|  |
| --- |
| **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 your faculty advisor and 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 rbegick@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 your college or university IRB. Include a copy of the signed and dated approval letter from the college or university IRB.  IRB Contact Information  IRB Administrator: Pam Bonds, RN CIM CIP  Covenant Medical Center IRB  700 Cooper  Saginaw, MI 48602  Phone; 989-583-6486  Email: [pbonds@chs-mi.com](mailto:pbonds@chs-mi.com)  Fax: 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

|  |  |  |
| --- | --- | --- |
| **STOP HERE:** |  | **Scroll to the bottom of this document and please complete the Exempt Category Determination Tool!**   * **If any time while completing the Exempt Category Determination Tool your project does not qualify for Exempt status, STOP and complete the Expedited/Full Initial Application** |
|  | |  |
|  | | **IF MEDICAL STUDENT OR RESIDENT (*the box below must be 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. **EXEMPT CATEGORY OF REVIEW:**
2. Please describe why your project is minimal risk:
3. Please select one of the categories below.  *Use the Exempt determination tool at the end of this document to assist. Full definitions of the categories are included in the determination tool.*

Category 46.104 (d)(1) Research conducted in common educational settings

Category 46.104 (d)(2) Research that only includes interactions involving educational tests-must meet criteria

Category 46.104(d)(3) Research involving benign behavioral interventions and collection of information from adults-must meet criteria

Category 46.104(d)(4) Secondary research for which consent is not required-must meet criteria

Category 46.104(d)(5) Research supported by federal agency studying public benefit or service programs-must meet criteria

Category 46.104(d)(6) Taste and food quality evaluation and consumer acceptance studies

**The submission is not subject to IRB review and regulations because it DOES NOT meet the following regulatory definition (i.e. is not human subject research)**

* **45 CFR 46.102 (d**) Research means a systematic investigation including research development, testing, and evaluation, designed to develop and contribute to generalizable knowledge. Activities which meet this definition constitute research

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
3. Funding application will be submitted by (date)
4. 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. Residents, Nursing Students, Medial Students, Graduate or Undergraduate Students;
2. No Yes The project includes the use of Covenant Resources
3. No Yes The University or Institution that I am attending has provided funding to help defer the cost of the study
4. No Yes **ONLY COMPLETE** **IF YES TO (b1i) and NO to (b1ii)—**the Covenant Board Contract Committee has seen and approved the project
5. **RESEARCH CATEGORY *(check all that apply)***

|  |  |
| --- | --- |
|  | Retrospective Medical Record Review |
|  | Education Research |
|  | Survey Research |
|  | Interview Research |
|  | Internet-based Research |
|  | Audio/Video/Photographic recordings |
|  | Analysis of Existing Data |
|  | Other (please explain); |

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):

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

a. Purpose of the Research Study;

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b. Hypotheses:

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| --- |
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c. General Design:

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|  |

d. Scientific Merit:

|  |
| --- |
|  |

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

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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)

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

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9. **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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10. **SUBJECT POPULATION:**

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

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|  |

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

c. **VULNERABLE POPULATIONS:**

1. 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, click default value “checked”*

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

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

i. 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 expected to be enrolled;

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

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2. **INCLUSION CRITERIA**; please describe

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3. **EXCLUSION CRITERIA**: please describe

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e. **RECRUITMENT:**

1. Who will make initial contact with the subjects:

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|  |

2. Who will recruit the subjects:

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|  |

3. Who will enroll subjects:

|  |
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|  |

f. **ADVERTISMENT:**

1. Will any of the following be used:

letters

flyers

posters

other (please list)

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

|  |
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|  |

g. **ASSOCIATION WITH SUBJECTS:**

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

ii. Describe the nature of the association;

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|  |

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

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|  |

h. **PAYMENTS for RECRUITMENT:**

1.  No  Yes Will someone receive payment for recruiting subjects’?

**IF YES ABOVE:**

i. What is the amount of the payment?

ii. Who will make the payment?

iii. Who will receive the payment?

i. **COMPENSATION of SUBJECTS:**

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

i. Total compensation:

ii. 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:**

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

**IF YES TO ABOVE:**

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

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

**IF YES TO ABOVE:**

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

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ii. 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:**

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

2.  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 #k2 ABOVE:**

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

**IF YES TO ABOVE:**

1. Describe how they will be addressed below

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11. **RISK TO SUBJECTS:**

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| --- |
| *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* |

a. Describe and assess any potential risks (physical, psychological, social, legal, economic) and assess the likelihood and seriousness of the risks?

