

Investigational Drug Online Content

Investigational Drug: An investigational drug is a chemical or biological drug that is used in a clinical investigation.

(1) An investigational drug can be:

- (a) A new chemical compound, which has not been approved by the FDA, or
- (b) An approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an IND application, in a clinical investigation. This includes: prescription drugs, over-the-counter drugs, nutritional supplements, herbal preparations, and legend items used for the diagnosis, treatment, cure, mitigation or prevention of disease and meeting the above definition.

NOTE: A physician may use a marketed drug in an unapproved manner in an individual patient without requiring a clinical study protocol or obtaining an IND for therapeutic, rather than investigational purposes (Title 21 CFR § 312.2[d]) (see VA's Off Label Drug Use Guidance at:

<http://vawww.pbm.va.gov/directive/Guidance%20Off%20Label%20Prescribing.pdf>)

This is an internal Web site and is not available to the public. The Veterans Integrated Service Network (VISN) Therapeutics Management Committee, the Chief of Staff, or the medical facility Director may apply more stringent controls regarding such drug usage.

(2) Concurrent medications, comparators, or rescue medications used in the investigational trial that are not the drug(s) being studied are not defined as investigational drugs, unless they are not commercially approved or not available through commercial channels.

NOTE: The preceding definitions also apply to drugs used for animal research that are stored in and/or supplied through pharmacy.

Investigational New Drug (IND) Application: An IND application is an application to the FDA that allows an investigational drug or biological product to be studied in humans. An IND application must be in effect prior to shipment and administration of investigational drugs or biological products (see 21 CFR 312).

When appropriate a VA Form 10-9012 can be attached in the Research Study Application. The PI upload to the VA form 10-9012 in the Research Study Application. The PI is able to do so in section G, question 8 and question 9 of the Research Study Application. The PI may also use the VA Form 10-9012 template that is readily available for use. This template can be accessed using the link available in Section G question 9. Please save section G before generating the template. After clicking the link, a document ribbon is generated with Open or Cancel option. A copy of this template also gets saved in the attachment section of the Application. The PI may choose to open the template and start making updates to the template or may choose to cancel to update it at a later time. Any changes saved to the document after the generation of the template will be saved to the attached document. The PI access the document by navigating to the Attachment section of the application.