Maintaining the IND

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To maintain an IND, the Sponsor-Investigator has three reporting responsibilities. Each type of report is time-sensitive and has a specific structure. The first two, Protocol Amendments and Safety Reports, are submitted when needed to report updated or unforeseen circumstances. The third type, the Annual Report, is submitted every year, even when no studies are in progress under the IND. Send all submissions following the instructions provided in the IND Acknowledgement letter received in response to the initial submission.

IND Protocol Amendments
Once an IND is in effect, the IND Sponsor-Investigator is responsible to amend it as needed to ensure that the clinical investigations are conducted according to protocols included in the application. An IND Protocol Amendment should have a IND Amendment Cover Letter and is a submission to an existing IND notifying the FDA of one or more of the following:

- New study protocol
- Change in an existing study protocol
- New investigator
- Transfer of IND Obligations

IND Annual Reports
An IND Annual Report requires a cover letter to CDER or CBER and is a brief report of the progress of studies conducted under an IND, due annually to the FDA within 60 days of the anniversary of the date that the IND went into effect.

IND Safety Reports
An IND Safety Report is expedited, written notification to the FDA of an adverse experience associated with the use of a study drug that is both serious and unexpected. “Associated with the use of the drug” is a Code of Federal Regulations term meaning “There is a reasonable possibility that the experience may have been caused by the drug.” An IND Safety Report consists of a MedWatch Form and a cover letter. It is due to the FDA within 15 calendar days of initial receipt of the SAE Report.

Need assistance or have regulatory questions? Please contact ResearchGo.

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