Trinity Health

IRB Application for Initial Review

Use this form for new study submissions (full board or expedited review)

Application Data Entry

Study Header

There may be IRB fees associated with this submission.

Before submitting to the IRB, you must submit your protocol for review by the Scientific Review Committee. Once provided with the completed form, attach a copy to this IRB submission. *(Required)*

Submitter:

Email: **Phone:**

Full Study Title *(Required)*

If your study has a grant, please make sure the study title is the same as that which is on the grant.

Preferred short study title:

Enter no more than 50 characters.

Study Type(s): *(Select all that apply to this study.)* *(Required)*

- ☐ Case Report
- ☐ Database
- ☐ Device
- ☐ Drug
- ☐ Emergent Use
- ☐ Expanded Access - Single Patient
- ☐ Expanded Access Use
- ☐ HUD - Emergent Use
- ☐ Humanitarian Use Device (HUD)
- ☐ Interventional
- ☐ Non-Engagement
- ☐ Non-Human Subjects
- ☐ Observational
- ☐ QA / QI
- ☐ Registry
- ☐ Retrospective Record Review
- ☐ Survey
- ☐ Tissue/Biologic

What is the primary department associated with this study. *(Required)*

Enter the name of the primary department below. *(Required)*

What is the condition being studied, type below: *(Required)*

Funding

Is there an industry sponsor for this study? *(Required)*

An industry sponsor is typically a pharmaceutical company or governmental agency.

Type the name of your sponsor below. *(Required)*

Please provide the Sponsor and/or CRO name(s) for this study.*(Required)*

Is there any other or additional funding source for this study? *(Required)*

If yes, provide information below: *(Required)*

Principal Investigator

Principal Investigator *(Required)*

Enter the full email address of the principal investigator for this study. If contact is not found, verify the email address is correct and the individual has been registered in IRBManager. If not found, complete the New Contact Form by clicking on the link below.

Is the principal investigator a student or resident? *(Required)*

Select your student year or level from the drop down list:

Is the principal investigator an employee of Saint Agnes, Saint Alphonsus, or Trinity Health?*(Required)*

You may enter the PI's email address above

PI Mentor/Advisor

PI Mentor / Advisor

List the Advisor for the principal investigator. *(Required)*

Enter the full email address of each Advisor/Mentor for this study.

Additional Study Personnel

Will any additional research personnel be working on this project? *(Required)*

Select all that apply: *(Required)*

- ☐ Sub-Investigator(s)
- ☐ Study Coordinator(s)
- ☐ Research Assistant(s)

Sub-Investigator Listing

Sub-Investigator(s) *(Required)*

You may enter the individual's email address above

Study Coordinator(s) Listing

Coordinators *(Required)*

You may enter the individual's email address above

Research Assistant(s) Listing

You may enter the individual's email address above

Study Sites / Other IRB Review

Study Site *(Required)*

Provide study site information below: *(Required)*

Are there any additional sites at which the investigator is performing this study? *(Required)*

- Yes
- No

List the additional site(s) below: *(Required)*

Has the Principal Investigator submitted this study for review by another IRB? *(Required)*

- Yes
- No

Did the other IRB approve or deny your submission? *(Required)*

Attach a copy of the other IRB's approval or declination letter. *(Required)*

Study Specific Information

Provide a brief summary of the project, including the overall study objective. *(Required)*

How many records do you anticipate reviewing for this study? *(Required)*

What is the total number of participants you anticipate enrolling in this study? *(Required)*

Will research participants receive any form of payment for their participation? *(Required)*

What method of payment will be used? *(Required)*
(e.g. Store card, debit card (VISA, MasterCard), check, cash)

What is the amount and frequency of payment(s) to research participants? ***(Include any CAP, if applicable.)*** *(Required)*
(e.g. $50 at study visits 1, 5 and completion of study).

Describe how payment to participants will be disbursed and recorded. *(Required)*

Subject Privacy/Confidentiality

Every protocol must address the following items relating to confidentiality. If you have a sponsor-supplied protocol, please address these questions as they relate to your specific site.

Will collected data contain any identifiers that can be *linked directly or indirectly* to the subjects? *(Required)*

If yes, explain: *(Required)*

Will data that is reported contain any identifiers that can be *linked directly or indirectly* to the subjects? *(Required)*

If yes, explain: *(Required)*

The protocol must contain all of the following:

Does the protocol contain an explanation of how you ensure the de-identification of research data? *(Required)*

If no, explain: *(Required)*

Does the protocol contain a description of how you will protect written research data? *(Required)*

If no, explain: *(Required)*

Does the protocol contain a description of how you will protect electronic research data? *(Required)*

If no, explain: *(Required)*

Indicate if you plan to review any of the following information during the conduct of this study.

(Required)

- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

Biospecimens/Radiologic Exposure

Does your study include collection of human source materials (i.e. blood products, tissues or body fluids) by invasive means? *(Required)*

Does your study include collection of blood that exceeds 50 ml (3 tablespoons) in an 8 week period, and does the collection occur more than two times per week? *(Required)*

Does your study include radiologic exposure (i.e. x-rays, CT, PET scans) or radiation therapies? *(Required)*

A/V or Photographing

Does your study include audio or video taping or photographing of research participants? *(Required)*

Specify how research participants are or are not identifiable and where in the protocol (page #) this is addressed. *(Required)*

Specify how long identifiers will be retained and any plans to destroy them, and where in the protocol (page #) this is addressed. *(Required)*

Specify who will have access to these items and where in the protocol (page #) this is addressed. *(Required)*

Specify how these items will be used outside the project (training, presentations or publications) and where in the protocol (page #) this is addressed. *(Required)*

Recruitment Process & Materials

Describe in detail the *recruitment process*, including how participants will be identified/recruited/screened for participation in this project (e.g. physician referral, informatics report, etc.).

