you will be taking to assure that subjects are protected, if appropriate, attach a copy of the plan.

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* 1. [ ]  No [ ]  Yes Is there a data safety monitoring committee or data safety monitoring board *(if yes, complete b)*
	2. Describe the composition, meeting schedule and frequency of the meetings

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**17. INFORMED CONSENT:**

 a. Describe your consent process including how people are identified a potential study subjects; *(physician referral, record review etc;)*

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1. Who will perform the screening of patients to determine eligibility?

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1. When does screening occur in relation to the signing of the consent?

|  |
| --- |
|  |

1. Who will obtain consent and inform and educate subjects?

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

 b. **WAIVER OF INFORMED CONSENT**:

 Based on your research project, select the option below (1 or 2) that applies to why you will not be obtaining a signed consent document.

**[ ]** i. The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context. *(Complete #3)*

*[ ]*  ii. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach on confidentiality *(Complete a-b, then #3)*

* + - 1. Explain why the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

|  |
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* + - 1. How will you ensure that each subject will be asked whether the subject wants documentation linking the subject with the research, and that the subject’s wishes will govern

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iii. 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:

* + - 1. The research involves not more than minimal risk to the subjects:

|  |
| --- |
|  |

* + - 1. The waiver or alteration will not adversely affect the rights and welfare of the subjects

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* + - 1. The research could not practicably be carried out without the waiver or alteration

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* + - 1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

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**18. HIPAA**

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| --- |
| **Identifiable Data Elements (these qualify as HIPAA)** |
| Name | Account number |
| Address (street address, city, county, zip code with more than 3 numbers or other geographic codes) | Certificate or license number |
| Names of relatives | Any vehicle or device serial number |
| Names of employers | Web URL |
| Birth Date | Internet protocol (IP) address |
| Telephone number | Finger or voice prints |
| Fax number | Photographic images |
| E-mail address | Health Plan Beneficiary Number |
| Social Security Number | Medical Record Number |
| Any other unique identifying number, characteristic, or code whether generally available or not in the public realm |  |

 a. [ ]  No [ ]  Yes Does the project involve protected health information as defined by HIPAA (see above)? **(If NO, skip to #16)**

 **IF YES TO ABOVE:**

 i. [ ]  No [ ]  Yes Are you requesting a waiver (or partial waiver of HIPAA Authorization)? (i.e. you are asking to use patient protected health information without obtaining patient consent)

* **IF NO**-include a separate HIPAA authorization form along with the informed consent (and skip i-viii below)
* **IF YES-**complete questions 1-8 below.

 1. Describe the specific health information that is needed?

|  |
| --- |
|  |

 2. Explain why the individual health information is necessary for the research?

|  |
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 3. Explanation of why a waiver (or partial waiver) is needed?

|  |
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|  |

 4. Description of the plan to protect any individual identifiers?

|  |
| --- |
|  |

 5. Description of the plan to destroy the individual identifiers at the earliest opportunity OR list reasons why they will be retained?

|  |
| --- |
|  |

 6. Provide assurance that the individual information will not be reused or disclosed improperly

 [ ]  No [ ] Yes Principal investigator agrees. If no, please explain

|  |
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 7. Provide a description of all planned uses and disclosures

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 8. The HIPAA waiver is designed primarily for retrospective review of medical records. List the period that the patient records will be accessed (i.e. patient admitted between 1/1/2018-1/1/2019)

|  |
| --- |
|  |

 b. **ELECTRONIC MEDICAL RECORD ACCESS (EPIC) for STUDENT INVESTIGATORS:**

i. **CMU Medical Students and Residents**:

The Director of Research at CMU will provide final review of your protocol, request your EPIC access from EPIC Security, and monitor your EPIC access. Please list your expected EPIC Access start and stop dates below:

EPIC ACCESS START DATE\_\_\_\_\_\_\_\_\_\_ EPIC ACCESS END DATE\_\_\_\_\_\_\_\_\_\_\_\_

ii. **ALL OTHER STUDENTS (Nursing, Graduate, Undergraduate):**

 EPIC is the EMR utilized at Covenant HealthCare. If you are proposing a research protocol that will include your need to access individual protected patient information at Covenant (from EPIC), you need to be a current Covenant employee

* Your Faculty Advisor must electronically sign the submission prior to initial IRB review.
* The IRB Administrator will make a request for student EPIC access once the project has been reviewed and approved.
* All Data collection must occur in the Health Information Management (HIM) Department at a dedicated work station. Arrangements with HIM will need to be made prior to data collection.

NO identifiable information can be removed from the organization

Please list your expected EPIC Access start and stop dates below:

EPIC ACCESS START DATE      EPIC ACCESS END DATE

**19.** **CONFLICT OF INTEREST:**

Note: Please complete the Conflict of Interest Policy Affirmation and Disclosure Statement included at the end of this application. The document and policy can also be found in the forms library in IRBNet and provided upon request.

 a. [ ]  No [ ]  Yes Have you or will you or a member of your immediate family receive from the sponsor of the research financial or other forms of compensation (such as ownership interest, stock options, etc.) whereby the value of the compensation or ownership interest to investigators conducting the study could be influenced by the outcome of the study?

