Research Procedure: Identifying sensitive or appropriately excluded data from EMR

Documenting the details of research participation in the electronic medical record (EMR) generally benefits study participants and clinical research billing. Partners affiliates are expected to order clinical research encounters and associated services in the participant's EMR. In rare circumstances, investigators may wish to exclude, or are unable to process, study data within the participant's EMR. For example, documentation of study data in the EMR may be unduly prejudicial to the participant, may have de-identified samples, or may inappropriately un-blind participants or investigators. Study teams wishing to exclude study data from the EMR must follow the process below.

EMR and sensitive or excluded requests for research

Study teams may request either (1) a "sensitive" study determination for all study data from the IRB or (2) exclusion of specified data from the EMR via Client Code for Research (CLR)

1. Requests for "sensitive" approval, for all study data to be processed by masking the title of the study within the EMR and keeping the protocol #, must be approved within the study's IRB application.[1] The Research Billing Review process will remain the same for "sensitive" studies.

2. If a request to exclude specified study data from an EMR is approved, the approval will provide a CLR# to charge the procedures/samples requested to the PeopleSoft # and pay the service provider.

Regardless of whether an exclusion request is granted, the EMRs of all participants will maintain a "Research Active" flag, designating the patient as a research participant, and at least one encounter is linked to the protocol # on the study-related date of service.

CLR # request process

1. Study team will complete the Request for Excluding Research Data within EMR form
2. Study team submits to Institution specific Research Billing Compliance contact for review within three business days
3. If deemed appropriate submission, study team will send form to service providing department
4. Service providing department sends to Partners Research Controller for approval within three business days, and submits final form to PeC via ServiceNow ticket for CLR # creation within two business days

Post CLR # approval process

1. Study team's use of CLR#:
    a. Add billing flag at the encounter level in the registration screen, which is the same as the standard research process, but does not check a box, instead selects from a drop down and searchers for CLR # to select
    b. Guarantor Type is Research, charges go directly to the study account via Epic into Insight
2. Institutions run PeC created report for tracking CLR #s generated
3. Institution confirms with study team that CLR can be closed at end of the quarter where the end date falls, study team submits ServiceNow ticket to PeC for CLR closure

[1] https://rc.partners.org/support-training/faq-library/partners-ecare-research-faqs/visibility#StudyInMedicalRecord