meet the enrollment criteria, because enrollment in the trial is closed, or because the trial site is not geographically accessible.

iii. The intended investigational drug/biologic is an approved drug product that is no longer marketed for safety reasons or is unavailable through marketing due to failure to meet the conditions of the approved application.

iv. The intended investigational drug contains the same active moiety as an approved drug product that is unavailable through marketing due to failure to meet the conditions of the approved application or a drug shortage.

When the expanded access IND or protocol has been procured from the FDA the following must be submitted to the IRB:

a. Initial Application in Cayuse IRB: an outline of the rationale for the use, including a description of available therapeutic options, an explanation of why use of this test article is preferable, description of the disease, the method of administration of the drug, dose, and duration of therapy. A description of the clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks

b. A copy of the written consent form that will be used to obtained informed consent. The consent form must contain all the elements of consent per FDA regulations, and must explain the purpose of the use of this investigational drug. The consent document must include an explanation of what data will be collected regarding the administration, to whom it will be shared and for what purpose(s), and the reporting requirements to the FDA and/or sponsor. Investigators treating a patient(s) with an investigational drug under expanded access are responsible for ensuring that the informed consent requirements are met.

c. The Approval/Acknowledgment IND or protocol letter from the FDA.

d. A copy of the current Investigational Brochure for the investigational drug.

Individual expanded access INDs, including emergency use, may be reviewed by the IRB Chair or other designated IRB member for concurrence before treatment use begins, if authorization for the waiver of convened IRB review has been obtained from the FDA (via FDA Form 3926). This is only applicable for protocols intended to treat one patient. Expanded access INDs for intermediate-size patient populations or widespread treatment use through a treatment IND or treatment protocol will be reviewed at a convened IRB meeting, following standard IRB procedures.

8.5 GROUP C TREATMENT IND

The Group C Treatment IND was established to provide a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are generally drugs that have completed Phase III trials and have shown evidence of reproducible efficacy in a specific tumor type. They are distributed only by the NIH under NCI protocols.

Although treatment is the primary objective in these cases, efficacy and safety data are also collected. However, since administration of Group C drugs is not done with research intent, the FDA usually grants a waiver of IRB requirements (21 CFR 105). If an investigator plans to treat cancer patients with Group C drugs, he or she is required to submit a copy to the IRB of the following documentation: (a) FDA letter waiving the requirement for IRB review, (b) the treatment

protocol, and (c) the FDA-approved informed consent document. An IRB Chair will review the document and decide whether a local IRB review is needed, then the IRB Chair's decision will be communicated to the investigator in writing.

8.6 INVESTIGATIONAL USE OF MEDICAL DEVICES

All clinical investigation of medical devices must comply with FDA regulations for investigational device exemptions (21 CFR 812).

Medical Device: an instrument, apparatus, implement, contrivance, implant, in vitro reagent, or other similar or related article, including component, part, or accessory, which is: (a) recognized in the official national Formulary, or the United States Pharmacopoeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans; or (c) intended to affect the structure or any function of the human body; and does not achieve any of its principal intended purposes through chemical action within or on the human body and is not dependent upon being metabolized for the achievement of its principal intended purposes.

Investigational Device: a device that is the object of an investigation. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

Investigation: a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

Medical Device Labeling: any label or written material on the device or material that accompanies the device. This can include instructions for use, advertising and promotional material. This information must be provided to the FDA during the Premarket Approval (PMA) process. Labeling must provide adequate directions for use, unless it is exempt; it cannot be false or misleading.

In Vitro Diagnostics (IVDs): Reagents, instruments and systems intended for use in the diagnosis of disease or other conditions, including a determination of state of health, in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVDs are medical devices as defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act, and may also be biological products subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket and postmarket controls. IVDs are also subject to the Clinical Laboratory Improvement Amendments (CLIA '88) of 1988. Under FDA's regulations governing the conduct of IVD device studies, the definition of "subject" includes individuals on whose specimens an investigational device is used (21 CFR 812.3(p)). As a result, an IVD study using human specimens involves human subjects. IVDs require an IDE if the proposed IVD study does not meet an exemption in 21 CFR 812.2. The requirements for an IDE depend on the level of risk that the study.

A. Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of