I. SCOPE:

This policy applies to (1) Tenet Healthcare Corporation and its wholly-owned subsidiaries and affiliates (each, an “Affiliate”); (2) any other entity or organization in which an Affiliate owns a direct or indirect equity interest greater than 50%; and (3) any hospital or healthcare facility in which an Affiliate either manages or controls the day-to-day operations of the facility (each, a “Tenet Facility”) (collectively, “Tenet”).

II. PURPOSE:

The purposes of this policy are to establish the requirements for Tenet Facilities desiring to participate in, or provide services for, research studies, including the Facility Research Committee (FRC), and to establish the Clinical Research Review Committee (CRRC).

III. POLICY:

All research involving human subjects occurring within Tenet must be approved consistent with applicable federal and state laws that govern research involving human subjects. All such research must be reviewed and approved by at least one Institutional Review Board (IRB).

IV. PROCEDURE:

A. Corporate Implementation

1. Clinical Research Review Committee

Tenet shall maintain a CRRC to serve as a resource for Tenet facilities and shall propose policies with respect to direction of research for Tenet. The CRRC will have oversight of all research performed at Tenet Facilities, including ambulatory facilities and Tenet-owned or operated physician practices.

   a. Membership, Quorum and Meeting Frequency of the CRRC

      The CRRC shall be a multidisciplinary committee with members drawn from various corporate departments. The CRRC must have a quorum of a majority of its members present to conduct business. Members may participate by telephone. The CRRC shall meet on a quarterly basis.

   b. Study Oversight

      The CRRC has the authority to end a study prior to completion or inhibit the study from starting by notifying the Tenet Facility’s CEO, Compliance Officer, and Clinical Research Coordinator of
the suspension or termination without regard to any previously granted approval. The Tenet Facility CEO shall notify the Tenet Facility’s IRB, MEC, any governmental entities to which the Tenet Facility is required by law to provide notification, and any person who is required to receive notice from the Tenet Facility pursuant to the terms of any contract related to the study.

c. Model Policies

The CRRC shall propose to the Tenet Management Quality, Compliance and Ethics Committee policies which with respect to clinical research activities at Tenet Facilities the CRRC believes are necessary to promote a clinical care environment and a culture of patient and employee safety consistent with the most current ethical, clinical and compliance standards in the US healthcare industry.

d. Tenet Database

(1) The CRRC shall direct and assure a database is maintained which tracks all research studies conducted by a Tenet Facility and all research patients receiving medical intervention as part of these studies.

(2) The CRRC shall direct and assure a spreadsheet is maintained to capture all research registry studies conducted by a Tenet Facility, student/nursing research that do not involve a medical intervention and all humanitarian use device (HUD) protocols; this spreadsheet will not contain any data that is reflected in the Patient Data Reporting (PDR) database.

2. Approval of Clinical Research Agreements

a. The Home Office Director of Clinical Research, or his/her designee, must approve each arrangement with a clinical research management or coordination company through the eCATS approval process prior to execution of the agreement.

b. Each study, inclusive of all study related documents as outlined in Law Department Policy L-15 Electronic Contract Approval Term Sheet (eCATS) and the associated Frequently Asked Questions for clinical research arrangements, shall be placed in a separate eCATS package to enable a review of the study.
B. Facility Implementation

1. Institutional Review Boards

Each Tenet Facility must identify, and engage by written agreement, at least one Institutional Review Board (IRB) to review the clinical research studies to be conducted at the Facility. The Tenet Facility must have a written agreement in place with every IRB it uses regardless if the IRB is listed on its Federalwide Assurance (FWA) (except for those studies providing services “incidental to research”). For the IRB(s) the Tenet Facility designates on its FWA (see Subsection IV.B.2., below), the Tenet Facility must maintain copies of the IRB’s written procedures covering the services provided to the Tenet Facility. If a Tenet Facility has its own internal IRB, the internal IRB must be registered with the Office of Human Research Protections (OHRP) and listed on the Tenet Facility’s FWA. The Tenet Facility internal IRB must have policies and procedures in place to comply with OHRP/U.S. Food and Drug Administration (FDA) regulations.

2. Federalwide Assurance

Each Tenet Facility must submit and keep current a Federalwide Assurance (FWA) thru OHRP to designate the IRB currently reviewing the greatest number of research studies for the Tenet Facility. If at any time the ratio changes, the Tenet Facility must amend its FWA. The FWA application must be reviewed prior to expiration or any time there is a change to the prior FWA application. If the Tenet Facility declines to select an option in Section 4(b) of the FWA, the Tenet Facility shall advise potential study sponsors and/or investigators.

