Driscoll Institutional Review Board (IRB) Guidance

Case Reports Three (3) Patients or Less

What constitutes a "case report"?

A case report (generally described as a retrospective analysis of one (1), two (2), or three (3) clinical cases) is intended to develop information to be shared for medical or educational purposes and not necessarily as "generalizable knowledge." As such, case reports do not meet the definition of "human subject research under the purview of an IRB."

Does a case report (3 patients or less) for medical, educational presentations or journal submission require an IRB review and approval?

In most cases NO, IRB approval is not required.

When a case report requires IRB review at Driscoll?

- Case Series

  When larger series of patients are being reported, investigators/authors usually begin to ask specific research questions and formal systematic collection of data occurs, moving these activities closer to prospectively designed research. If more than three cases are involved in the analysis, the activity will be considered "research" and requires the submission of an initial application (Cayuse) for IRB review.

- FDA regulated

  FDA regulations do not provide for exemption from IRB review when research involves existing data/specimens and the investigator records information without identifiers or linking codes. Nor do FDA regulations define "human subjects" with reference to the identifiability of the subject or of the subject's private information. As such, any case report, case study, and/or case series involving a subject participating in an FDA-regulated clinical trial requires IRB review.

- As requested

  In certain cases, journals/organizations may require a letter, or other acknowledgment, from an IRB prior to publication or presentation of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case.

Requesting Driscoll IRB to make a formal determination that my case report is not research.

If you are seeking an IRB determination that a case report is not research submit a not-human subjects research (NHSR) application through the Cayuse submission platform (Activities Without Plan for Research).

Are there HIPAA implications associated with publication of case reports?

YES. 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. HIPAA requires written authorization for certain uses and disclosures of an individual's protected health information, including publication of a single case report.

Authors who **remove** 18 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.

It is the responsibility of the author to ensure compliance with patient privacy, institutional rules, and federal regulations. It is also the responsibility of the author to ensure that (i) no photos or illustrations that contain identifiable features are included the case report (e.g. pictures of a patient's face or tattoos should not be included or the identifying information should not be visible) and (ii) the case(s) described in the report are not so unique or unusual that it might be possible for others to identify the patients in the case reports.

Protected health information should NOT be removed from Driscoll premises or be sent outside of Driscoll by the researcher without written permission or Data Use Agreement.

Medical/Pharmacy Residents/Medical Students Requesting IRB Review

- Case Report 3 patients or less (Driscoll Patients) – see flowchart (next page)

Links/Resources:

- CITI Training (Biomedical, COI) or equivalent
  - SharePoint: Human Subject Projection Required CITI Training
  - Website (no Driscoll single sign-on (SSO)): Institutional Review Board - Driscoll Children's Hospital
- Request for Guest Access to Cayuse - Note: for those who don't have Driscoll SSO
  - Send an email to Priya.Desai@dchstx.org cc: IRB.Office@dchstx.org with subject line: **New Cayuse Guest User Request**
  - Include the following details for requested user(s): First name, Last name, and a contact email (institution assigned email)
- Case Report Form
  - SharePoint: Institutional Review Board - Forms/Templates - All Documents – Activities Without Plan to Conduct Research folder - Case Report Form Folder
  - Website (no Driscoll SSO): Institutional Review Board - Driscoll Children's Hospital – Case Report Template with Instructional Guide Version 1.7.2025
- Case Report in Cayuse
  - Cayuse Link: dchstx.app.cayuse.com
  - Website (no Driscoll SSO): Contact Priya.Desai@dchstx.org cc: IRB.Office@dchstx.org
  - Schedule a Cayuse walkthrough with Priya if necessary

- Case Report 3 patients or less (Non-Driscoll Patients – e.g. for Medical Student Case Report Competition) – see Flowchart (next page)

Contact for Further Information:

