CHAPTER 8: EMR: Scheduling, Registration, Linking and Billing

8.1 Open DaFIS Account

Once the IRB approval is received and the Clinical Trials Contract is executed by both UC Davis and the sponsor, the HS Contracts office notifies Extramural Accounting to set up the extramural account. Following that, a finance manager of the Department can open a DaFIS account. A DaFIS account is like a bank account that covers bulk account transactions and salaries for clinical research personnel.

8.2 Enter the information into the Bridge (CTSC SOP#13)

The Bridge (https://ctscassist.ucdmc.ucdavis.edu/redcap) is a database that houses the information needed to create a research study record in the EMR. The Bridge links IRB approvals with EMR study files. A Kerberos ID/ password is required to access the Bridge data. A representative from a department is responsible to enter study information into the Bridge.

Per P&P 2317, all research studies (expedited and fully reviewed) that meet one of the following criteria must be documented in the Bridge and Epic and the study participants (subjects and controls) must also be associated in EPIC:

- All Studies that utilize a drug or device;
- All studies that involve any charge or billing component (including billing to a third party payor insurance, study sponsor, or patient);
- All studies that include, as part of their protocol, any clinical intervention, including the invasion of any participant (control or subject’s) body cavity (e.g., blood draw) when such an invasion takes place within a UC Davis Medical Center licensed facility.

Upon review and approval of the UCDHS Compliance Office, some exceptions may apply.
CTSC SOP#13 outlines the steps necessary to complete the Bridge information. Once this information is complete, the study is transferred into the EMR.

1. Send request and sign the User Agreement for the Bridge: [https://ctscassist.ucdmc.ucdavis.edu/redcap/surveys/?s=INFGig](https://ctscassist.ucdmc.ucdavis.edu/redcap/surveys/?s=INFGig)


Follow the procedures outlined in CTSC SOP#13 to annotate the required information in the Bridge. Information required for completing a record:

- PI Provider ID (drop down list)
- Coordinator Name
- Coordinator PPSID (Employee #)
- Department (drop down list)
- Study Short name
- NCT# (ClinicalTrials.gov), mandatory requirement for billing
- Does the study have patient care services billed in UC Davis Health System?
- Coverage Analysis questions (many)
- Determination if this is a qualifying clinical trial
- Physician/coordinator attestation
- Upload Billing Grid (if any)
- DaFIS Number, Valid (start) dates and Valid (finish) dates

The updated information will be displayed in the EMR 24-48 hours after the upload.

### 8.3 Research Study Maintenance

Study Subjects (including controls), and their Encounters and Orders must be associated with the Research Study in Epic /EMR. Such association achieves the following:

- Creates a Bill Hold to separate billing streams to Study Accounts and Insurance Accounts
- Identifies all research study subjects (controls included)
- Tracks study procedures and services for Health Information Management Disclosures
- Creates notification for billers to issue correct claims

The basic information about the study is transferred from the Bridge to the EMR. Once the study is in EMR it needs to be further annotated.

### 8.3.1 Research Study Maintenance

Research Coordinators are typically assigned a particular EMR template (RC 110) to access EMR research functionalities.
All research functionalities can be accessed via the Research Home Dashboard (Screenshot below):

"Research Study Maintenance" hyperlink on the Research Dashboard will lead to the research study file in the EMR. Several tabs have to be annotated to complete the study in EMR:

1. **Study information and description** The short study name, IRB approval #, study code, and a full description of the Study name appears in this section.

2. **Users and Providers** tab is used to update or add Principal Investigator and Coordinator’s information.

3. **Billing Setup.** For all studies, independent of the payor type, click “Create Records Necessary for Billing.” This generates a “dummy patient record” and initiates tracking of research-related charges.

Clinical research staff who does not have access to the dashboard, should use Epic menu: Patient Care – **Research Study Maintenance**. Save Research Study Maintenance as Favorites (using Epic button).
8.3.2 Generate records necessary for billing

Starting July 2014, the Bridge supplants the paper-based “Bulk Account Application Form” for most studies. A *Dummy Patient Record* (an equivalent of the Bulk Account, now called “Research Account”) is generated by using EMR functions. To create a Dummy Patient Record, the tab “Billing Setup” in the Research Study Record must be completed. For all studies, independent of the payor type, the study coordinator must click on “Create Records Necessary for Billing.” This generates “dummy patient record” and initiates tracking of research-related charges.

A “dummy patient record” must be generated in EMR for each study whether or not billing to a research study is actually required.

The paper Research Account Application Form may still be used for studies conducted on the UC Davis campus. For policy on establishing a Research Account via the paper process, see the Hospital Policy and Procedure # 1815 [http://intranet.ucdmc.ucdavis.edu/policies/hospital_policies_and_procedures/financial_management/1815.shtml](http://intranet.ucdmc.ucdavis.edu/policies/hospital_policies_and_procedures/financial_management/1815.shtml)

**CTSC SOP#13** provides steps for completing the Billing Setup in the EMR for research studies.

8.4 Associate the Patient with the Research Study

A study subject must be associated with the Research Study in Epic EMR. This is done after the study subject signs the Informed Consent. The initial signed Consent Form and all Consent revisions (if a patient was re-consented), must be uploaded into the EMR for each patient enrolled in the study. Health Information Management is responsible for the consent upload. The signed Consent paper copies may be sent to HIM by interoffice mail or can be scanned directly into the OnBase document handling system by the research team.