If this is a retrospective record review, explain where you will obtain the data (e.g. EPIC EMR, private practice records), how you will access the information, and who will extract the data. *(Required)*

Will any recruitment materials/advertisements be utilized for this study? *(Required)*

Recruitment materials include, but are not limited to: phone scripts, radio, tv, newspaper ads, posters, brochures, online web postings, etc.

List each recruitment item and explain where it will be used and by what means it will be distributed. *(Required)*

*You will be asked to **attach copies** of all advertisements/recruitment materials in the Study Documents section at the end of this form.*

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Vulnerable Populations

Vulnerable Populations *(Check all that apply)* *(Required)*

Additional populations considered vulnerable include:

Persons in nursing homes
Unemployed or impoverished persons
Homeless persons
Refugees
Patients in emergency situations
Subordinate personnel (e.g. members of the armed forces, persons kept in detention)

- [ ] NONE
- [ ] Children <18
- [ ] Economically Disadvantaged
- [ ] Educationally Disadvantaged
- [ ] Elderly/Aged
- [ ] Employees or Students
- [ ] Illiterate
- [ ] Impaired Decision Making Capacity
- [ ] Mentally Ill
- [ ] Minorities
- [ ] Neonates
- [ ] Non-English Speaking
- [ ] Pregnant Women/Fetuses
- [ ] Prisoners
- [ ] Terminally Ill

Adults w/Decisional Impairment - Appendix E

Describe the expected range of participant impairment. Explain how, and by whom, the capacity to consent/ assent will be determined. *(Required)*

Indicate whether assent will be obtained and, if so, describe the process. If assent will not be obtained, explain. *(Required)*

What is the plan for obtaining consent from the participant's legal guardian or legally authorized representative? *(Required)*

If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing consent. If you expect no fluctuation, state as such. *(Required)*

Select the one category that best describes the research and provide corresponding information, if risk is greater than minimal. *(Required)*

Minimal Risk: *The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical and psychological examinations or tests.*

Explain how anticipated benefits, compared to risks, are as favorable as the alternatives (e.g. other treatments). *(Required)*

Explain how the risk presents only a minor increase over minimal risk.

Children <18 Questions

Select the category that best describes this research. *(Required)*

- ○ Not greater than minimal risk
- ○ More than minimal risk is presented by an intervention or procedure that holds the prospect of direct benefit for the individual child, or by a monitoring procedure that is likely to contribute to the child's well-being
- ○ More than minimal risk is presented by an intervention or procedures that DOES NOT hold the prospect of direct benefit for the individual child, or by a monitoring procedure that is NOT LIKELY to contribute to the child's well-being

Explain how the risk is justified by the anticipated benefit to the individual child. *(Required)*

Explain how the relation of the anticipated benefit to the risk is at least as favorable to the child as that which would be presented by available alternative approaches (e.g. other treatments). *(Required)*

Explain how the risk represents a minor increase over minimal risk. *(Required)*

Explain how the intervention or procedure presents experiences to children that are reasonably comparable with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. *(Required)*

Explain how the intervention or procedure is likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or improvement of the child's disorder or condition.
(Required)

Do you plan to obtain assent from the children, or do you propose to waive the assent requirement? *(Required)*

Explain the process of obtaining assent from the children. *(Required)*

- *Define the assent plan specific to each age group of potential child participants (e.g. age 5-7 verbal assent; age 8-12 verbal assent with a written information page, age 13-18 written/signed assent document and a discussion)*
- *Define who will perform the assent discussion.*
- *Define where the assent discussion will take place.*
- *Define if the child will be provided with time to allow them to consider being part of the study without the investigator or study staff present.*
- *Define if the parent will be present during the assent discussion.*

Describe the children population for whom a waiver of assent is being requested. *(Required)*

Select one of the following to justify your request for waiver of assent. *(Required)*

- ○ All children will be unable to provide assent because of their age
- ○ Some children will be unable to provide assent because of their age
- ○ All children will be unable to provide assent because of their maturity or psychological state
- ○ Some children will be unable to provide assent because of their maturity or psychological state
- ○ Assent from children will not be obtained because the research is minimal and meets the adult criteria for waiving of consent - 45 CFR 46.116(d)

If all or some of the children are unable to provide assent because of their maturity or psychological state, provide justification. When relevant, include a discussion of the range of expected maturities and

psychological states of the children, how these will be evaluated and by whom, and how the determination of capability to assent will be made. *(Required)*

Indicate the age range for which assent will not be obtained *(Select all that apply):* *(Required)*

The IRB generally considers children 7 years of age and older capable of giving assent.

☐ < 7 years ☐ 7-11 years ☐ 12-15 years ☐ 16-17 years

Provide justification for your request of a waiver of assent for children older than 7 years of age. *(Required)*

Do you plan to obtain parental permission (consent) or do you propose to request a waiver of parental permission (consent)? *(Required)*

Explain the process of obtaining parental permission (informed consent) from the parent(s) to allow the child to participate in the research. *(Required)*

- *When would the parent(s) be approached*
- *Where will the parent(s) be approached*
- *Who will introduce the study*
- *Who will conduct the informed consent discussion*
- *Will the parent(s) be provided with time to allow them to consider their child being part of the study without the investigator or study staff present*
- *Will the family be allowed time to discuss the choice to participate with others*
- *Will the family be allowed time to consider being part of the study without the investigator or study staff present*

NOTE: Unless the research is FDA-regulated, a waiver of parent/guardian permission may be granted at the discretion of the IRB when:

- Permission would be waived in accordance with Federal regulations, Trinity Health Policies & Procedures and ethical guidelines OR
- Soliciting permission would not protect the child (e.g. neglected or abused children) AND
- Appropriate mechanisms for protecting child subjects is substituted AND
- A waiver would not be inconsistent with Federal, state or local law (e.g. waivers of parent/guardiance permission are prohibited for FDA-regulated research)

Is the research minimal risk to children? *(Required)*

Explain why the waiver of parental permission will not adversely affect the rights and the welfare of the children: *(Required)*

