
SOP Number ADM-011-01
SOP Name Epic Research SOP
Effective Date 01/AUG/2012

1.0 SCOPE

1.1 All research participants who are being seen solely for a research visit or who are simultaneously receiving medical treatment and enrolled in a research protocol must be registered in the Epic system for all visits involving a billable procedure, service, technical/facility fee, or a drug/device.

2.0 PURPOSE

2.1 A uniform and consistent process will be adhered to when a research participant receives services at UC Health.

2.2 All research procedures and services as outlined by the research protocol must be charged to the appropriate research study account according to regulations and contract terms.

3.0 DEFINITIONS

3.1 **Outpatient Research Participant:** For the purpose of this procedure, an outpatient research participant is defined as any participant enrolled in a research study that is physically seen and has a research visit, test or procedure performed on any UC Health or University of Cincinnati Physicians Company (UCPC) property.

3.2 **Inpatient Research Participant:** For the purpose of this procedure, an inpatient research participant is defined as a UC Health clinical inpatient simultaneously enrolled in a research study and undergoing a research study related procedures or a subject admitted solely for research purposes.

4.0 PROCEDURES

4.1 The PI (Principal Investigator) and/or designee responsible for study conduct will obtain all required approvals prior to enrolling participants into a research study

4.1.1 Funding source finalized/approved

4.1.2 IRB approval obtained

4.1.3 UC Health approval obtained

4.2 Standard naming convention for entering all studies in Epic

4.2.1 PI last name

4.2.2 Research Study name

4.2.3 IRB number

4.2.4 Location of Research Study

- 4.2.4.1 The University Hospital (TUH), The Drake Center (TDC), West Chester (WC), Ambulatory Surgical Hospital (UPSH), or University of Cincinnati Physician Company (UCPC). If multiple locations are involved, a research study ID will be generated for each location.
- 4.3 Account set up by UC Health (e.g. UC Health Research Compliance in coordination with Epic IT support) in Epic
 - 4.3.1 Account will be set up using minimally required fields to identify and bill the research study. The PI and/or designee responsible for study conduct may enter additional information if it is needed.
- 4.4 Case type in IDX set up by UCPC with department as the guarantor for professional fees
- 4.5 Participant enrolled (informed consent signed)
- 4.6 The PI and/or designee responsible for study conduct associates participant with the research study in Epic
 - 4.6.1 This is done at the patient level not the encounter level
- 4.7 The PI and/or designee responsible for study conduct associates the participant's encounter with the research study on the day the billable services occur
 - 4.7.1 If association of an encounter occurs after the day of service/close of encounter, the PI and/or designee responsible for study conduct must manually notify the appropriate individuals to correct the error:
 - 4.7.1.1 UC Health Research Compliance - research-finance@uchealth.com, fax: 513-584-4639
 - 4.7.1.2 UCPC - clinicaltrialbilling@ucphysicians.com
- 4.8 The PI and/or designee responsible for study conduct is responsible for clearly identifying the procedures that are part of the research study versus those deemed standard of care. Procedures that are part of the research study should be listed on the research encounter form.

Under no circumstances should research procedures be billed to a clinical account or clinical procedures billed to a research account.

 - 4.8.1 Orders are entered in Epic
 - 4.8.1.1 The diagnosis of V70.7 is associated for research only visits
- 4.9 The Research Encounter Form is sent to the appropriate location when research visits/procedures occur. E-mail notification can be sent to UC Health Research Compliance and UCPC:
 - 4.9.1 UC Health Research Compliance - research-finance@uchealth.com, fax: 513-584-4639

-
- 4.9.2 UCPC - clinicaltrialbilling@ucphysicians.com
 - 4.10 Professional Fees
 - 4.10.1 The PI and/or designee responsible for study conduct will verify charges for professional Fees for UCPC
 - 4.10.2 The PI and/or designee responsible for study conduct will submit a check request (with HCFA as backup documentation) to UCPC General Accounting
 - 4.10.3 General Accounting will transfer funds (expense to research account, clinical revenue)
 - 4.11 Technical Fees
 - 4.11.1 UC Health Research Compliance will verify charges for technical fees for UC Health
 - 4.11.2 UC Health Research Compliance will reconcile the Research Encounter Form with the Research Billing Worksheet
 - 4.11.3 Research procedures are billed to the research account
 - 4.12 The PI and/or designee responsible for study conduct will notify the UC Health Research Compliance and UCPC via email when the research study and/or participant is inactive or complete:
 - 4.12.1 UC Health Research Compliance - research-finance@uchealth.com, fax: 513-584-4639
 - 4.12.2 UCPC - clinicaltrialbilling@ucphysicians.com

5.0 LIST OF ATTACHED FORMS

5.1 ADM-011-01 A1 Epic Research Forms

- 5.1.1 Research Billing Worksheet
- 5.1.2 Clinical Research Study Cost Estimate – UC Health Hospital Services
- 5.1.3 Clinical Research Study Cost Estimate – UCPC
- 5.1.4 Research Encounter Form

6.0 REFERENCES

- 6.1 None

7.0 APPROVAL

Signature on file
VP of UC HEALTH RESEARCH OR DESIGNEE

12/JUL/2012
DATE