3. Facility Research Committee

Each Tenet Facility must establish an internal Facility Research Committee (FRC) to review all research policies and associated materials as well as each proposed research study.

a. Membership

The FRC shall be a multidisciplinary committee with representatives from areas involved in the research process, including, but not limited to, Patient Access, Finance, Pharmacy, Nursing, Imaging, Revenue Cycle and Medical Staff Services. At least one member of Facility’s A-Team shall serve as a voting member of the FRC. The Facility’s Risk Manager and Compliance Officer (CO) are ex-officio, non-voting members of the FRC. Facility’s CEO is responsible for
b. Quorum and Meeting Requirements

The FRC shall have an initial meeting when the committee is formed and then meet no less often than monthly. Meetings may be waived if there are no policies or associated materials or studies to review. The FRC must have a quorum of a majority of its voting members present to conduct each meeting. Members may participate by telephone. Without a quorum, FRC meetings must be postponed. The members of the FRC may consult each other regarding the review of a research study outside of FRC meetings.

c. Minutes

The FRC minutes shall reflect a brief description of the discussion of each study with greater details surrounding any studies that were denied. Minutes shall include the following information:

(1) Date of meeting

(2) Information on all policy reviews including name of policy and policy effective date

(3) Name of study

(4) Names of voting members present and absent to verify quorum

(5) Written summary involving discussion points

(6) Tally of votes indicating “for,” “against,” and/or “abstain”

d. Research Policies and Associated Materials

Each Tenet Facility must have research policies in place. The Tenet Facility’s FRC shall be responsible for reviewing all research-related policies and associated material, such as Policy Flashes and other communications, upon publication and ensuring the policies are adopted and/or implemented. Each Tenet Facility shall adopt the Model Facility Clinical Research Manual or shall review its existing policies and ensure that the existing policies meet the minimum standards of the Model Facility Clinical Research Manual. Any Tenet Facility’s changes to the Model Facility Research Manual...
require the prior written approval of the Home Office’s Director, Clinical Research and Director, Policies and Procedures Management before submission of the policy for final FRC approval.

e. Review of Proposed Studies

The FRC shall review each proposed study in order to determine whether individual research studies are appropriate for Tenet Facility. The FRC evaluates each study’s impact on the organization, including staffing, patient safety, supplies and reimbursement. The FRC also evaluates each study against the Facility’s mission, vision, and strategic plan. The FRC shall not base its decision on the volume or value of any actual or anticipated referral, or other business generated by the Principal Investigator but shall not be precluded from basing its decision on the operational or financial burdens which may be borne by the Facility by participation in any research study. Attachment A FRC Review Considerations includes examples of factors the FRC may wish to consider. The FRC must initially screen and then provide final approval of the study before study services may be performed by the Facility.

(1) Informed Consent Document Review

The IRB is responsible for approving the form and content of research study-related informed consent documents. However, the FRC must review the informed consent document to verify that the document accurately states the patient’s financial obligations. The informed consent must be written so that the verbiage in the cost section and the injury section is consistent with the cost analysis sheet and terms of the Clinical Trial Agreement. The informed consent is a tool that the FRC shall use to identify what services will be performed within the study and who will be providing payment for those services.

(2) Communication of Decisions

The FRC shall communicate its decisions in writing to the Tenet Facility CEO and the Principal Investigator. If the FRC does not approve a research study, then the FRC must include a reason to the Principal Investigator.
(3) Review Fees

The FRC shall conduct its work in the normal course of the Tenet Facility’s operations and shall not charge for reviewing a research study.

f. Relationship of Facility Research Committee to Institutional Review Board

FRC review does not replace IRB review. FRC approval of a study is contingent upon the study receiving the Tenet Facility’s IRB’s approval. Notwithstanding the foregoing, if the Facility provides only ancillary services which are incidental to the fundamental research objective, it is sufficient to confirm approval by the sponsor’s or Principal Investigator’s IRB and approval by the Tenet Facility’s FRC and its IRBs are not required. The factors to determine if the Tenet Facility’s services are considered conducting research or are incidental to research are described in Attachment B. (See also: Job Aid- Outpatient Services Provided by Research Services Agreements).