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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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12. **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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13. **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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14. **CONFIDENTIALITY OF SUBJECT DATA:**

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

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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:**

1. Why this is necessary?

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2. 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?

**15. 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:**

1.  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 i-viii below.

i. Describe the specific health information that is needed?

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

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

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

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

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vi. 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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vii. Provide a description of all planned uses and disclosures

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viii. 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)

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

1. **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\_\_\_\_\_\_\_\_\_\_\_\_

2. **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\_\_\_\_\_\_\_\_\_\_\_\_

16. **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:**

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

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

|  |
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|  |

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.

|  |
| --- |
| 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

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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.

|  |
| --- |
| 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty or Staff Advisor Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Director of Research, CMU College of Medicine Date

**EXEMPT CATEGORY Determination Tool**

**DIRECTIONS FOR USE:**

**1. Read the short and long desriptions of the Exemption categories (1-6)**

**2. Select the appropriate exemption category (s) for research (using check box)**

**3. For the exemption category selected, complete the corresponding QUESTIONS to assure qualification for the exemption**

*EXEMPTION CATEGORY #1 (***45 CFR 46.104 (d)(1))**

|  |
| --- |
| GENERALLY USED FOR: Research conducted in normal educational settings |
| Regulatory Definition:  Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods |

To qualify for this exemption, BOTH questions must be answered YES.

N Y Research conducted in established or commonly accepted educational settings that involve normal educational practices. *If no, STOP. Research does not qualify for this exemption.*

N Y Normal educational practices are not likely to adversely impact students learning or assessment of educators. *If no, STOP. Research does not qualify for this exemption*

To determine normal educational practices, **ONE** statement must be answered YES. If no, STOP-research does not qualify for this exemption

N Y Educational strategies

N Y Evaluation of effectiveness of or comparison of instructional techniques

N Y Curricula

N YClassroom management methods

*EXEMPTION CATEGORY #2* ***(*45 CFR 46.101(d)(2))**

|  |
| --- |
| GENERALLY USED FOR: Research conducted in Educational Setting with intention of recording information |
| Regulatory Definition*:*  Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:   1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;   (ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing employability, educational advancement, or reputation; or  (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by§ ll.111(a)(7). |

**QUESTIONS**:

N Y Does the research involve children? *If YES; you MUST answer next question*

N Y Does the research involve educational tests, survey procedures, interview procedures, or observation of public behavior (including visual and auditory) where the investigator will participate in the activities being observed?

*If YES, STOP.* R*esearch does not qualify for this exemption. IF NO, continue to next question*

**ONE** of the following criteria must be YES. *If NO, STOP. Research does not qualify for this exemption*

**Research involving use of educational tests, survey procedures, interview procedures, or observation of public behavior if;**

N Y Information obtained is recorded by the investigator where the identity of the subject cannot be readily ascertained, directly or through identifiers linked to the subjects

N Y Disclosure of the subject’s responses outside of the research would not place them at risk (financial, criminal, civil, employability, educational advancement, reputation)

N Y Information about the subject is recorded by the investigator where subjects CAN be readily ascertained (directly or by identifiers linked to subject) AND an IRB has conducted a LIMITED IRB REVIEW and made a determination.

*3.*  *EXEMPTION CATEGORY #3* **45 CFR 46.101(d)(3)** (i)

|  |
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| GENERALLY USED FOR: Research involving benign behavioral interventions and the collection of information from ADULT SUBJECTS |
| ***Regulatory Definition:***  Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:  *A.* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;  *B.* Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or  *C.* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by§ ll.111(a)(7).  (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii)If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. |

**QUESTIONS**:

N Y Does the research involve benign behavioral interventions *(must answer YES to* ***ALL*** *of the below. If NO, STOP-research does not qualify for this exemption.*

Is the intervention:

N Y brief in duration

N Y harmless

N Y painless

N Y not physically invasive

N Y no significant lasting impact

N Y subjects will not be embarrassed or offended by interventions

**USAGE OF DECEPTION:**

NY Does the research involve deception*? (If YES, you* ***MUST*** *answer the next question)*

*IF YES TO ABOVE (and deception will be used) then the answer to following question must be YES in order to qualify for the exemption. If, NO…skip question below and go to* ***SUBJECTS****.)*

NY Did the subject authorize the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he/she will be unaware of or misled regarding nature and purpose of research.