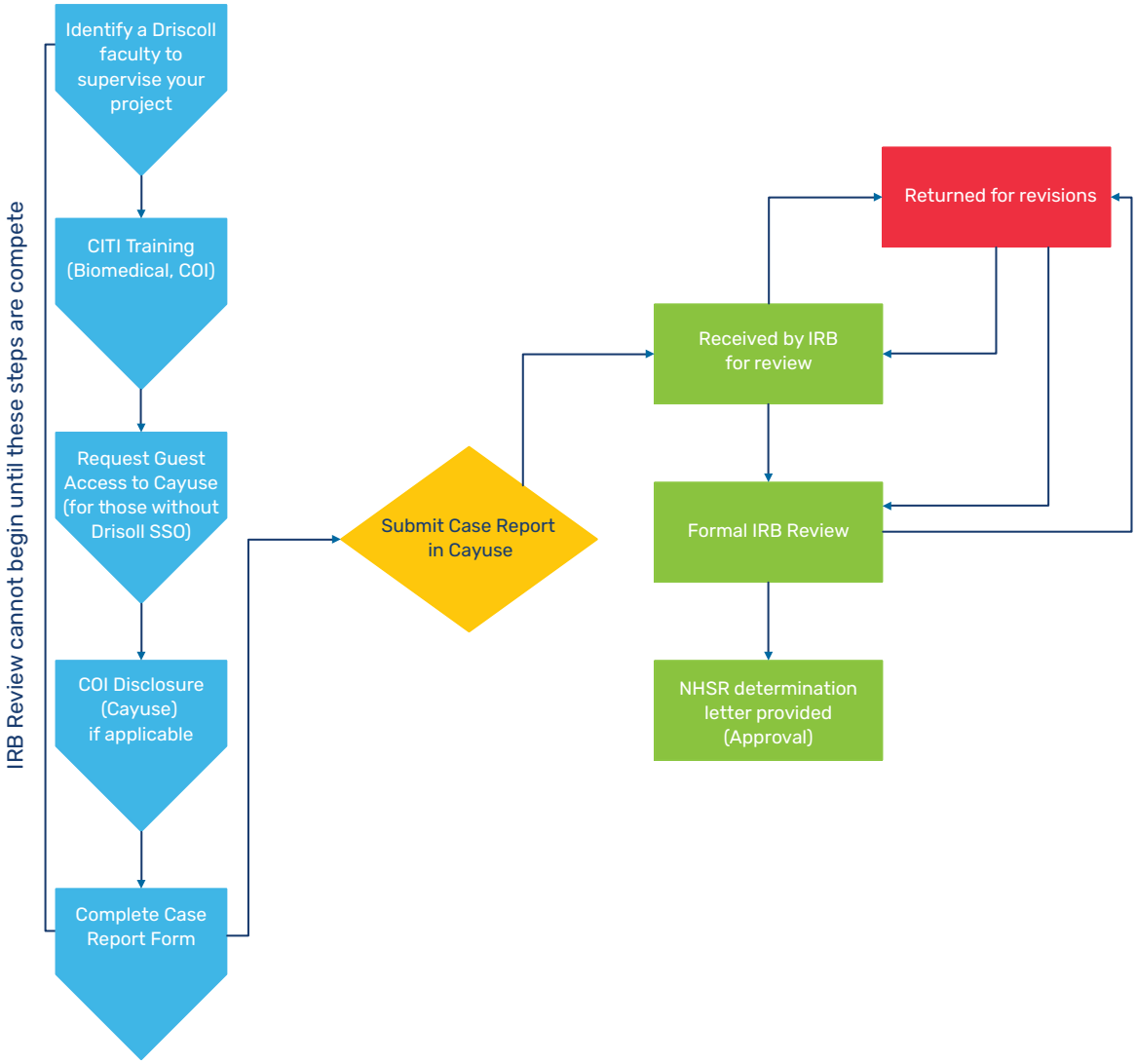
Medical Residents/Students POC: Gabriela.Rodriguez@dchstx.org CC: IRB.office@dchstx.org

Other DHS Department: Priya.Desai@dchstx.org CC: IRB.office@dchstx.org

Cayuse/Driscoll CITI: Priya.Desai@dchstx.org CC: IRB.office@dchstx.org

HIPAA Related matters: Lauren.Parsons@dchstx.org CC: IRB.office@dchstx.org

Case Report Flow Chart - Driscoll Patients



Case Report Flow Chart - Non-Driscoll Patients