

FRC Checklist

Version Date 6/27/17

Meeting Date _____ Facility _____

When Does Study go into FRC:	After completion of draft cost and time sheet (pre e-cats submission and IRB approval)
Membership:	The FRC shall be a multidisciplinary committee with representatives from areas involved in the research process, with consideration of, but not limited to, Patient Access, Finance, Pharmacy, Nursing, Imaging, Revenue Cycle and Medical Staff Services. At least one member of Entity's A-Team shall serve as a voting member of the FRC. The Entity's Risk Manager and Compliance Officer (CO) are ex-officio, non-voting members of the FRC. The Tenet Entity shall maintain a written committee roster that includes which members are voting members.
	Voting members for the FRC should not include Personnel's that have any conflict with any trials being considered. For example, voting members cannot include study research coordinator, study nurse, research director, etc. The roster template for Tenet should be used to list all voting members and should be kept up to date as members change.
Quorum:	<p>Quorum is met using the equation $(1/2n) + 1$ (n equals the total voting members); total voting members divided by half then adding one.</p> <p>If met, continue with meeting.</p> <p>If not met, cancel meeting.</p>
Minutes:	<ol style="list-style-type: none"> 1) Date of meeting 2) Policy Full Name, Version Date, and Policy Effective Date. Policy should be discussed in detail. 3) Name of study (to include full title and phase)—Add first study, name the cost and time, discuss the impact for each patient and operations, then do same for study 2, study 3, etc. 4) Names of voting members present and absent to verify quorum 5) Written detailed summary involving discussion points noted in review of materials in next section 6) Tally of votes indicating "for", "against" and/or "abstain" for each study reviewed
Review of Materials:	<ol style="list-style-type: none"> 1) ICF 2) Cost and Time Sheets 3) QCT Form-if not qualifying, discussion needs to be surrounding and insuring Sponsor will pay for all services 4) Discussion surround whether a post-market study is only being written by the Sponsor in order to promote the product by creating a protocol that requires patients insurance (Anti-Kickback Statute prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referrals of Medicare or Medicaid beneficiaries) 5) If the study is requiring specimens for a non-specified study; Analyze use of specimens as part of a defined protocol rather than a sponsor built protocol that would turn over specimens without a defined protocol use (NIH study/substudy for specimen collection allowable) 6) Discuss who is paying for IP (drug or device), discussion of consequences if this is a Category B device and how much it will cost the Patient for each payer if insurance denies.. Discussion around a research study which may appear to plant drugs and devices in the community without legitimate need for such research study. 7) Ensure all equipment is available 8) Staffing is available-ensure research staff with expertise are available, i.e. CATH Lab nurses for cardiology study involving CATH LAB 9) Risk and benefits and if risk outweigh the benefit (ICH GCP 2.2), consider not approving study without discussion documented 10) Is PI qualified to do this type of study and does PI have CITI and GCP training 11) Confidentiality of records. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement (Tenet IS approval is not required if the falls under the category of Clinical Research)
Operations and Facility Impact:	<p>For each department, evaluate feasibility and how the study involves the department:</p> <ul style="list-style-type: none"> -Radiology -Phlebotomy -Lab Services -Inpatient Nursing - Physician services -Outside Services -Pharmacy -Material Management -HIM
Voting:	Only alternate members listed on the FRC roster as alternate voting members can vote for the voting member in their absence that has been delegated in your main roster.