IND Application Reporting: Protocol Amendments

Once an IND application is in effect, the sponsor of the application may amend the application as needed to ensure that the clinical investigations are conducted according to protocols included in the IND application. Sponsors are expected to submit protocol amendments for new protocols or changes to existing protocols **before** implementation of the respective changes. New studies may begin when the sponsor has submitted the change to FDA for its review **and** the new protocol or changes to the existing protocol have been approved by the Institutional Review Board (IRB) with the responsibility for review and approval of the studies. If the IND application sponsor desires FDA to comment on a submission, they should submit a request for such comment and the specific questions that FDA's response should address.

When several submissions with minor amendments are expected within a short period, sponsors are encouraged, to the extent feasible, to include all amendments in a single submission.

Any specific technical information referenced in an IND application amendment as already submitted to FDA in the original IND application is expected to be identified by name, reference number, volume, page number, and date of submission. The general types of protocol amendments are shown below.

New protocol should be identified as **"Protocol Amendment: New Protocol"**	If a sponsor intends to conduct a study that is not covered by a protocol already contained in their IND application, the sponsor is expected to submit to FDA a protocol amendment containing a copy of the new protocol and a brief description of the most clinically significant differences between it and the previous protocols.

Changes to existing protocol(s) should be identified as **"Protocol Amendment: Change in Protocol"**	A sponsor of an IND application is expected to submit a protocol amendment in cases when there are changes in the existing protocol that significantly affect safety of subjects, scope of the investigation, or scientific quality of the study. Such amendment should contain a brief description of the change and reference (date and number) to the submission that contained the original protocol. For example, changes requiring an amendment to an IND application may include: • Any increase in drug dosage or duration of exposure of individual subjects to the drug beyond that described in the current protocol, or any significant increase in the number of subjects under study. • Any significant change in the design of a protocol (such as the addition or elimination of a control group). • Addition of a new test or procedure intended to improve monitoring for, or reduce the risk of, a side effect or adverse event; or elimination of a test intended to monitor safety. ***Note:*** a protocol change intended to eliminate an apparent immediate hazard to human subjects may be implemented immediately, provided that FDA is subsequently notified by protocol amendment and the reviewing IRB is also notified.
Addition of a new investigator should be identified as **"Protocol Amendment: New Investigator"**	A sponsor of an IND application is expected to submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol. The amendment should include the investigator's name, the qualifications to conduct the investigation, and any reference to the previously submitted protocol, if relevant. FDA should be notified within 30 days of the investigator being added.

Related Information

- Investigator-Initiated IND Applications (/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications)