

Does my research use a drug?

A drug is any substance that achieves its primary intended purpose through chemical action within or on the body of man or other animal and is dependent upon being metabolized to achieve its primary intended purpose.



If the substance used in your study is unapproved for the study's indication and its purpose is to treat, cure, diagnosis, or prevent a disease or condition in all likelihood it will be considered an Investigation drug and an IND will be required.

Does my research use a device?

Basically a device is an object that its intended use is not achieved through chemical action or by being metabolized by the body.

Will this study require an Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA?

Many factors play into a determination of whether or not your study requires and IND/IDE including the current labeling of the product, intentions for changing the label, the risk of the product, and the population the product is being used on.

For questions related to investigational product regulatory issues please contact:

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Future Topics

Visit www.somewebsite.com for our schedule

DSMB's and AE Reporting

Research Drug Accountability

Medical Devices: classes, risks and regulations

Roles of the sponsor

Roles of the investigator

Clinical Trial Agreements

The 10 Questions Every Clinical Researcher Should Ask BEFORE Doing Research With a DRUG or DEVICE...

...and the people who can answer them!



Children's Hospital Boston
A teaching affiliate of Harvard Medical School



What is my role in a drug/device trial?

You may have different responsibilities depending on your role. Roles on an FDA regulated study may include:

- Sponsor (Independently funded)
- Sponsor-Investigator (Independently funded)
- Investigator (Site Investigator with an outside sponsor)



How does FDA regulation affect my responsibilities for study oversight and monitoring?

Monitoring is necessary to assure adequate protection of the rights of human subjects and the safety of all subjects involved in clinical investigations and the quality and integrity of the resulting data submitted to the Food and Drug Administration (FDA).



For questions related to monitoring and clinical trial documentation please contact:

Education and Quality Improvement Program (EQuIP)

www.childrenshospital.org/research/equip

Am I doing this investigation with other investigational sites?

Issues you will have to consider when working with another site or sponsor:

- Funding
- Insurance
- Drug accountability
- Responsibility of investigators
- Monitoring
- Liability language
- Intellectual Property (IP) issues

For questions related to contracts with outside parties for research please contact:

The Clinical Trials Office (CTO)
<http://childrensinnovations.org/>

Is intellectual property associated with the conduct or potential findings of my research?

Issue to consider:

Who owns any current patents?

Who owns the data?

Who publishes the results of the study?

For questions related to intellectual property please contact:

The Technology & Innovation Development Office (TIDO)



How does FDA regulation affect my data management?

In the event of an audit you may be required to show source document verification for every variable you collect. There should also be audit trails on your case records of who entered that data and how it has been changed. CRP has database technology that can help ensure that your data management procedures are FDA compliant.



How does FDA regulation affect my responsibilities for safety and adverse event reporting?

Investigators and sponsors have specific responsibilities for Adverse Event (AE) reporting to FDA, IRB and other applicable oversight parties. These procedures vary by study and should be outlined in the protocol, manual of operations, and Data Safety Monitoring Plan (DSMP) so that everybody on the trial knows what they are supposed to report when an AE occurs.

For questions related to project and data management please contact

Clinical Research Program

<http://web2.tch.harvard.edu/crp/>

What will happen if I do my drug/device research without an IND/IDE?

It depends...but if you were required to have one and didn't file it could result in:

- Failure to get your results accepted by a journal
- Prosecution for violation of Federal Law
- The results from your investigation may not be able to be submitted to the FDA and the FDA may require additional studies be conducted under an IND/IDE

Your best bet is to know your study objectives and inquire about these issues in the beginning to know if your study will require an IND.