

IRB REVIEW ACTIONS

1. Approve Research as Submitted

The IRB may approve research as submitted and reviewed by the IRB if the Committee determines that all of the relevant regulatory requirements are satisfied. Operationally, this means that the IRB approves the research protocol and research consent form and other documents as submitted, with no change.

2. Require Modifications in Research to Secure Approval

Alternatively, the IRB may require modifications in the research to secure approval if the IRB determines that all of the relevant regulatory requirements would be satisfied if the investigator modifies the research protocol and research consent form as required by the IRB. Operationally, this means that the IRB provides the investigator with explicit modifications, and does not ask for additional information or for clarification of issues that may affect the risk benefit assessment or other regulatory requirements for IRB approval.

For example: The IRB requires the investigator to exclude patients with a serum creatinine ≤ 3.0 ; the IRB requires the investigator to discontinue subjects if their blood pressure goes above 140/100.

In order to obtain IRB approval, the investigator must simply concur with the IRB's required modifications and make the changes to the affected documents. If the investigator disagrees with the IRB's required modifications, the protocol must be re-reviewed at a convened meeting of the IRB that originally reviewed the protocol. Minor changes included with the response may be approved by expedited review in accordance with Policies & Procedures.

3. Defer Action

When the IRB needs additional information from the investigator in order to determine whether all of the relevant regulatory requirements are satisfied, the IRB must defer action until the information is provided and then must review the response at a convened meeting of the IRB that originally reviewed the protocol.

For example, the protocol submission may lack preclinical data or data from previous trials, without which the IRB cannot fully assess the risks and potential benefits. The protocol lacks sufficient safeguards to minimize risk, such as drop criteria, and the Committee hasn't specified the drop criteria that would minimize the risk.

4. Disapprove Research

When the IRB has all of the information it needs to determine whether all of the relevant regulatory requirements are satisfied, and determines that the requirements cannot be satisfied by making modifications in the research, the IRB must disapprove the research.