Explain why the research would be so difficult as to be nearly impossible to carry out without the waiver of parental permission: *(Required)*

Whenever appropriate, will children and their parent(s)/guardian(s) be provided with additional pertinent information after their participation.? *(Required)*

Would soliciting parental permission possibly jeopardize the child's well-being (e.g. neglected or abused children)?
(Required)

Explain why obtaining parent/guardian permission would not protect the child. *(Required)*

Provide a detailed outline of the alternative, appropriate safeguards that will be put into place to protect the child. *(Required)*

Will the parent(s) or guardian(s) be present with the child during discussions of the research? *(Required)*

Will incentives be offered to the research participants? *(Required)*

Specify to whom incentives will be offered. *(Required)*

Specify the incentives. *(Required)*

Will sensitive or private information (e.g. questionnaires, test results) be shared with the parents/ guardians? *(Required)*

Explain how sensitive information (e.g. questionnaires, test results) will be shared with the parent(s)/ guardian(s). *(Required)*

Is it possible that participation could continue beyond the time the child participant is 18 years of age?
(Required)

Describe the process you will use to re-consent participants who have turned older than 18 years of age. *(Required)*

Is there a possibility that any of the research participants will be wards of the State or any other agency or institution? *(Required)*

Explain how the waiver will not adversely affect the rights and welfare of the participants. *(Required)*

Explain why the research would be so difficult as to be nearly impossible to carry out without the waiver. *(Required)*

When appropriate, will participants and their parent(s)/guardian(s) be provided with additional pertinent information after their participation is complete? Explain why or why not. *(Required)*

Select one of the following options: *(Required)*

- ☐ The research presents no more than minimal risk of harm to participants and involves no procedures for which written assent is normally required outside of the research context. [45 CFR 46.117(c)(2)]
- ☐ The only record linking the participant and the research would be the assent document, and the principal risk would be potential harm resulting from a breach of confidentiality. [45 CFR 46.117(c)(1)]

What is the specific protocol-based justification supporting the statement selected above? *(Required)*

Attach a copy of the oral assent script that will be used during the assent process. *(Required)*

Will the study findings be reported to the participant's parent(s) or guardian(s)? *(Required)*

Describe what will be provided and how findings will be communicated (example: analysis of study information indicates subjects are at increased risk): *(Required)*

Pregnant Women/Fetuses - Appendix G

Select the category that best describes this research. *(Required)*

- ☐ Not greater than minimal risk
- ☐ Greater than minimal risk

The risk to the fetus is (check one): *(Required)*

- ☐ Not greater than minimal risk - prospect of direct benefit for the woman and/or fetus
- ☐ Not greater than minimal risk - WITHOUT prospect of direct benefit, but the purpose of the research is development of important knowledge that cannot be obtained by any other means
- ☐ Greater than minimal risk - caused soley by procedures that hold the propsect of direct benefit for the woman and/or fetus

Does this study hold the prospect of direct benefit to the participant? *(Required)*

Does this study hold the prospect of direct benefit to the fetus? *(Required)*

The father's consent must be obtained for research that holds the prospect of direct benefit solely to the fetus, unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

Explain how the risks are the least possible for achieving the objectives of the research. *(Required)*

Describe pre-clinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women), where scientifically appropriate, that provide data for assessing potential risks to pregnant women and fetuses. NOTE: May refer to a page or section in the protocol document. *(Required)*

Neonates - Appendix H

State who (other than the investigators or other key research personnel) will determine the viability of a neonate. *(Required)*

What procedures will be used to determine viability? *(Required)*

Describe pre-clinical studies and clinical studies, where scientifically appropriate, that provide data for assessing potential risks to neonates. *(Required)*

The viability of neonates to be involved in the research is: *(Required)*

- ☐ Uncertain Viability
- ☐ Non-viable
- ☐ Both

For neonates of uncertain viability, the risk to the neonate is (Check one):

The consent of either parent or either parent's legally authorized representative (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity) is required, except that the consent of the father (or his legally authorized representative) need not be obtained if the pregnancy resulted from rape or incest.

- ☐ The research has allowed the opportunity for increased attempts for the survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective
- ☐ No added risk will result from the research, and the purpose of the research is development of important knowledge that cannot be obtained by other means
- ☐ N/A

For neonates of uncertain viability, explain how the research meets one of the two conditions in the previous question.

If you selected N/A, continue to the next question.

For non-viable neonates, explain how the following condition for inclusion is met:
There will be no added risk to the neonate resulting from the research.

The consent of both parents is required. The consent of a legally authorized representative of either or both of the parents of a non-viable neonate will not suffice. If either parent is unable to consent because of unavailability, incompetence or temporary incapacity, the consent of one parent will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

For non-viable neonates, explain how the following condition for inclusion is met:
The purpose of the research is the development of important knowledge that cannot be obtained by other means.

The consent of both parents is required. The consent of a legally authorized representative of either or both of the parents of a non-viable neonate will not suffice. If either parent is unable to consent because of unavailability, incompetence or temporary incapacity, the consent of one parent will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

Prisoners - Appendix I

Select from the following, the category(s) that which best describes the involvement of prisoners in the research. *(Required)*

- ☐ This research will examine the possible causes, effects, or processes of incarceration and/or criminal behavior, provided the study presents no more than minimal risk or inconvenience to the participants.
- ☐ This research will examine prisons as institutional structures or prisoners as incarcerated persons, provided the study presents no more than minimal risk or inconvenience to the participants.
- ☐ This research will examine a condition(s) particularly affecting prisoners as a class of people (for example, vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- ☐ This research will examine practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.
- ☐ This research is an epidemiologic study (1) to describe the prevalence or incidence of a disease by identifying all cases, or (2) to examine potential risk factor associations for a disease, provided the study presents no more than minimal risk or inconvenience to the participants, and prisoners are not a particular focus of the research.

