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# USE OF INVESTIGATIONAL DEVICES IN HUMAN SUBJECTS RESEARCH

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**This procedure describes the regulations and WSU IRB procedures for use of investigational devices. If the devices are to be used in the hospital setting, investigators must consult the research offices at the individual institutions (e.g. MVH, GSH, VA etc.) and meet the requirements of the institution before a device can be used in a patient.**

**B. Background**

All clinical investigations of devices must have an approved IDE (Investigational Device Exemption) from the FDA or be exempt from the IDE regulations. First one must determine if something is a device according to the federal definitions.

## C. Medical Device Definition

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy

## D. Medical Device Classes

In 1976, Medical Device Amendments to the Food, Drug and Cosmetic Act gave the FDA the responsibility for assuring the safety and effectiveness of devices intended for human use. In implementing these Amendments, the FDA has classified devices according to their level of risk.

Class 1 Medical Devices
Class 1 Medical Devices include those devices for which safety and effectiveness can be assured as long as there is compliance with provisions for notification of defects, repair, replacement or refund, records and reports. Device manufacturers are required to also avoid distribution of adulterated, misbranded, or banned devices.

Class 2 Medical Devices
Class 2 Medical Devices are those that require something more than proper labeling and quality assurance to ensure their safety and effectiveness.

Class 3 Medical Devices
Class 3 Medical Devices are those that are life-sustaining, life-supporting, implanted in the body, or of substantial importance in preventing impairment.

510(K) Devices
When a new device is substantially equivalent to one marketed prior to enactment of the Medical Devices Amendments (1976), it may be sold without additional proof of safety and effectiveness under Section 510(K) of the Federal Food, Drug and Cosmetic Act. These devices are commonly referred to as "510(K) devices." A sponsor planning to market the device must notify the FDA 90 days in advance of placing the device on the market. If the FDA agrees that the device is substantially equivalent to one already on the market, the device may then be sold without further research. Research activities involving a 510(K) device do not require an FDA Investigational Device Exemption (IDE) prior to approval by the IRB.

If the FDA determines that a new device is not substantially equivalent to a pre-amendment device, the new device is automatically designated a Class 3 medical device and the sponsor is required to obtain pre-marketing approval from the FDA. Studies conducted to develop safety and effectiveness data for such devices must be conducted according to the FDA requirements on Investigational Devices.

## E. Exemptions for Devices

If something is determined to be a device, one must then determine if the device is exempt from FDA regulations. Devices that are exempted from 21 CFR 812 are described in §812.2(c) of the IDE regulation. A summary of the FDA regulations for studies exempt from the IDE regulation include:

1. A legally marketed device when used in accordance with its labeling
2. A diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing:
    - is noninvasive; *
    - does not require an invasive sampling procedure that presents significant risk;
    - does not by design or intention introduce energy into a subject; and
    - is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure;

    *Noninvasive when applied to a diagnostic device or procedure, means one that does not by design or intention:
    -Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os.
    -Blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered noninvasive.
3. Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
4. A device intended solely for veterinary use;
5. A device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects."
6. A custom device

According to 21CFR812.2(c) (7) a custom device as defined in 812.3(b) is exempt unless the device is being used to determine safety or effectiveness for commercial distribution. A custom device means a device that:

- Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- Is not generally available to, or generally used by, other physicians or dentists;
- Is not generally available in finished form for purchase or for dispensing upon prescription;
- Is not offered for commercial distribution through labeling or advertising; and
- Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

Depending upon the nature of the investigation, those studies which are exempt from the requirements of the IDE regulation may or may not be exempt from the requirements for IRB review and approval under Part 56 and the requirements for obtaining informed consent under Part 50. For guidance regarding the applicability of these regulations with respect to investigations being conducted under the provisions of §812.2(c), contact the FDA IDE Staff at (301) 594-1190.

Additional guidance for an in vitro diagnostic device studies can be found on the FDA web site (FDA Guidance Document for IVD Devices; IDE Approval Process)

## F. Significant and Nonsignificant Risk Devices

If a device is determined to NOT be exempt from the IDE regulations- a determination must be made if the device is either significant risk devices or non-significant risk.

Determination of Significant/Non-Significant Risk Status

Sponsors are responsible for making the initial risk assessment regarding an investigational device.

A non-significant risk device is one that does not present significant risk to the research subject. Investigators should clearly explain in their protocol to the IRB why the sponsor believes the device to present no significant risk to study participants and provide supporting information, such as reports of prior

investigations. The investigator should inform the IRB whether the FDA or any other IRB (IRB) has made a risk assessment and what the results of those assessments were.

