Research Compliance Department (RCD) (734)712-5470
Trinity Health Michigan Regional Institutional Review Board (IRB)
aasjirbsubmissions@trinity-health.org

NON-HUMAN SUBJECT RESEARCH (NHSR) DETERMINATION FORM

PROJECT LEADER INFORMATION

NAME AND CREDENTIALS	TITLE	DEPARTMENT AND INSTITUTION

WORK ADDRESS	EMAIL	CONTACT PHONE#
	The address will be used on correspondences and sent to the email provided	

PROJECT INFORMATION

TITLE OF PROJECT

SELECT THE TYPE OF ACTIVITY

If your project is limited to one of the items below, then it is likely not Human Subjects Research (see Page 2 examples)

☐	Program Evaluation/Quality Assurance Review/Quality Improvement Project (Refer to QI vs Research Checklist)	☐	Research Using Public or Non-Identifiable Private Information/Databases about Living Individuals, i.e., NIS, etc.
☐	Case Report	☐	Research Using Health Information from Deceased Individuals
☐	Course-Related Activity	☐	Instrument/Questionnaire Development
☐	Journalistic or Documentary Activity	☐	Other: provide a description below.

PROVIDE A BRIEF DESCRIPTION OF THE PROJECT, INCLUDING WHAT YOU PLAN ON DOING WITH ANY RESULTS.

DESCRIBE THE POPULATION BEING STUDIED

DATA COLLECTION: Describe methods used, including all data sets, variables collected, and de-identification of data

NAME OF PERSON SUBMITTING FORM	EMAIL	PHONE

EXAMPLES OF ACTIVITIES GENERALLY CONSIDERED NOT TO BE HUMAN SUBJECTS RESEARCH

PROGRAM EVALUATION/QUALITY ASSURANCE REVIEW/QUALITY IMPROVEMENT PROJECT:

The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting. Note: The purpose of a QA study is to assure known quality. Program Evaluation (PE) aims to assess that a program is doing what it is intended to do. Generally, QI is designed to improve the quality of a service, a program, a process, etc. A QA, QI, or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure that a service, a program, or a process is functioning optimally. Such projects are usually for internal auditing purposes only. The activity is most likely not human research if the following are true:

a) Monitoring an existing process and not changing any aspect of the process
b) Usual and customary care will be provided throughout the conduct of the project
c) The data is currently accessed and used routinely as part of the investigator's usual care/daily activities

NOTE: THE QI vs Research Checklist must be completed and dated prior to the activity taking place. The completed checklist must be retained on file for review as requested.

CASE REPORT

The project consists of one or two case reports which describe an interesting treatment, presentation, or outcome for a single patient. A critical component is that the investigators did nothing to the patient with prior "research" intent. Any activity involving three or more case reports is considered research and requires the submission of a full study application for review.

COURSE-RELATED ACTIVITY

Data is collected from course participants as part of routine class exercises or assignments explicitly related to educational/teaching activities and will not generate information needing additional investigation or analysis. NOTE: If additional activities are done with participants, then it should be submitted to the IRB for review.

JOURNALISTIC OR DOCUMENTARY ACTIVITY

Interviews or investigation activities focusing on specific events that may be reported or published in print newspapers, online magazines, a documentary video, or other forms of medium.

PUBLIC OR NON-IDENTIFIABLE PRIVATE INFORMATION ABOUT LIVING INDIVIDUALS:

Analysis of publicly available data sets or private data provided to the investigator that contains no protected health information (PHI). In addition, the investigators do not have any mechanism to ascertain the individual's identity in any manner.

RESEARCH USING HEALTH INFORMATION FROM DECEASED INDIVIDUALS:

This activity is limited to analyzing data about deceased individuals (identifiable or not) only. According to the DHHS, deceased individuals cannot be 'Human Subjects' for the purpose of research. Still, according to the FDA, they may be 'Human Subjects,' and the use of decedents' information in accordance with HIPAA regulations requires a decedent certification form.

INSTRUMENT/QUESTIONNAIRE DEVELOPMENT:

Limited to obtaining feedback from individuals, affected or not, on questions for developing/constructing data collection tools (surveys/questionnaires); data is not being collected on the individuals themselves. The development process may apply to aspects of reliability and validity testing of the instrument or questionnaire. However, once the process begins to test discriminant, concurrent, or predictive validity, it may be considered human subject research and require IRB submission/review/approval.

For further information on determining if your project is not human subject research, refer to the following: Is an Activity Human Subjects Research Covered by 45 CFR Part 46 (Chart 01)

Note: Even if it is not considered 'human subject research,' institutional policies, HIPAA, FDA regulations or other state or local laws may still apply to the activities above.