4. Cost Analysis

Tenet Facilities must complete a Cost Analysis document for every study that involves any medical intervention(s). At a minimum, a draft cost analysis document must be submitted to the FRC containing all the services to be provided by the Tenet Facility. The final cost analysis sheet needs to be uploaded into eCATS when the study contract package is submitted for review and approval. The Principal Investigator and Tenet Facility’s CFO must sign the Cost Analysis prior to execution of the eCATS package. Any Tenet Facility with PDR capability must have the CFO approve the cost analysis electronically within the PDR application, otherwise the approval by the CFO shall be done manually on the hard copy that is maintained in the regulatory binder for the study. The Principal Investigator for the study is required to manually sign the cost analysis sheet which also shall be maintained in eCATS.


Each patient account that includes a research study service/procedure, regardless if the service is Standard of Care within the study or only for research purposes, must be placed on bill hold until a manual review of the account is completed and any non-billable charges are identified on the patient account and moved to the sponsor or investigator’s account.
6. Facility Databases

Each Tenet Facility conducting research shall maintain the required PDR database of all research studies conducted at the facility, including relevant data on the patients enrolled in each study. Those Tenet Facilities not having PDR capability must maintain an alternate electronic database using the required template with the names of all studies and patients enrolled in each study and submit a copy of the updated database from the prior month to the Home Office Director, Clinical Research by the 5th day of each month. All Tenet Facilities shall track all studies that do not have a medical intervention, such as registry studies and HUD studies, and provide that spreadsheet within their yearly self-assessment audit uploads. All records required by this Subsection IV.B.6. must be available for audit purposes.

7. Registry Studies

Registry studies involving clinical interventions are subject to all the requirements of any other clinical research trial. These requirements include, but are not limited to, IRB review and approval, FRC review and approval, clinical research database entry, cost analysis, bill hold and facility use agreement. Registry studies that involve only the retrospective collection of data are of low risk to Tenet patients and facilities and therefore, do not require FRC review and do not need to be tracked in the clinical research database. All other relevant corporate policies still apply (policies on information privacy, referral source agreements, etc.) to data collection-only studies. Each data collection-only registry study requires a facility use agreement for the outside sponsor to use patient medical records to collect data. IRB approval is required for data collection only studies if the study data and/or findings will be published.

8. External Audits

In the event that any regulatory authority, any IRB or any research sponsor gives notice of an audit or investigation of research at a Tenet Facility, whether related to a specific study or related to the research program generally, the Tenet Facility shall notify its Research Coordinator. The Research Coordinator shall provide immediate notice to the Tenet Facility’s Compliance Officer and the Home Office Director, Clinical Research, including copies of any correspondence from the body conducting the review. The Home Office Director, Clinical Research may participate in any review at his/her discretion and shall be included in any exit conference. Upon completion of the review, the Tenet Facility shall
provide a copy of any findings to the Research Coordinator and the Home Office Director, Clinical Research. If any corrective action is required, the Tenet Facility shall prepare the corrective action plan and provide the same to the Home Office Director, Clinical Research for review and approval prior to submission.

The foregoing shall not apply to routine monitoring by study sponsors and their designees. Routine monitoring is limited to regular visits from sponsors to verify compliance with protocols and does not include reviews prompted by observed non-compliance with protocols or good research practice.

C. Responsible Person

The Research Coordinator is responsible for ensuring that all Tenet Facility individuals adhere to the requirements of this policy, that these procedures are implemented and followed, that instances of noncompliance with this policy are reported to the facility’s Compliance Officer.

D. Auditing and Monitoring

Audit Services will audit adherence to this policy as part of the Full Scope Audit process. Quality Management will audit adherence to this policy as part of the Self-Assessment process.

E. Enforcement

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, up to and including termination. Such performance management may also include modification of compensation, including any merit or discretionary compensation awards, as allowed by applicable law.

V. REFERENCES:

- Model Facility Clinical Research Manual
- Federal Policy for the Protection of Human Subjects, or Common Rule
- The Belmont Report
- Law Department policy L-15 Electronic Contract Approval Term Sheet (eCATS) and Frequently Asked Questions
### Regulatory Compliance Policy

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- Job Aid - Outpatient Services Provided by Research Services Agreements

**VI. ATTACHMENTS:**

Attachment A: FRC Review Considerations

Attachment B: Process for Determining if Facility is Conducting Research

Attachment C: Comparison Chart for Clinical Research