Within the Research Studies activity, the study team is responsible for continuous update of the “Status” field.

Status choices include:

- **Enrolled**: Study registration completed
- **Active on Treatment**: Treatment initiated
- **Follow up**: No longer on active treatment, but will continue to monitor
- **Off Study**: Follow-up completed; Adverse event, or compliance lost to follow-up
- **Prescreening**: Patient signed consent and is aware they are being considered for trial participation
- **Screening**: Patient is active on study while being screened.
- **Screen Failed**: Patient did not meet eligibility criteria

If “Enrolled,” “Active on Treatment” or “Follow-up” are selected, then the Patient Header will display “Research: Active” (this will alert other EMR users that the patient may have research related activities).

Follow **CTSC SOP#13** and the EMR Quick Start Guide for details
8.5 Associate Encounters to the Study

Associating Encounters to the Study results in a bill hold, which means that all charges related to the encounter are being held for coordinators review. It is possible to link past and future encounters.

Scheduled office visits can be linked to a research study by the front office staff while scheduling/checking in a patient or by the CRC via the Research Studies activity.

Follow CTSC SOP#1.3 and refer to the EMR Quick Start Guide for instructions on linking encounters.

8.6 Associate Orders to the Study

Associating Orders to the study creates a visual cue ("Beaker") that appears next to the associated order. The orders still need to be associated to the primary diagnosis and the V70.7 or Z00.6 diagnosis code ("Examination of clinical research participant").

Follow CTSC SOP#1.3 and refer to the EMR Quick Start Guide for instructions.

Pathology services (laboratory):

1. If the study is in EMR, but the results of a particular laboratory testing are not recorded in the EMR, complete the Research Checklist as well as Secured Fax and/or Secured Print Forms as well as and FAX to the Client Services. Next, the Requisition Form specific for the study will be created by the Pathology Client Services. It needs to be filled out for every sample. Requisition MUST accompany the sample to the laboratory. A "dummy patient account" generated in the Research Study Record should be added to the Requisition Form.

2. If the study is entirely bypassing the EMR (i.e., studies from the Davis Main Campus), obtain the Research Account number from Patient Financial Services, and complete Research Checklist, Secured Fax/Secured Print forms to obtain the Requisition Form.

The Pathology Forms can be found on Clinical Trials website – Tools for Study Management http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html

8.7 Billing Review

“Research Billing Review” Reports are used to verify that technical and professional charges for research patients are being routed to the correct account. The coordinator selects a patient from the report and clicks “Billing Review” to review the charges. If a charge was incorrectly assigned to insurance or the study, this can be corrected using the “Research Correction” option. In addition, Restrictions in this report could be changed to show previously completed charges.

A Department/Division/Center may find it practical to have only one or two individuals designated to review the Billing Reports for the entire study (all patients). In this case, these Billing Review individuals should be added to the Research Study Record under “Users and Providers” tab as “Study Coordinators.” Only names added into the “Study Coordinators” box will enable designated individuals to access the “Patients needing Billing Research Review at the Study Level.” Coordinators added at the patient level are able to see the “Patients needing Billing Research Review at the Patient Level” only.
Only one review is required. If a patient is reviewed at the Study Level, there is no need to review the same charges at the patient level.

To find this report, click “Epic” button and follow down to “Reports.” Then find “My Reports.” In the Report Library search by using “Billing Review” as the keyword. Add the appropriate reports to the Report space for easy access!

If the “Patients needing Billing Review” Report takes a long time to run, save time by running the report and saving it afterwards. The next time the saved report is opened, any new charges for the patients already captured by the report will be automatically added. The saved reports open almost instantaneously. Keep the same report for days or months and open it periodically to check for new charges.

If enrollment continues, the new patients will NOT be on the previously saved reports. Also, at any given time the report captures only those patients that have active billings.

To Save the report, select “Options” tab and choose “SAVE RESULTS” (not “Save View”). Name the file and choose an Expiration date for the report. Work the saved report as usual.

Once the reports reached the expiration date, the choice is to keep it longer or rerun the report. The old saved reports can be deleted by right-clicking on the report and selecting “Delete.”

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**Important:** The 4 calendar day window for charge review is the billing system’s default. This includes holidays and weekends. The study staff has 4 days from the time of discharge to provide the review of both Inpatient Charges and Outpatient Charges. After the 4-day window closes, the charges are reported to the Department Managers as outstanding.

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Follow [CTSC SOP#13](#) and the EMR Quick Start Guide for details.

### 8.8 EMR Research Functionality Training Materials


**Additional materials:**

- Policy 2382 “Research Subjects Patient Registration, Healthcare Information Collection, Sharing and Maintenance”
- Policy 2317 “Documentation of Research Studies And Participants In the Bridge And Electronic Medical Record Systems”
- CTSC SOP #13 “Create and Manage Research Studies in EMR/Epic”