Q: How often does the IRB meet?
A: The IRB meets the 1st – 4th Thursdays of every month. The IRB does not meet on the 5th Thursday of a month or on Jefferson holidays. IRB #152 & IRB #2405 meet on the 1st & 3rd Thursdays of the month. IRB #153 meets on the 2nd & 4th Thursdays of the month.

Q: Does it matter which IRB reviews my research?
A: For most submissions, it does not matter which IRB reviews your research because all of the Boards have members with a similar range of expertise. For submissions that are NOT APPROVED, you must re-submit to the same IRB that previously reviewed the submission.

Q: What is the institution’s federal-wide assurance (FWA) number, and what is the expiration date?
A: Jefferson has two FWA numbers, one for the university, and one for the hospital. The university FWA number is 00002109 with expiration date 3/1/18. The hospital’s FWA number is 00002142 with expiration date 4/2/17.

Q: How long does it take from submission to full review by the IRB?
A: In general, submissions received by Friday will be assigned to the IRB reviewers the following Wednesday and then reviewed at the IRB meeting the Thursday of the following week. Please note that the IRB does not meet on the 5th Thursday of a month or on Jefferson holidays.

Q: How long does it take from submission to receipt of formal IRB approval?
A: It takes an average of 30 working days from submission to receipt of formal IRB approval. This includes the time it takes for the PI to respond to the IRBs comments and can be shortened by responding in a timely fashion.
Q: Are any approvals required other than that of the IRB?

A: Approvals are required for studies involving the Emergency Department, echocardiography, radiology, oncology, radiation, recombinant DNA technology and the Nursing Department. Please see the OHR-1 for complete information.

Q: Is an executed clinical trial agreement required prior to IRB submission?

A: An executed clinical trial agreement is not required prior to IRB submission, but the Office of Research Administration (ORA) should be asked to initiate contract negotiations at the same time the submission is made to the IRB. Once the study is IRB-approved, the clinical trial agreement can be signed.

Q: How long does it take from initiation of the contract negotiations to final contact approval?

A: It takes 30 – 60 days from initiation of the contract negotiations to final contact approval.

Q: What are the other requirements before you may execute a clinical trial agreement?

A: The budget, Medicare coverage analysis (MCA), IRB and internal approvals are required before a clinical trial agreement can be executed.

Q: How long does it take to get all approvals for a study (IRB, clinical trial agreement, regulatory documents)?

A: The length of time it takes to get all approvals for a study depends on several factors, but all the processes can be done simultaneously to ensure the shortest possible approval time.

Q: Has the IRB ever had an FDA inspection? What was the outcome of the most recent inspection?

A: Yes, the IRB has had FDA inspections. The most recent one was a routine inspection in March 2014. The inspection resulted in no significant concerns being reported by the FDA inspector and no response required from the IRB.