Provide the name, type of facility, and the location of each local, state or federal facility to be used. *(Required)*

Describe the possible advantages to participating prisoners (i.e. comparerd to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison). *(Required)*

Describe any additional steps that will be taken to avoid undue influence (i.e. considering the limited choice environment of the prison). *(Required)*

Explain how the risks involved in the research are similar to risks that would be accepted by non-prisoner

participants. *(Required)*

Explain how prisoners will be selected for the study and/or assigned to treatment groups. *(Required)*

The selection of participants within the prison and procedures for assignment to various groups within the research (e.g. experimental vs. control groups) should be designed to be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

Describe safeguards in place to provide assurances that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole. *(Required)*

Prisoners must be clearly informed in advance that participation in the research will have no effect on their parole.

Describe follow-up examinations or care of participants (including frequency and duration they will be available) to be provided after their participation has ended, as applicable, taking into account the varying lengths of indvidiual prisoners' sentences. *(Required)*

Employees/Students - Appendix J

Record of participation or non-participation will not be linked to academic or employment record. *(Required)*

Participants will not be directly recruited by their instructor or supervisor. *(Required)*

Record of participation or non-participation will not be made available to individuals who assess the student or employee academic record or job performance. *(Required)*

Participants are *assured* that their status (education, employment and/or promotion) will not be affected by a decision to participate or not. *(Required)*

Participants are *assured* that participation is voluntary (no signs of coercion). *(Required)*

Participants are *assured* that confidentiality will be protected/maintained. *(Required)*

Participants are offered an alternative to participation. *(Required)*

Access, Use, Disclosure of PHI

Will study staff access, use or disclose information that originated in the medical record for the purpose of screening, obtaining contact information or other information for research purposes? *(Required)*

Will this study employ the use of a consent form? *(Required)*

Informed Consent

What are you proposing for the informed consent process? *(Required)*

List all who will be performing the informed consent process *(e.g. principal investigator, sub-investigator, research coordinator, etc.)*? *(Required)*

Explain when you expect the informed consent process will take place. *(Required)*

(Example: Consent will be presented to patient at clinic visit; he/she will be able to take home for review. Once all questions have been answered, the patient will be asked to sign the consent form at their screening visit.)

Where will the informed consent process take place? *(Required)*

(Example: In the clinic; in the Emergency Department; in the Clinical Trial Unit, etc.)

How much time will participants have to make a decision? *(Required)*

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3) The research could not practicably be carried out without the waiver or alteration; and

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Describe how the alteration deviates from normal consent procedures. *(Required)*

Will the alteration of informed consent apply to all participants? *(Required)*

If no, describe for which populations the waiver or alteration is being requested. *(Required)*

Explain why the research involves no more than minimal risk to the individual. *(Required)*

Minimal Risk means the probability and magnitude of harm is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of the general population.

Explain why the research will not adversely affect the rights and welfare of subjects. *(Required)*

Explain why the research would not be possible to conduct without an alteration of consent. *(Required)*

When appropriate, will information be provided to the participant once the research is complete? *(Required)*

If no, please explain: *(Required)*

Will PHI be used in this study? *(Required)*

If yes, please explain: *(Required)*

Informed consent is one of the fundamental principles that underlie and guide the conduct of ethical research involving human subjects and is mandated by federal regulations (45 CFR 46). In order to be eligible for a waiver of informed consent, you must meet all of the criteria outlined below.

Does the proposed research, in its entirety, involve greater than minimal risk? **If yes, your study is ineligible for waiver of informed consent.** *(Required)*

Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Explain how your study meets the criteria for minimal risk.

Does the waiver of informed consent adversely affect the rights and welfare of the subjects? **If yes, your study is ineligible for waiver of informed consent.** *(Required)*

Explain how waiving the informed consent process does not affect the rights and welfare of subjects.

Could the proposed research be practically carried out without the waiver of informed consent? **If yes, your study is ineligible for waiver of informed consent.** *(Required)*

Explain why the research cannot be practically carried out without the waiver of informed consent.

Will this research involve the use of identifiable private information or identifiable biospecimens?

(Required)

If using identifiable private information or identifiable biospecimens, could the research be practicably carried out without using such information or biospecimens in an identifiable format? **If yes, this project is ineligible for a waiver of consent. Please submit an informed consent form.** *(Required)*

When appropriate, will pertinent information be provided to subjects later? *(Required)*

If yes, explain how and when pertinent information will be provided to participants.
(Required)

If no, explain why pertinent information will not be shared with participants. *(Required)*

Select the appropriate category for your Request for Waiver of Documentation of Informed Consent: *(Required)*

- ○ Research presents no more than minimal risk of harm to subjects AND the research involves no procedures for which written consent is normally required outside of the research context (§45 CFR 46.117(c)(2)).
- ○ 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern (§45 CFR 46.117(c)(1)).
- ○ A short form written consent document stating that the elements of informed consent required by §45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. A written summary of what is to be said to the subject or the subject's representative shall be approved by the IRB before use. There shall be a witness to the oral presentation, and the witness shall sign both the short form and a copy of the summary. A copy of the summary shall be given to the subject or representative, in addition to a copy of the short form (§45 CFR 46.117(b)(2)).

Attach a copy of the short-form consent and study summary to be provided to the participants. *(Required)*

Waiver of HIPAA Authorization

Select from the list below everything that you will be doing with PHI: *(Required)*

- ☐ Screening (including looking in medical record, getting contact information or checking eligibility, verbally asking medical staff, reading on a board)
- ☐ Chart review
- ☐ Alteration of HIPAA - changing how specific elements of HIPAA are used (e.g. omitting the requirement to obtain a signed authorization because authorization is being obtained verbally)
- ☐ Other

You selected other. Please explain. *(Required)*

Chart review where:
(Required)

- [ ] All data exists now (Full or Partial waiver of HIPAA)
- [ ] Some of the data will exist in the future (Partial waiver of HIPAA can be granted ONLY for retrospective review. Waiver of HIPAA Authorization cannot be granted for data that does not yet exist.)
- [ ] All data exists in the future (This study is not eligible for a waiver of HIPAA)

Will you be using or disclosing psychotherapy notes? *(Required)*

If yes, your study is not eligible for a Waiver of HIPAA Authorization.

