	Regulatory Compliance Job Aid	No.	COMP-RCC 4.47
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	JOB AID - OUTPATIENT SERVICES PROVIDED BY RESEARCH SERVICES AGREEMENTS	Effective Date:	08-18-17
		Retires Job Aid Dated:	03-21-13
		Previous Versions Dated:	

I. SCOPE:

This Job Aid applies to clinical studies requiring only outpatient services according to a written agreement between single payer (usually the study sponsor, a research organization, or a Principal Investigator) and a Tenet Entity refers collectively to Tenet Facilities and Tenet Practices). In each agreement, the payer agrees to pay for all the services ordered. The Tenet Entity agrees to not submit a bill for any services to the patient or patient's health insurance. On the billing side, such arrangements are commonly referred to as "client bill" accounts.

II. PURPOSE:

The purpose of this Job Aid is to explain the requirements for different types of outpatient services provided according to the terms of research services agreements. Some requirements will differ based on the Tenet Entity's level of involvement in the research.

III. PROCEDURE:

Refer to COMP-RCC 4.47, Attachment B, Factors to Determine if a Tenet Entity is Conducting Research and determine if the proposed outpatient services fall into the category "Conducting Research" or "Incidental to Research."

A. Services Considered "Conducting Research"

1. The Tenet Entity's FRC must review and approve the study, although the FRC does not need to obtain a full clinical protocol for each study.

2. The Tenet Entity and the payer must have a written agreement, approved according to the Law Department policy Electronic Contract Approval Term Sheet (eCATS) and fully executed before the first services are provided.[1] The eCATS package created should contain an executive memo, completed encounter ticket template, and the agreement.

3. An Institutional Review Board (IRB) must review and approve the study. If the IRB reviewing the study also is the Tenet Entity's primary IRB (the IRB the Tenet Entity uses the greatest percentage of time), that IRB must be designated on the Tenet Entity's Federalwide Assurance. There must be a written agreement between the Tenet Entity and the IRB for the review of this study.

[1] A template agreement is available on the CAM under the designation "Letter Agreement Research-Only Service 1.0A

4. The Tenet Entity's research staff or DRA shall follow the process for creating research accounts, entering the study information into the PBAR, NextGen, or RisLinq research maintenance table or if your Entity does not have these billing applications, then Entity should enter into its software application to create client accounts, along with the date the study opened (found on the IRB approval letter). Patient Access shall be provided with the designated research ID and the payer's name and address to enable Patient Access to create the client account. (See also Conifer "Clinical Research" Policy- 02.01.20A/"Clinical Research Procedure" 02.01.20C and Tenet "Billing Within Research Accounts" Policy CR2.04).

5. The Tenet Entity's Research Staff shall complete a template Research Encounter Ticket Involving Studies under Category of Conducting Research (Research Encounter Ticket- Conducting Research) and distribute copies of the completed template to the study doctor(s) before the Tenet Entity provides services under the agreement. The Research Staff shall request the study doctor to complete the bottom portion of the form when ordering services covered by the services agreement. The form shall be faxed to the Tenet Entity prior to the patient arriving or the patient may be given the form to bring to the Tenet Entity when the services are to be performed.

6. During the registration process, Patient Access staff will create a patient account when the patient arrives and will ask each patient if he/she is a clinical research patient. If yes**,** the services/charges from the patient account will then be moved to the client account specifically created for the study.

7. When patients respond affirmatively, the staff will place the patients' accounts on bill hold.

8. The Tenet Entity must either obtain a copy of the patient's signed research informed consent at the time of registration or have a process in place to obtain the consent when needed. Accreditation standards such as The Joint Commission's standard RI.01.03.05 require facilities to keep a copy of the research consent on the medical record. The Joint Commission will accept a process that produces the research consents in a timely fashion, e.g., within the day of the audit request. Tenet Entities wishing to develop this process in lieu of obtaining consent forms must complete a survey to demonstrate their ability to obtain research consent upon an auditor's request. See Sampling Criteria for Auditing Performance, located on the Clinical Research SharePoint website.

9. Provide the research services and bill the services according to established processes.

B. Services Considered "Incidental to Research"

1. The Tenet Entity's FRC does not need to review studies for services considered "incidental to research."

2. The Entity does not need to obtain a full clinical protocol for each study.

3. The Tenet Entity and the payer must have a written agreement, approved according to the Law Department policy Electronic Contract Approval Term Sheet (eCATS) and fully executed before the first services are provided.[2] The eCATS package created for an "Incidental to Research" study should contain an executive memo, completed encounter ticket template, and the agreement.

4. The Tenet Entity's research coordinator or DRA shall follow the process for creating research accounts, entering the study information into the PBAR research maintenance table or if your entity does not have these billing applications, then Entity should enter into its software application to create client account, along with the date the study opened (found on the IRB approval letter) and providing Patient Access with the designated research ID and the payer's name and address to enable Patient Access to create the client account. See also Conifer "Clinical Research" Policy-02.01.20A/ "Clinical Research Procedure" 02.01.20C and Tenet "Billing Within Research Accounts" Policy CR2.04).