**SUBJECTS**:

To qualify for this exemption, BOTH questions must be answered YES

N Y Does the research involve adults? *IF NO, STOP-research does not qualify for this exemption. If YES, go to next question.*

N Y Did the subject **prospectively** agree to intervention or information collection (audiovisual, data entry, verbal, written responses) *If NO, STOP-research does not qualify for this exemption.*

*If YES, to* ***both*** *of the above then,* ***one*** *of the* ***following*** *criteria must be YES*

N Y Information is recorded so the identity of subjects cannot be readily ascertained, directly or through identifiers linked to subjects

N Y Disclosure of responses outside the research would not place subjects at risk for criminal or civil liability, or damage financial standing, employability, educational advancement, or reputation

N Y Information recorded in such a manner that the identity of subjects **can be** ascertained (directly or indirectly by linked identifiers) **AND** the research protocol will be submitted to the IRB for a **Limited IRB** review and determination.

*EXEMPTION CATEGORY #4* **45 CFR 46.101(d)(4)**

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| GENERALLY USED FOR: Information collected for either research studies or other proposed research or non-research purposes. |
| Regulatory definition:  Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  **(i)** The identifiable private information or identifiable biospecimens are publicly available;  **(ii)** Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;  **(iii)** The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ‘‘health care operations’’ or ‘‘research’’ as those terms are defined at 45 CFR 164.501 or for ‘‘public health activities and purposes’’ as described under 45 CFR 164.512(b); or  **(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable** private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 **U.S.C. 3501 *et seq.*** |

**Questions:**

N Y Was the information collected for either research studies or other proposed research or non-research purposes, *If NO, STOP.* ***Research is not secondary research and does not qualify for this exemption****. If YES continue below.*

*Must answer YES to* ***one*** *of the following to qualify for this exemption*

The identifiable private information or biospecimens must be one of the following*:*

N Y Publicly available

N Y Information that is recorded in a manner that the subjects identity **cannot be readily ascertained** directly or through identifiers linked to the subjects AND the investigator does not contact subjects or attempt to re-identify subjects

N Y Information this is collected and analyzed is identifiable health information regulated under HIPAA for purposes if “healthcare operations” or “research” or “public health activities and purposes”

N Y Research is being conducted on behalf of a Federal department or agency using government generated or collected information obtained for non-research activities, IF the research generates identifiable private information that is or will be maintained on information technology that is subject to E Government act (see iv above)

*EXEMPTION CATEGORY #5***45 CFR 46.101(d)(5)**

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| GENERALLY USED FOR: Research conducted or supported by a Federal Department or Agency |
| Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.**(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.** |

To qualify for this exemption, statement answer to first question must be YES.

N Y Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads or subordinate agencies that have been delegated authority. *If NO, STOP. Research does not qualify for this exemption. IF YES, Continue below;*

To qualify for this exemption, **one** statement below must be YES. *If* ***NO*** *to all, STOP. Research does not qualify for this exemption.*

Projects are designed to study, evaluate, or otherwise examine:

N Y Public benefit or service programs.

N Y Procedures for obtaining benefits or services under public benefit or service programs.

N Y Possible changes in or alternatives to those public benefit or service programs or procedures

N Y Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs.

N Y The research or demonstration project is already published on a publicly available established list prior to commencing the research project

***EXEMPTION CATEGORY #6* 45 CFR 46.101(b)(6)**

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| GENERALLY USED FOR: Taste and Food Quality evaluation |
| Regulatory Definition:  Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration |

To qualify for this exemption, statement answer must be YES.

N Y Taste and food quality evaluation and consumer acceptance studies, *If NO, STOP. Research does not qualify for this exemption.*

To qualify for this exemption, **one** statement answer must be YES. If NO TO BOTH, STOP. *Research does not qualify for this exemption.*

N Y Wholesome foods without additives are consumed

N Y A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by FDA or approved by EPA or Food Safety and Inspection Service of USDA.

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**NHSR (Non-Human Subject Research) 45 CFR 46.102 (l**)

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| USED WHEN: The following submission is **not** subject to IRB review and regulations because it **DOES NOT** meet the following regulatory definition (i.e. is not human subject research) |
| Regulatory Definition:  *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. |

**If YES to any of the statements below, the activity DOES NOT MEET the regulatory definition of human subject research and does not require IRB oversight**

N Y Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

N Y Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

N Y Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

N Y Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.