Why is it not practical for you to obtain each person's permission (HIPAA authorization)? *(Required)*

If you could realistically obtain permission from each participant, you will not be granted a waiver of HIPAA.

- ○ Screening (for eligibility criteria) in order to approach people for HIPAA authorization. (It would be impractical to obtain HIPAA authorization if only a few people might be eligible.)
- ○ Gathering contact info only, in order to obtain HIPAA authorization. (Not practical to obtain contact information using another method.)
- ○ This is a retrospective chart review of existing data. (It would be impractical to obtain authorization from each patient when reviewing such a large number of charts.)
- ○ Other

You selected other. Please explain *(Required)*

Select from the list below why the research could not practicably be conducted without access to and use of the Protected Health Information (PHI); i.e. Why is the PHI necessary in order to conduct your study?
(Required)

You selected other. Please explain *(Required)*

Indicate how you will protect the PHI from improper use and disclosure. *(Select all that apply)* *(Required)*

- [ ] Identifiers will be stored separately
- [ ] Data will only be shared within the study team
- [ ] Data will be kept in a database that is password protected
- [ ] Other

You selected "other". Provide additional details.
(Required)

Describe your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or that such retention is otherwise required by law. *(Required)*

Do you assure that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for oversight of the research project, or for other research for which the use or disclosure of the protected health information would not be permitted? *(Required)*

Please explain:
(Required)

The waiver will permit the researcher to access, use, or disclose only the specific individually identifiable health information for which access, use, or disclosure is being requested. Select all sources of data will you access, use or disclose:

(Required)

- [ ] Electronic Records
- [ ] Paper Records
- [ ] Verbal
- [ ] Images
- [ ] Other

Will any of these images include PHI such as medical record number, patient name? *(Required)*

Ensure any identifiers on the images are also selected on the PHI list.

Please detail the other data sources you will access, use, or disclose for this study.
(Required)

Who owns the data? ***(It is important that we understand who is responsible for the data to be used for this study.)***
(Required)

- [ ] Your private practice office
- [ ] Agnes or Alphonsus, or Another Trinity Health
- [ ] Ministry Other

You indicated someone other than your private practice, Agnes, Alphonsus, or Trinity Health owns the data. Please explain. *(Required)*

State how you have secured permission to use this source of data. *(Required)*

If you are accessing or using data/images/records from the health record that is owned by your private practice, who will extract the data? *(Check all that apply)* *(Required)*

- [ ] Research study team member who is a member of the workforce at the private practice
- [ ] Research study team member who is NOT a member of the workforce at the private practice
- [ ] A member of the workforce at the private practice who is not a research team member
- [ ] Other (not listed above)

Does the person have the required Business Associate Agreement with the private practice that allows him or her to extract this data?
(Required)

If you do not, please contact the private practice's HIPAA Privacy Officer or private practice legal dept for forms and approval

Attach a copy of the Business Associate Agreement with Agnes, Alphonsus, or Trinity Health *(Required)*

Please explain why this person is not part of the research team. *(Required)*

Generally individuals gathering data for research purposes must be part of the research team.

Explain who will be extracting the data. *(Required)*

If not an employee or member of workforce, you must have the required Business Associate Agreement.

If you are accessing or using data/images/records from the health record that is owned by Agnes, Alphonsus, or another Trinity Health ministry, who will extract the data? *(Check all that apply)* *(Required)*

Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate 45 CFR 160.103.

- [ ]
- [ ] Research study team member who is a member of the workforce for Trinity Health Ministry
- [ ] Research study team member who is NOT a member of the workforce for Trinity Health Ministry
- [ ] A member of the workforce for Trinity Health who is not a research team member (required for de-identified or limited data set data extractions)
- [ ] Other (not listed above)

Do you have a Business Associate Agreement? *(Required)*

Attach a copy of the Business Associate Agreement with Agnes, Alphonsus, or Trinity Health. *(Required)*

For forms and approval, contact:

HIPAA Privacy Officer: **Iversonm@mercyhealth.com - OR - *Legal Department:* GRLegal@mercyhealth.com**

Please explain why this person is not part of the research team. *(Required)*

Generally individuals gathering data for research purposes must be part of the research team.

Explain who will be extracting the data. *(Required)*

If not an employee or member of Mercy Health or Trinity Health workforce, you must have the required Business Associate Agreement with Mercy Health or Trinity Health

If you are accessing or using data/images/records from the health record that is owned by another entity, who will extract the data? *Check all that apply* *(Required)*

- ☐ A research study team member who is a member of the workforce for the "Other" organization
- ☐ A research study team member who is NOT an "Other" organization
- ☐ A member of the workforce for the "Other" organization who is not a research team member
- ☐ Other (not listed above)

If not an employee or member of "other" organization's workforce, does the person have the required Business Associate Agreement that allows him or her to extract this data? *(Required)*

If you do not, please contact the other entity's HIPAA Privacy Officer or private practice legal department for forms and approval.

Attach a copy of the Business Associate Agreement. *(Required)*

Please explain why this person is not part of the research team. *(Required)*

Explain who will be extracting the data.
(Required)

If not an employee or member of Agnes, Alphonsus, or Trinity Health workforce, you must have the required Business Associate Agreement with Trinity Health.

