

RESEARCH BILLING REFERENCE FOR RESEARCH STUDY STAFF

Frequently Asked Questions

about USC Research Billing Policies

Why is all this necessary?

Research-related items and services must be accurately and comprehensively tracked to avoid billing insurance or government payers for items and services that have been paid for by the research sponsor, have been promised free in the informed consent, or are only for collecting research data. Additionally, research-related items and services that can be billed to insurance must be submitted in accordance with a complex set of coding guidelines. Inappropriate billing for research-related items and services can trigger fines, penalties, and sanctions under Medicare fraud and abuse statutes.

What is TRUE?

TRUE is a website and a database that contains protocol and study participant information for all clinical trials that are open on the Health Science Campus of USC. TRUE is maintained by the USC Clinical Research Organization (CRO). TRUE can be accessed at <https://uscnorris.com/CRO/>. To request a TRUE account and TRUE training please contact CRO at (323)223-4091.

What do I do when I have a new study participant?

You should fax the signed consent and HIPAA documents to CRO at (323)987-2139. This must be done within 24 hours of when the consent was signed. These documents will be uploaded in TRUE. The study participant will be registered in TRUE and you will be able to see the participant listed on the TRUE page for that study. Please check TRUE on a regular basis to make sure that all of your participants are listed and that all participants who are off study have an off-study date.

What if I discover that I didn't send the consent and HIPAA to CRO within 24 hours?

Contact the TRUE Database Manager at CRO at (323)223-4091 for specific instructions. You will be asked to explain the reason for the delay and help us correct any bills that may have been released.

What do I do when a patient fails screening, is withdrawn from the study, or has completed the study?

Please send an email to TRUE (CROTRUE@med.usc.edu). Include the participant's medical record number, the study IRB number or CIC number, and the off-study date.

What happens after the participant is registered in TRUE?

The study participants' bills will be placed on hold. A secure email is sent out to notify the billing teams for the hospitals and the physicians that a new participant has been enrolled in a study.

What is a Coverage Analysis (also referred to as a Medicare Coverage Analysis or MCA)?

The analysis consists of determining the Medicare eligibility of the study based upon Medicare guidelines and a complete review of the protocol to determine which of the clinical "events" mentioned within the protocol can be reimbursed by Medicare or other third party payers. The payer designations on the ROF are taken from the MCA.

What is a Research Order form (ROF)?

The ROF is a study-specific order form. When completed and used correctly, the ROF serves as a clinical order and also defines which services are provided as part of a research study, for a particular study participant, on a particular date of service. Billers and bill auditors will access the completed ROFs in the medical record. They will use the completed ROFs in order to bill the charges to the appropriate payer.

When should I use ROFs?

ROFs should be used for all study services at Keck Hospital, Norris Hospital, the Outpatient Clinics and Labs. ROFs should be used from the time that the consent is signed, through the very end of the patient's follow-up.

What services should be checked off on the ROF?

All services that are on the study calendar, that are being provided to the participant, should be checked-off on the ROF. This includes all screening and follow-up visits and services that are designated by the protocol.

What if the services are standard of care?

If a service is listed on the study calendar - even if it is standard of care - a research order form must be used to order the service. The ROF defines which service will be billed to the study account and which services will be billed to the participant's insurance.

The Medicare regulations on clinical trials serve as our guide for billing all payers. Medicare requires that we use special codes to identify conventional care that is provided as part of a trial. We are all responsible for compliance with these regulations.

The participant is only being seen annually for follow-up study visits that they would have even if they weren't on the study. Do I need to complete an ROF?

Yes. All services on the study calendar, included follow-up, must be ordered on an ROF.

What if study services are provided for an inpatient?

ROFs are approved for use as order forms at Keck and Norris Hospital. One ROF should be used for each date of service. ROFs can be brought to admitting at the time of admission. They can also be completed on the unit or brought to the unit. The ROFs should then be filed into the medical record along with all other written orders.

Can I fill out an ROF as a verbal order or telephone order?

No.

Where do I find a blank ROF for my study?

Blank, study-specific ROFs are posted on the TRUE Website. They are sometimes modified, so please obtain ROFs from TRUE, and do not keep copies of blank ROFs.

Does a physician have to sign the ROF?

The ROF is a clinical order form, and must be signed by a practitioner (physician, NP, or PA) who would normally sign orders for that patient.

Does the diagnosis need to be written on the ROF?

Yes. Since the ROF is a clinical order form, the diagnosis must be written onto the form. If the participant is a healthy volunteer, write "healthy volunteer" on the form.

What should I enter in Visit#/Cycle & Day?

Please mark your entries to coincide with the columns on the study calendar as much as possible.

Can I use patient labels on the ROF?

Yes, but you may only use the thin label with the name of the patient, date of birth and medical record number.

What do I do with the ROF after it has been filled out and signed?

The ROF should be turned in to the department or entity that will be scheduling or performing the service. The ROFs should be filed into the participant's medical record as soon as possible after the service. If you find that you have the original ROF, please take it or send it to Medical Records for inclusion in KeckCare/Cerner.

What if a participant started off at County, but now needs to come to Keck or Norris Hospital?

Check with admitting to see whether the patient can have the service at Keck or Norris. If they can, you must ensure that the Keck Medical Center Medical Record Number is sent to TRUE.

What do I do if a participant contacts me about a bill they received?

If the bill is from the Norris or Keck Hospitals, contact the Office of Research and Investigator Support at 323-865-3573. . If the bill is from USC Care Medical Group for physician services, call 626-457-4096

Who can I contact for questions?

For questions about TRUE contact CRO at (323)223-4091.

For questions about hospital research billing policies, contact the Office of Research and Investigator Support at 323-865-3573.