

**Helfgott Research Policy:
Retrospective Case Series Research -
EPIC Queries for Student Research**

Research students who intend to conduct a retrospective case series and wish to find cases by querying EPIC do not need IRB approval. However, they still must write a scientific protocol for review and approval by the Scientific Review Committee (SRC). This document should follow the general format of a scientific protocol with specific emphasis on the following:

- **Inclusion/exclusion criteria** (search criteria) must be clearly outlined a priori. Under no circumstances should students be searching EPIC and reading cases to ‘get a sense for’ what they want to investigate.
- **A systematic, a priori process** for selecting charts that will be included in the series once the query has been run must be included.
- **Protection of human subjects** should be clearly described. Once an EPIC query has been run, *students must explicitly state that they will not open a chart belonging to anyone they recognize as NCNM staff, faculty, or student.* We have no way of filtering out charts for NCNM employees and students, thus we rely on the honor code to protect the privacy of those members of our own community who have received services at NCNM clinics. While all patients who are seen at our clinics have been made aware that this is a teaching facility and their case may be used for teaching purposes, NCNM employees and students should not be included case reports or case series unless individual consent has been obtained.
- **A data management plan** must clearly describe how students will manage cases while they are extracting data. Where will they keep the list of MRN’s for inclusion in their study (in a locked file in the locked document room at Helfgott)? How will they ensure this list is kept confidential? We often hear students refer to Human Subjects and Data Management protocol sections as “boiler plate”. All mentors need to ensure that these sections are written first hand (and fully understood) by the student proposing the research.
- Students should acknowledge that queries will not begin until SRC approval has been granted.
- **Signatures must be obtained** from the primary SRC reviewer and NCNM’s EPIC site specialist before students can start their research. Once signatures are in place the EPIC site specialist will help students perform their EPIC queries.