What are the dates of records that you wish to access?
(Required)

Enter the dates of the records, not dates that you will physically be reviewing them.

mm/dd/yyyy through mm/

Select the specific Protected Health Information for which access or use is necessary. *(Required)*

- ☐ Name (including Initials)
- ☐ Address
- ☐ Elements of dates (Birth Date, Admission Date, Date of Service, Date of Death, etc.)
- ☐ Ages over 89
- ☐ Telephone number
- ☐ Fax number
- ☐ E-Mail address
- ☐ Social Security Number
- ☐ Medical Record Number/FIN
- ☐ Health Plan Beneficiary Number
- ☐ Account numbers (credit card, etc.)
- ☐ Certificate/License numbers
- ☐ Vehicle Identifiers/serial numbers (incl. license plate number)
- ☐ Device Identifiers/serial numbers
- ☐ Website URLs
- ☐ Internet protocol (IP) Addresses
- ☐ Biometric identifiers (incl. voiceprints and fingerprints)
- ☐ Full face images and comparable images
- ☐ Any other unique identifying numbers, characteristics or codes (unless otherwise permitted by the Privacy Rule for re-identification)

Please specify other unique identifying numbers, characteristic or code (linked study identification numbers, etc.).
(Required)

Is this the minimum necessary PHI that is needed in order to conduct this study? *(Required)*

Please revise your list to only include the absolute minimum necessary PHI.

Will the PHI be shared with anyone externally? *(Required)*

State their name and affiliation:
(Required)

How will the PHI be shared? ***(Select all that apply)*** *(Required)*

- VPN
- Encrypted e-mail
- Other

Please specify how PHI will be shared.
(Required)

PI Waiver of HIPAA Attestation

- **I declare that the information provided on this form accurately reflects my research intentions and all of the PHI that will be accessed, used or disclosed.**
- **If my intentions change, I acknowledge that I am required to resubmit this form to the IRB for review and determination.**
- **I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.**
- **I agree to seek permission from the IRB before reusing participant medical record information for a different purpose or disclosing it to any other person or entity, except as required by law.**
- **I will not re-use this information for other research for which the use or disclosure of protected health information is requested without first gaining permission from the IRB.**

Please sign Attestation: *(Required)*

Alteration of HIPAA

For which elements of HIPAA are you requesting an alteration? *(Required)*

Examples include making an exception to the required language in an authorization form or eliminating the requirement to obtain a signed authorization (e.g., authorization provided over the phone).

Why could this research not be practicably conducted without the requested alteration of HIPAA?
(Required)

Explain why the research could not practicably be conducted without access to and use of the Protected Health Information (PHI); that is-- why is it necessary to have the PHI in order to conduct your study? *(Required)*

The use or disclosure of Protected Health Information must involve no more than a minimal risk to the *privacy* of individuals. Per HIPAA Regulations each question below must be answered in order to document that the use of a waiver meets the definition of minimal risk to privacy.

Explain your plan to protect the identifiers from improper use and disclosure.

(Required)

Describe your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or that such retention is otherwise required by law. *(Required)*

Do you assure that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for oversight of the research project, or for other research for which the use or disclosure of the protected health information would not be permitted? *(Required)*

- ○ Yes
- ○ No

Select the specific Protected Health Information for which access or use is necessary under the alteration. *(Required)*

☐ Name (including Initials)	☐ Address	☐ Elements of dates (Birth Date, Admission Date, Date of Service, Date of Death, etc.)
☐ Telephone number	☐ Fax number	☐ E-Mail address
☐ Social Security Number	☐ Medical Record Number/FIN	☐ Health Plan Beneficiary Number
☐ Account numbers (credit card, etc.)	☐ Certificate/License numbers	☐ Vehicle Identifiers/serial numbers (incl. license plate number)
☐ Device Identifiers/serial numbers	☐ Website URLs	☐ Internet protocol (IP) Addresses
☐ Biometric identifiers (incl. voiceprints and fingerprints)	☐ Full face images and comparable images	☐ Any other unique identifying numbers, characteristic or code (unless otherwise permitted by the Privacy Rule for re-identification)

Please specify other unique identifying numbers, characteristic or code (linked study identification numbers, etc.). *(Required)*

Is this the minimum necessary PHI that is needed in order to conduct this study? *(Required)*

- ○ Yes
- ○ No

Please revise your list to only include the absolute minimum necessary PHI.

Device Information

Device Type: *(Required)*

- ○ HUD
- ○ Investigational Device or Investigational Use of an Approved Device
- ○ FDA-Approved Device (cleared for marketing and used according to intended use)

HUD

Name of Device *(Required)*

Name of Manufacturer *(Required)*

Humanitarian Use Device Exemption Number (HDE#): *(Required)*

Attach a copy of the FDA letter granting HDE approval. *(Required)*

Is the HUD being used in a research study or as designated by the FDA? *(Required)*

Is this HUD being used in a research study or as designated by the FDA? *(Required)*

Provide a brief description of the device and its approved indications. *(Required)*

Provide the proposed rationale for choice of this device (compared to other devices that could be used). *(Required)*

Attach a copy of all HUD materials (Participant Information Booklet, Manuals, Guides, Handouts and Pamphlets) *(Required)*

Investigational Device

Enter the name of your investigational device. *(Required)*

If there is more than one device being investigated, click on REPEAT after completing this page to enter information on additional investigational devices.

Device Status *(Required)*

What is the name of the sponsor/manufacturer of the device? *(Required)*

Provide a brief description of the device. *(Required)*

Provide the proposed rationale for choice of the device (compared to other devices that could have been used). *(Required)*

Is this device classified as significant risk or non-significant risk? *(Required)*

- Significant Risk
- Non-Significant Risk

As a non-significant risk, you must justify that the device is not intended as an implant and poses no serious risk to the health of the patient. Please indicate where this is addressed in the protocol (page # and section) or provide a written explanation. *(Required)*

As a non-significant risk, you must justify that the purpose of the device is not to support or sustain life and does not present a serious risk to the health or the patient. Please indicate where this is addressed in the protocol (page # and section) or provide a written explanation. *(Required)*

As a non-significant risk, you must justify that the purpose of the device is not for use of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of health, and does not present a serious risk to the health of the patient. Please indicate where this is addressed in the protocol (page # and section) or provide a written explanation. *(Required)*

As a non-significant risk, you must justify that the device does not otherwise pose a serious risk to the health of the patient. Please indicate where this is addressed in the protocol (page # and section) or provide a written explanation. *(Required)*

Is an IDE required? *(Required)*

What is the IDE Number? *(Required)*

Who is the IDE Holder? *(Required)*

If this is an Investigator-held IDE, describe the process for assuring compliance with FDA regulations pertaining to sponsors (e.g. recordkeeping, reporting).

