

## El Paso - Ambulatory Clinic Policy and Procedure

Title: <b>SCHEDULING OF APPOINTMENTS FOR SUBJECTS PARTICIPATING IN RESEARCH TRIALS</b>	Policy Number: <b>EP 1.18</b>
Regulation Reference:	Effective Date: <b>07/2014</b>

### Policy Statement:

Every patient encounter, including those involving research activities, shall be scheduled through the Texas Tech University Health Science Center El Paso Practice Management System (GE Centricity Business – GECB).

### Scope and Distribution:

This policy applies to fee for service contracts, industry sponsored or investigator initiated clinical trials. It does not apply to federal or state funded grants.

### Procedure:

1. All locally obtained labs and studies shall be ordered through the electronic medical record (EMR) and available to any provider treating the patient through use of the EMR.
2. Neither third party payers nor patients shall be billed for any service or test required solely by an individual's participation in a research trial.
3. Patient care which is standard of care and not related to a subject's participation in a research trial shall be billed to the patient and/or third party payor using existing billing policies.
4. Description of Research appointment type and implications- An appointment type named "Research" will be set up for departments and providers upon request. A user chooses the research visit type when scheduling a visit under the research program. When using the research visit type, under the "Search" option, the user will select "detail". This selection allows the user to override an existing appointment visit type with the research visit type. Upon saving the selected appointment slot, the user will receive an overbooking message. The user must accept overbooking in order to reserve the research visit.
5. Appointments involving research related activities in whole or in part shall be scheduled using the Research appointment type. Appointments which are not anticipated to involve research related activities may be scheduled using routine appointment types.
6. The Principal Investigator (PI) or designee is responsible for scheduling visits involving investigators on the protocol and for determining which appointment type to use.
7. Patients seen in a research appointment type must receive and have documented in EMR the information to support Meaningful Use requirements including the following information:
  - a. Vital signs
  - b. BMI
  - c. Allergies review
  - d. Medication review
  - e. Smoking status

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If a research visit type is used, and the visit involves ONLY research related activities, the PI shall state “research visit only”. No other provider documentation is required in the EMR. Investigators are responsible for completing and maintaining source documents and case reports forms as required by the study sponsor. These documents are not filed in the EMR.

If the visit involves research and non-research related activities, the documentation shall support the appropriate billing of non-research related activities.

Participants in research trials seen for situations unrelated to their participation in the research trial shall have medical record documentation performed pursuant to existing policies and procedures.

8. Description of research visit type functionality and billing workflow: Billing for “research” visits should be billed with FSC 412 (Research Case). This FSC is a non-statement producing FSC, meaning any charge listed under this FSC will not be included in any patient statement billings. Charges entered with this FSC will adjust at 100% with pay code 743 (Research Case Write-Off).

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Signatory approval on file by: Michael J. Romano, M.D. Associate Dean of Clinical Affairs Clinic Operations Committee, Chair Texas Tech University Health Sciences Center at El Paso	