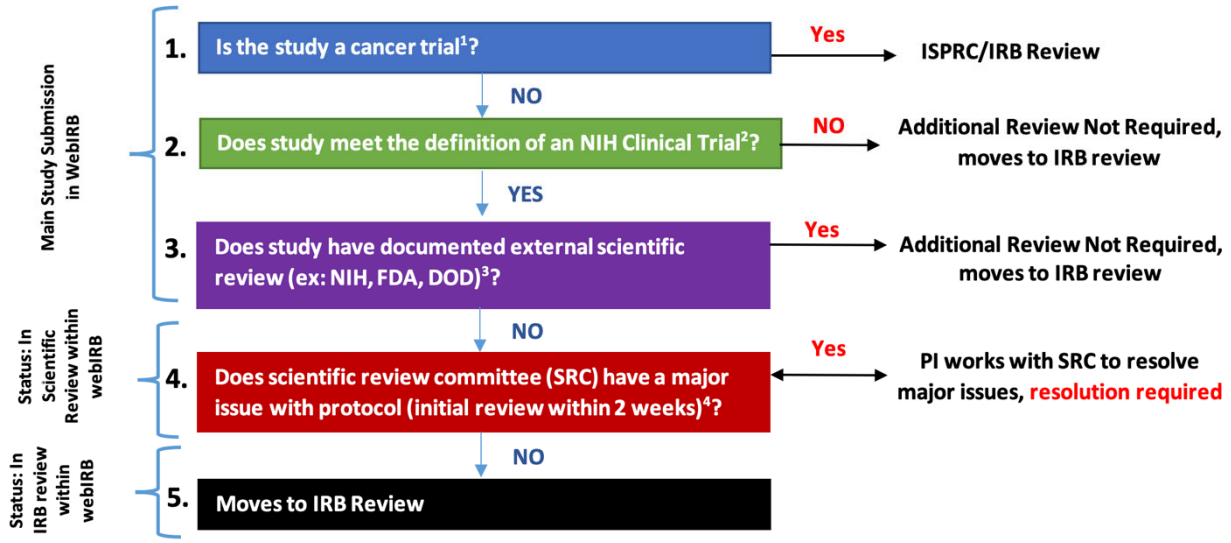
Scientific (Protocol) Review Policy Criteria and Workflow



[1] This will be determined by an answer to an existing question in the IRB Electronic Submission System that has been in use for many years.

[2]This will be determined via responses provided by the Principal Investigator to questions in the IRB Electronic Submission System modeled after the NIH Decision Tool using four (4) questions to determine if the study meets the definition of an NIH Clinical Trial. A Protocol must be uploaded for review if a study meets the NIH definition of a Clinical Trial. Incorrect responses to these questions will lead to delays in study activation that will be attributed to the PI.

[3]This will be determined automatically for sponsors that are known to require peer review. For other sponsors this will be determined based on the responses provided by the Principal Investigator to a question about documented external scientific review in the IRB Electronic Submission System. The UCLA Office of Compliance Services will conduct audits of responses to this question. UCLA Health may request to review this documentation prior to rendering services and allowing access to patient populations. Incorrect responses to this question will lead to delays in study activation that will be attributed to the PI.

[4]SRC review will be a status in the IRB Electronic Submission System. Final disposition and review time will be tracked as part of the study activation process and as a key performance indicator. Major and Minor Correspondence will be sent from the SRC committee directly to the Principal Investigator. Studies with Major Correspondence issues will require resolution prior to IRB review.