The scientific and scholarly validity review is conducted in the following manner:

For federally sponsored research, the peer review process (e.g., during the study section sessions) provides scientific and scholarly review.

For research subject to FDA review, there is a rigorous review that includes the scientific design of the research (e.g., during the IND or IDE evaluation stage).

For research occurring in the Clinical Translational Research Center, representatives of the CTRC Council who are also voting members of the IRB perform the scientific review.

For research conducted within the University of Pennsylvania’s Cancer Center, the Clinical Trials Scientific Review and Monitoring Committee provides scientific and ethical evaluation.

For both department-funded research and that conducted by faculty without external sponsorship, the signature of the chair of the departments or the deans of schools have responsibility for ensuring that scientific review of the protocol has occurred.

For student research, the faculty sponsor named on the IRB application is responsible for ensuring the scientific and scholarly validity of the proposed research.

The IRB evaluates whether the design of the research protocol is sound and minimizes risks to participants. For protocols where the protocol design is unusual or novel, in addition to the protocol being assigned to primary reviewer(s) with relevant expertise, input from ad hoc consultants is also obtained.

The principal investigator should present information in the protocol to justify the statistical basis for the protocol design, the number of subjects per comparison group and the ability to identify and recruit such number of subjects during the proposed duration of the investigation.

If there is any question raised in the mind of the IRB reviewer that the research will not achieve the objectives proposed, the following steps should be considered. If the protocol is scheduled for independent scientific review by an internal or external peer review body, the IRB reviewer may condition enrollment in the research trial on the submission of written documentation of the approval by the internal or external peer review group. The IRB will not authorize an approved informed consent until such documentation is received and approved by the Executive Chair or other IRB member authorized by the IRB.

The IRB reviewer may contact the principal investigator to clarify the issue. If contacted, the principal investigator must be advised to provide follow-up with the submission of written material that summarizes the discussion with the IRB reviewer.

The IRB reviewer, wishing to remain anonymous, should contact the IRB Chair or Executive Chair with their concerns. The Chair may contact the investigator directly or through written correspondence generated by the IRB coordinator. The principal investigator must be advised to follow-up with the submission of written material that summarizes the discussion with the IRB Chair.
If it is unclear whether there will be external or internal review the IRB may request that the department chairperson conduct such a review employing either internal or external resources and provide a report to the IRB.

If the IRB reviewer, Chair or Executive Chair does not receive sufficient information to resolve the question they may request the HRP Director to obtain an independent consultant opinion.

The consultant will be chosen by the Executive Chair. The consultant may be internal or external depending on the advice of the Executive Chair. The result of the consultant’s review will be submitted to the IRB. Such external consultants are not to be considered voting members of the IRB.