FORM: Certification of Review Preparatory to Research

This form is for a Researcher / Investigator to request permission to review a limited number of records that contain protected health information (PHI) prior to conducting research to formulate a research hypothesis, assess the feasibility of a project, or determine the availability of data. Use and disclosures made under a Preparatory to Research Certification are subject to the HIPAA disclosure accounting requirement. The Researcher / Investigator listed below is required, per Trinity Health Michigan Policies and Procedures, to contact the HIPAA Privacy Office to submit an accounting of disclosure related to your use or disclosure of PHI.

This Preparatory to Research Certification will expire after one (1) year from the date granted by the Privacy Board/IRB in writing.

GENERAL STUDY INFORMATION

IRB Project #:			
Project Title:			
Researcher / Investigator:			
Investigator Status:	☐ **TH Workforce Member**	☐ **Non-Workforce Member**	
Phone Number:		**Email:**	
Address:			

PREPARATORY TO RESEARCH

***To Custodian of Patient Information**: Federal privacy standards issued by the Department of Health and Human Services (DHHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permit Trinity Health Michigan to make patient information available for review by an Investigator for protocol development and study feasibility, provided that the following representations are obtained from the Investigator (45 CFR 164.512(i)(1)(ii)).*

Check all that apply.

1. Purpose(s) for which access to records maintained by or on behalf of Trinity Health Michigan is (are) sought:	☐	Protocol Development (Option 1)
	☐	Identification / Contact of potential research participants - not permitted for non-workforce members (Option 2)

2. Describe the nature and scope of the protected health information to which access is sought.

3. Check the protected information you wish to access.

☐	Name	☐	Device identifiers and serial numbers
☐	Elements of dates including birthdate, admission date, date of death, and all ages ≥ 89 years of age	☐	Full face photographic images and comparable images
☐	Fax Number(s)	☐	Email Address(es)
☐	Social Security Number	☐	Telephone Number(s)
☐	Health plan beneficiary numbers	☐	Certificate or license number(s)
☐	Medical Record Numbers / Account Numbers	☐	Website URLs
☐	Vehicle identifiers and serial numbers including license plate	☐	Geographic information, smaller than State (i.e., city, county, zip code)
☐	Biometric identifiers (e.g., fingerprints, voiceprints)	☐	Account number(s), including banking/payment information
☐	Any other unique identifying number, characteristic, or code:		

RESEARCHER / INVESTIGATOR ATTESTATION

The Researcher / Investigator represents that:

a. Access to the requested information about the patients is sought solely for the purpose(s) indicated above.
b. The requested patient information is necessary for the research purpose(s) indicated above.
c. No individually identifiable patient information will be copied by the Investigator or removed from Trinity Health Michigan premises during the course of or following the review, and
d. The Investigator must await acknowledgement from the Trinity Health Michigan Research Compliance Department prior to accessing records.

SIGNATURE OF INVESTIGATOR	**DATE OF SIGNATURE**