5. The Tenet Entity's Research Staff shall complete a template Research Encounter Ticket Involving Studies under Category of Conducting Research (Research Encounter Ticket-Incidental to Research) and distribute copies of the completed template to the study doctor(s) before the Tenet Entity provides services under the agreement. The Research Staff shall request the study doctor to complete the bottom portion of the form when ordering services covered by the services agreement. The form shall be faxed to the Tenet Entity prior to the patient arriving or the patient may be given the form to bring to the Tenet Entity when the services are to be performed.

[2] A template agreement is available on the CAM under the designation "Letter Agreement Research-Only Service 1.0A

6. During the registration process, Patient Access staff will create a patient account when the patient arrives and will ask each patient if he/she is a clinical research patient. If yes, the services/charges from the patient account will then be moved to the client account specifically created for the study.

7. The Tenet Entity does not need to obtain the patient's signed research informed consent.

IV. REFERENCES:

COMP-RCC 4.47 Clinical Research Compliance Requirements – dated 3-10-16

V. ATTACHMENTS:

Research Encounter Ticket – Study Falls Under Category of Conducting Research
Research Encounter Ticket – Study Falls Under Category of Incidental to Research

RESEARCH ENCOUNTER TICKET FOR PATIENTS RECEIVING OUTPATIENT SERVICES PAID FOR BY SPONSOR -NO INSURER BILLING COMPONENT INVOLVED
***STUDY FALLS UNDER CATEGORY OF "CONDUCTING RESEARCH"**

ENTITY NAME _____

Directions: Entity Research Staff - Before the study starts enrollment, create a template for the study by filling out all blocks in the first three sections (Abbreviated Study Title through 8 digit Registry Number) and list at the bottom on the numbered lines all the services that will be provided based on the contract agreement for this study. Give copies of the completed study template to study doctor's office. The Principal or Sub-Investigator will be required to complete the remainder of this encounter ticket inclusive of circling the services that will be performed when their patient needs to have a specific procedure(s) conducted as part of a study in which the sponsor or PI is providing payment for all services done at this Entity for this study.
Directions: Principal Investigator or Sub-Investigator- Please fill out all items from the Patient Name thru to Study Doctor Signature/Date (Bold Print). Either have the patient bring this form to the Tenet Entity and give to the patient access representative when arriving for services or fax the document to # _____ prior to the patient arriving for services.

Abbreviated Study Title	
Date of Approval by the Entity Facility Review Committee (FRC)	
Tenet Entity Study Research ID #	

TYPE OF STUDY	
DRUG NAME	
DEVICE NAME	

IRB name and IRB study approval date	
Clinical Trial Agreement approved in eCATS- eCATS # and date of approval	
Consent Cost Section language verifies all services paid by Sponsor- Entity Research Staff –Verify by initialing box	
PI name/ PI email address	
PI phone #	
Study Staff name	
Study Staff Phone #/ S.C. email address	
8 digit Clinical Registry Number	

SPONSOR INFORMATION	
Sponsor Name	
Device Study-IDE #	
Drug Study- IND #	
FDA approved; Yes or No	
Patient Billing Account #	

Patient Name	
Patient Birthdate	
MRN #	

Circle name of test and corresponding CPT code for each requested test to be conducted on _____(date) at Tenet Entity.

1) _____

2) _____

3) _____

_____ _____ _____

Study Doctor- Print Name **Study Doctor – Signature** **Date**

- See COMP-RCC 4.47 Job Aid - Process for Determining if Facility is Conducting Research
- Version # 3 Dated 3-10-2016

RESEARCH ENCOUNTER TICKET FOR PATIENTS RECEIVING OUTPATIENT SERVICES PAID FOR BY SPONSOR -NO INSURER BILLING COMPONENT IS INVOLVED AND *STUDY QUALIFIES IN THE CATEGORY OF "INCIDENTAL TO RESEARCH"

ENTITY NAME _____

Directions: Entity Research Staff - Before the study starts enrollment, create a template for the study by filling out all blocks in the first three sections (Abbreviated Study Title through 8 digit Registry Number) and list at the bottom on the numbered lines all the services that will be provided based on the contract agreement for this study. Give copies of the completed study template to study doctor's office. The Principal or Sub-Investigator will be required to complete the remainder of this encounter ticket inclusive of circling the services that will be performed when their patient needs to have a specific procedure(s) conducted as part of a study in which the sponsor or PI is providing payment for all services done at this Entity for this study.

Directions: Principal Investigator or Sub-Investigator- Please fill out all items from the Patient Name thru to Study Doctor Signature/Date (Bold Print). Either have the patient bring this form to the Tenet Entity and give to the patient access representative when arriving for services or fax the document to # _____prior to the patient arriving for services.

Abbreviated Study Title
Tenet Entity Research Study ID Number

IRB name and IRB study approval date	
Clinical Trial Agreement approved in eCATS-eCATS contract # and date approved.	
PI name	
PI phone #/ PI email address	
8 digit Clinical Registry Number	

Patient Name	
Patient Birth Date	
Hospital or Study Doctor MRN #	

CIRCLE THE SPECIFIED SERVICES/PROCEDURES and associated CPT codes for each service to be conducted on _____(date) at Tenet Entity.

1) _____

2) _____

3) _____

_____ _____ _____

Study Doctor- Print Name **Study Doctor – Signature** **Date**

- See COMP-RCC 4.47 Job Aid - Process for Determining if Facility is Conducting Research
- Version # 3 dated 3-10-16