Institutional Review Board (IRB)

Case Report Form

CASE REPORT (3 PATIENTS OR LESS)

Title of Study: _____

Investigator(s)/Author(s): _____

Faculty/Advisor/Sponsor: _____

Purpose: ☐ Publications ☐ Conference Presentation ☐ Other:

Summary:

Description of the process for the de-identification of data or the process for obtaining HIPAA authorization from the patient or legally authorized representative (LAR) if Protected Health Information may be included.

Data is recorded in a manner that reduces the risk of a breach of confidentiality:

☐ Identifiers are not viewed by the research team. The providers of the data only provide the data to the researchers in a de-identified format. Investigators cannot identify the human subjects.

☐ Data has identifiers, but identifiers are removed. Data is recorded in a de-identified manner only.

☐ Data has identifiers, but identifiers are stored in a separate linking list stored in a different location than the data set. Therefore, in an unlikely event of a breach, the recipient will not be able to link the data to the identifiers.

Data is stored in a secure manner. Security measures include:

☐ Data limited to listed study personnel.

☐ Data is stored on a password protected computer.

☐ Computer or electronic devices housing data is stored in a restricted access location: _____

_____

Conflict of Interest:

☐ Yes, complete outside interest in Cayuse (dchstx.app.cayuse.com/profile#disclosures)

☐ No, all authors declare that they have no conflicts of interest

MRN # (For Audit and Tracking Purposes): _____

DCH Location (Department or Coordinating Center): _____

Person Providing Information:

Name: _____ Driscoll Email: _____

Date of Submission: _____

Investigator(s) and Assigned Tasks: ☐ N/A

Name	Role	Affiliation	*Assigned Tasks (see list below; utilize cooresponding number)

*Assigned Tasks

1. Determine Eligibility
2. Data Collection
3. Reporting
4. Publication, Write-up
5. Other: _____

Reminder:

Although there is no requirement of IRB approval for a case report, the HIPAA Privacy Rule restricts how protected health information (individually identifiable health information) may be used and disclosed. The protected health information should NOT be removed from Driscoll premises or be sent outside of Driscoll by the researcher in the course of the review.

HIPAA requires written authorization from the patient for certain disclosures of the patient's PHI, including publication of a case report. The author of the case report must obtain the signed authorization of the patient, or the patient's legal representative if the patient is deceased, to publish the patient's information in the article.

Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.

A case report is a medical/educational activity that does not meet the DHHS definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, the activity does not have to be reviewed by the DCH IRB.

In certain cases, journals may require a formal determination from the IRB that a case report does not constitute research. Researchers seeking an official IRB determination that a case report is not research should submit a not-human subjects research (NHSR) application through the Cayuse submission platform: dchstx.app.cayuse.com.