Attach a copy of the FDA letter(s) providing the IDE number. *(Required)*

Describe how the investigator(s) are qualified to utilize the study device(s) and perform the procedures required by the study (describe any specialized device training). *(Required)*

It is required that investigative devices be used under the direction of an approved and authorized investigator(s), to ensure its use or implantation only in research subjects. Please describe the process for device accountability, storage and recordkeeping to ensure the device will be distributed and used according to the approved protocol. *(Required)*

Are you proposing to utilize the device in an "off-label" use to evaluate its safety and effectiveness for a new indication? *(Required)*

Is this an Investigator-initiated trial? *(Required)*

If this is an investigator-initiated trial, attach a letter of support for the device to be used in the proposed manner from the device manufacturer. *(Required)*

If this is an investigator-initiated trial, and you are proposing to utilize the device in an "off-label" use to evaluate its safety and effectiveness for a new indication, provide a written explanation supporting the Significant Risk (SR) or Non-Significant Risk (NSR) determination. You may reference the protocol section that contains this information or you should enter the information here.

If there are no other investigational devices, click NEXT to continue to the next page, and click NEXT again to continue completion of this form.
If there *are* additional investigational devices, click NEXT to continue to the next page, and then click REPEAT to enter information for another device.

FDA-Approved Device

Name of Device *(Required)*

Device Status *(Required)*

Device Classification *(Required)*

Provide a brief description of the device. *(Required)*

Provide rationale for choice of this device (compared to other devices that could be used). *(Required)*

Describe how the investigator(s) are qualified to utilize the study device(s) and perform procedures required by the study. (Describe if there is any specialized device training.) *(Required)*

It is required that investigative devices be used under the direction of an approved and authorized investigator(s), to ensure its use or implantation only in research subjects. Please describe the process for device accountability, storage and recordkeeping to ensure the device will be distributed and used according to the approved protocol. *(Required)*

Are you proposing to utilize the device in an "off-label" use to evaluate its safety and effectiveness for a new indication? *(Required)*

Is this an Investigator-initiated trial? *(Required)*

If this is an investigator-initiated trial, attach a letter of support for the device to be used in the proposed manner from the device manufacturer. *(Required)*

If this is an investigator-initiated trial, and you are proposing to utilize the device in an "off-label" use to evaluate its safety and effectiveness for a new indication, provide a written explanation supporting the Significant Risk (SR) or Non-Significant Risk (NSR) determination. Please indicate where this information can be found in the protocol (page # and section) or provide a written explanation. *(Required)*

If there are no other FDA-approved devices, click NEXT to continue to the next page, and click NEXT again to continue completion of this form.
If there *are* additional FDA-approved devices, click NEXT to continue to the next page, and then click REPEAT to enter information for another device.

Drug Information

Indicate the drug type: *(Required)*

Study Phase *(Required)*

- I
- II
- III
- IV
- Other

If other study phase, please specify.

e.g. Phase I/II, Phase IIb, etc.

What is the generic name or active ingredient of the drug? *(Required)*

What is the brand name of the drug (if applicable)? If not available, state as such. *(Required)*

What is the name of the sponsor or manufacturer of the drug? *(Required)*

What is the dose and dosage form of the drug (e.g. 10 mg. tablet)? *(Required)*

What is the frequency of drug dispension and the route of administration? *(Required)*

Does the drug/biologic have an Investigational New Drug (IND) Number? *(Required)*

Enter the IND#. *(Required)*

IND Holder *(Required)*

☐ Investigator ☐ Sponsor ☐ Third Party

If the IND Holder is the investigator, describe the process for assuring compliance with the FDA regulations pertaining to sponsors (recordkeeping and reporting).

If IND Holder is a third party, enter the name of the third party in the space below.

If there is no IND Number, please confirm the following statements by reading and checking each box.

- ☐ This investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- ☐ The drug that is undergoing investigation is lawfully marketed as a prescription drug product and the investigation is not intended to support a significant change in the advertising of the product.
- ☐ The investigation does not involve a route of administration or dosage level or use in a patient population that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- ☐ The investigation will be conducted in compliance with the requirement for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50.
- ☐ The investigation will be conducted in compliance with the requirement of 312.7 (product marketing).

Attach a copy of either the FDA Approval Letter with the assigned IND number, or a copy of the FDA letter indicating the use of the drug/biologic in this study is IND exempt. *(Required)*

Provide the rationale for the choice of this agent in the research *(compared to other drugs that could have been used).* *(Required)*

Attach a copy of the package insert for the FDA-approved drug or biologic. *(Required)*

Describe the process for ensuring investigational drug accountability, storage and recordkeeping to ensure that the drug will be used according to the protocol, under the direction of the approved investigator(s). *(Required)*

Is preparation and repackaging of the supplied product necessary before administration or dispensing? *(Required)*

Who will perform the preparation and repackaging of the supplied product? *(Required)*

Where will these activities be performed? *(Required)*

Describe the investigator(s)' qualifications to utilize the study drugs/biologics and perform the procedures required by the study. *(Required)*

Describe if there is any specialized drug/biologic training.

If there are no other study drugs, click NEXT to go to the next page; then click NEXT again to continue completion of this form.

If there are additional study drug(s), click NEXT to go to the next page; then click REPEAT to enter information for another drug.