**IF YES TO ABOVE:**

 i. [ ]  No [ ]  Yes Has a statement addressing potential conflicts of interest been included in the consent document? **(IF NO, COMPLETE a BELOW)**

 1. Explain why you believe such a statement is not necessary for the protection of human subjects.

|  |
| --- |
|  |

 b. [ ]  No [ ]  Yes Have you or will you submit an FDA 3454 or 3455 Conflict of Interest form?

 c. [ ]  No [ ]  Yes Are you aware of any individual who has a financial interest which may create an organizational conflict of interest? See Covenant Administrative Policy 12.09 “Conflict of Interest” for definitions and additional information.

|  |
| --- |
| 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 biological items, drugs, radioisotope labeled drugs, or to medical devices to the IRB or appropriate government agencies.
* As the Principal Investigator on this project, I certify by my signature (electronic or wet ink) upon submission of this document that the information provided in this application is accurate and fully describes all procedures regarding human subjects under which I will conduct this research.
* I agree to accept responsibility for my sub-investigators and other personnel involved on this project, regarding 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 may be obligated to continually review this activity. Therefore, I agree to furnish progress reports to the committee when appropriate or requested.
* I have completed the “IRB Committee Confidentiality Agreement” (attached to the bottom of this form and available in the forms library in IRBNet.)
* I, and any Sub Investigators listed on the application have completed, the “Conflict of Interest Policy Affirmation and Disclosure Statement.” (attached to the bottom of this form and available in the forms library in IRBNet.)
* FOR Undergraduate or Graduate Students:

I have notified my faculty or staff supervisor. They concur that the research can be safely completed without endangering human subjects. Further, my faculty or staff supervisor has read the submitted proposal and is willing to supervise me, the investigator. \*\*Individuals must electronically sign the package on IRBNet prior to submission (preferred method) or submit an application (scanned) with a wet ink signature. An electronic signature on IRBNet will represent the individual’s attestation that this is an electronically verified report confirmed by the Principal Investigator. |

# CONFIDENTIALITY AGREEMENT

I understand and agree that information disclosed orally or in written form or discussed at the meeting may include confidential information that is proprietary to commercial entities sponsoring the proposed research and/or involves the privacy rights of individuals.

I agree that I will not disclose or divulge in any manner any confidential or private information revealed at the meeting in any form or manner to any third party for any purposes whatsoever. "Confidential or Private Information" as used in this Agreement shall not include:

 1. Information or knowledge in my possession prior to disclosure at the IRB meeting, or from the Covenant Medical Center

2. Information generally available to the public or thereafter becomes generally available to the public through a source other than the Covenant Medical Center IRB;

3. Information that was rightfully obtained by me from a third party, who, I believe, is under no obligation of confidentiality to the Covenant Medical Center IRB with respect to such information.

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| [ ]  I have read and agree to the information above |

**Conflict of Interest Policy Affirmation and Disclosure Statement**

For both Covenant IRB and Covenant Central Research Dept use

Local Board Reference Number (listed in IRBNet): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agenda Date and Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

THE UNDERSIGNED is a member of the Institutional Review Board or an Investigator for a proposed Clinical Research Study, at Covenant HealthCare System, or Covenant Medical Center, Inc. The undersigned hereby affirms and acknowledges that he/she has access to and/or received and read the Covenant Medical Center IRB Policy (#IRB 9-1) “Conflict of Interest” and the Covenant Administrative Policy (#AP 1209 “Conflict of Interest”) and agrees to abide by these policies. The aforementioned policies can be found in IRBNet under Forms and Templates, in COVnet, or emailed upon request.

I hereby certify, to the best of my knowledge, that I or a member of my “immediate family” have the following interests / relationships in the following entities which may / does create a Conflict of Interest:

## Name of Organization Address Description of Interest

Please list NONE if appropriate. Do not leave blank \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If no financial / other relationship exists, then please write NONE in one of the spaces provided above.

“Financial Interest” shall mean any arrangement or transaction pursuant to which the family member has, directly or indirectly, through business, investment or household, either:

1. A present or potential ownership, investment interest or compensation arrangement in any entity which the IRB or Covenant has or may have a business transaction or arrangement; or
2. A payment arrangement with a company that does business with Covenant. Payment is described as compensation or remuneration for personal or professional services, any types of securities, meals, entertainment, travel, gifts, grants, honoraria, donations, sponsorships, research funding or grants, medical education or other in-kind services. See Policy 9-1 for further details.

“Immediate Family” shall mean spouse or domestic partner, parents, children, or anyone who resides with the IRB member or investigator or who is the IRB member of investigators dependent for tax purposes.

I hereby certify that the above information is true, correct and complete to the best of my knowledge, information and belief.

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| --- |
| [ ]  I have read and agree to the information above |

* An electronic signature in IRBNet indicates the individual’s attestation that this is an electronically verified document confirmed by the Principal Investigator. It is an indication that he/she has acknowledges, agreed to, and completed (if applicable) the Confidentiality Agreement and the Conflict of Interest Disclosure Statement.
* The wet ink signature of the Principal Investigator on the application indicates he/she has acknowledged, agreed to, and completed (if applicable) the Confidentiality Agreement and the Conflict of Interest Disclosure Statement.

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Principal Investigator Date

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Faculty or Staff Advisor Date

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 Director of Research, CMU College of Medicine Date