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 to the address provided in the IND Acknowledgement letter received in response to the initial submission.

IND Protocol Amendments
一旦IND生效，IND Sponsor-Investigator有责任根据所包含的临床研究方案来更新IND。IND Protocol Amendment应该有一个IND Amendment Cover Letter，并是向现有的IND通知FDA的一个或多个以下内容的提交：

- 新的研究方案
- 已有研究方案的变更
- 新的研究人员
- 转移IND义务

IND Annual Reports
一个IND Annual Report需要一个封面信给CDER或CBER，是关于在IND下的研究进展的简要报告，应自IND生效之日起60天内提交给FDA。

IND Safety Reports
一个IND Safety Report是迅速的，以书面方式通知FDA与使用研究药物有关的严重且出乎意料的不良事件。"与药物有关"是指"有合理的可能性表明该经验可能由该药物引起。"一个IND Safety Report由MedWatch Form和cover letter组成。它应在SAE Report收到之日起15个日历日之内提交给FDA。

Need assistance or have regulatory questions? Please contact the CTSI Office of FDA Affairs.

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