Appendix D - Databases

Describe the plans to control the data being collected so it will be used only for the research project for which you are requesting approval. *(Required)*

Describe in which types of format the electronic data will be stored in *(e.g. Excel, Access, REDCap)*. *(Required)*

Describe who will be responsible for maintaining the confidentiality of the data. *(Required)*

Describe what computer and drive the data will be stored on. *(Required)*

Describe who has access to the data. *(Required)*

Describe the measures for protecting the physical security and software security of the data. *(Required)*

Describe the process for ensuring that authentication and authorization are required for those who have access to medical data by providing firewalls, data encryption, and password protection. *(Required)*

Describe a contingency plan for dealing with any breach of confidentiality. *(Required)*

Describe where the data may be presented while the study is ongoing (i.e. conferences, publications). *(Required)*

Describe how the data may be presented while the study is ongoing (i.e. as research, as quality). *(Required)*

Describe how the data will be stored once the study is complete (who will have it, where will it be stored, and who will have access to it). *(Required)*

Invoicing

Are you requesting waiver of IRB fees? *(Required)*

Waiver of IRB fees must be approved by the Research Compliance Department.

Please provide justification for your request to waive IRB fees. *(Required)*

Provide the invoice contact name. *(Required)*

Provide the mailing address for IRB invoicing. *(Required)*

Provide the contact's email address. *(Required)*

Provide the contact's phone number.

Provide any special instructions for invoicing.

Study Documents

Please list each document exactly as you want it to appear in the IRB approval letter. Include document title, version number and/or date. *(Required)*

If listing more than one document, please bullet point your list.

I

Attach the protocol. *(Required)*

Attach the consent form(s).

Attach assent form(s), if applicable.

Attach all data collection tools you will use for this research study.

Include your data collection form(s), study key, CRFs, surveys, questionnaires, etc.

Attach all recruitment materials/advertisements, if applicable.

This includes, but is not limited to: newspaper, radio or tv ads; posters; brochures; phone scripts; online web postings.

Attach the Investigator's Brochure, if applicable.

Attach any additional supporting documents here. **Select the APPROPRIATE ATTACHMENT TYPE for each.**

Investigator/Study Staff Documents

Attach copies of the required CITI training certificates for all research study personnel. This includes HSR, RCR & COI, plus GCP if this is a clinical trial. ***CITI training link:*** ***https://www.citiprogram.org/index.cfm?pageID=14***

(Required)

Required training certificates: *Human Subject Research (HSR), Responsible Conduct of Research (RCR), Conflicts of Interest (COI). If you are involved in a clinical trial, you are also required to complete the Good Clinical Practice (GCP) training.*

Attach a copy of the principal investigator's current Curriculum Vitae. ***(CV should be dated and/or signed within the past three years.)*** *(Required)*

Confidentiality Agreement

Are there any study team members who are not employed by Agnes, Alphonsus, Trinity Health Physician Partners or Trinity Health? *(Required)*

Enter contact information ***(email address)*** **for all study team members who are not employed by Agnes, Alphonsus, Trinity Health Physician Partners or Trinity Health.** *(Required)*

Individuals not affiliated with Mercy Health or Trinity Health must sign a Confidentiality Agreement. These individuals will be notified by email of the need for their sign off on our Confidentiality Agreement.

No answer provided.

Application Data Entry Complete

If you are the principal investigator, please proceed to the next page to read the investigator assurance and provide your electronic signature. If you are not the principal investigator, go to the next page and click on SUBMIT. An email will be sent to the PI requesting his/her review of this form and their electronic signature.

Investigator Assurance

- **I have the time and adequate resources required to responsibly conduct (according to Good Clinical Practice, ethical principles of the Belmont Report, federal and state regulations and the Mercy Health or local Regional Health Ministry policies) and oversee all activities of this trial.**
- **I have reviewed the current Grand Rapids Regional Institutional Review Board policies (https://www.trinityhealthmichigan.org/research-compliance/grand-rapids) and acknowledge my responsibilities as the Principal Investigator.**
- **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 will ensure the selection of human research subjects for participation is equitable, and appropriate safeguards are included to protect the rights and welfare of vulnerable populations (e.g. children, cognitively impaired, economically disadvantaged, prisoners, pregnant women, employees, students).**
- **I will ensure the Protection of Data as outlined in the Grand Rapids institutional policies. I acknowledge that failure to properly secure patient data can result in civil or criminal sanctions and fines should the data be subject to a security breach or inappropriate disclosure.**
- **I acknowledge I have been advised there are IRB fees associated with this submission, and acknowledge I may be billed for these fees.**
- **I confirm that I will not change any of the procedures, forms or protocols used in this study without first seeking review and approval from the Mercy Health Regional Institutional Review Board.**

Principal Investigator acceptance of responsibility for an individual with access to Confidential Information:

(Applies to physicians, physician practices, other individual or facility providers, a vendor that is not a business associates, payers, any other unaffiliated organization)

- **I accept responsibility for all actions and/or omissions by my employees, agents and/or research study staff involved in this study.**
- **I agree to notify the Trinity Health Resolution Center (1-888-667-3003) within 5 business days if any of my employees, agents and/or research study staff who have access to Trinity Health systems or applications no longer need or are eligible for access due to leaving my practice/company, changing their job duties or for any other reason.**
- **I agree to report any actual or suspected privacy or security violations made by my employees, agents and/or research study staff to the Mercy Health/Trinity Health Privacy Official or Security Official.**
- **I understand tha Trinity Health may terminate my employee's, agent's and/or research study staff's computer access.**

- **I declare that the information provided on this form accurately reflects my research intentions and all of the PHI that will be accessed, used or disclosed.**
- **If my intentions change, I acknowledge that I am required to resubmit this form to the IRB for review and determination.**
- **I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.**

● I agree to seek permission from the IRB before reusing participant medical record information for a different purpose or disclosing it to any other person or entity, except as required by law.

● I will not re-use this information for other research for which the use or disclosure of protected health information is requested without first gaining permission from the IRB.

By signing, you acknowledge your responsibilities as the principal investigator for this study.*(Required)*