The IRB then will make an independent assessment of the risk of the investigational device to be used in the study. If the IRB agrees that the devices poses no significant risk to research subjects, the investigator will not be required to obtain an IDE from the FDA to conduct the study. If the IRB instead believes that the device poses significant risk to research subjects, the investigator will be notified by the IRB. The investigator in turn is required to notify the sponsor of the IRB's decision, and the sponsor must notify the FDA of the IRB determination regardless of whether the study is ultimately conducted at WSU. Investigational devices determined by the IRB to pose significant risk to research subjects will be reviewed according to the requirements described below.

Significant Risk Device Criteria

Sponsors are responsible for making an initial risk assessment regarding an investigational device. A significant risk device by definition is an investigational medical device that presents a serious risk to the health and safety of the research subjects. According to 21CFR812.3(m) a Significant Risk (SR) device study is one where the device presents a potential for serious risk to the health, safety, or welfare of a subject **and**:

- is intended as an implant*; or
- is used in supporting or sustaining human life; or
- is for use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or
- otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

*Implant means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants."

Note: If the participant must undergo a procedure as part of the investigational study, e.g., a surgical procedure to implant the device, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device.

## G. Who must apply for an IDE?

The sponsor of the clinical trail is responsible for submitting the IDE application to the FDA (21CFR812.40) and obtaining Institutional Review Board (IRB) approval before the study can begin. Foreign companies wanting to conduct a clinical study in the U.S. MUST have a U.S. sponsor. Under certain circumstances a WSU researcher who has invented a device may wish to submit an IDE and would therefore also act as the sponsor.

## H. IDE (and IND) Applications

The IND or IDE application must contain sufficient data from animal and in vitro studies to demonstrate the likelihood that the product will be safe and effective for the purpose indicated. If the FDA agrees that the data are sufficient to support a decision to initiate clinical trials, and the proposed protocol is acceptable, the FDA will provide an IND or IDE number to the protocol. Specific requirements for protocol design are set forth in FDA Regulations.

**IDE:** The investigator is required to wait for the FDA scientists to review the materials submitted, and if necessary request additional information, require modifications, and approve or disapprove the application before proceeding with the clinical trial. The IRB will not provide approval to enroll subjects in the study until the FDA has either provided an IDE number or advised the principal investigator that an IDE is not required.

**IND :** The investigator is required to wait 30 days after submitting the IND application to the FDA before enrolling subjects. During this time the FDA scientists will review the materials submitted, and if necessary request additional information or require modifications. The FDA may send the sponsor an IND #, however this is not an approval to proceed. The IRB will not provide approval to enroll subjects in the study until the 30 day time period has passed.

## I. Device Studies in Pediatric Patients

Because the pediatric population represents a particularly vulnerable group, specific measures are needed to protect the safety of pediatric study subjects. Adult devices may be inappropriate for use in pediatric subjects for a variety of reasons, or may require specific design changes and/or specific labeling to accommodate their use in pediatric subjects. Researchers should consider the following when developing devices or planning a clinical trial for devices intended for pediatric subjects:

- height
- weight
- growth and development
- disease or condition
- hormonal influences
- anatomical and physiological differences from the adult population

- activity and maturity level
- immune status.

If clinical data are needed to support a pediatric indication, researchers should make every effort to gather data that adequately addresses each targeted pediatric subgroup. In some cases, the expected benefit and safety can be determined without separate studies in each subgroup. That is, it may be extrapolated from one age group to another. In other cases, such as with neonates, clinical data gathered specifically in that subgroup will likely be needed. Researchers should be prepared to provide data for each targeted subpopulation or a justification as to why it is either not needed or can be Please review the FDA publication Premarket Assessment of Pediatric Medical Devices for additional information about research involving pediatric medical devices.

## J. Unanticipated Adverse Device Effect Reports

The reporting requirements for adverse device effects are different from those for drugs and biologics. The sponsor-investigator must immediately conduct an evaluation of any unanticipated adverse device effect. If this effect presents an unreasonable risk to subjects, the sponsor-investigator is required to terminate all investigations as soon as possible, but no later than five working days after the sponsor makes this determination. This also must occur within 15 working days of when the sponsor was notified of the adverse effect.

**K. Emergency Use of a Device** (excludes Humanitarian Use Devices – see appendix of this procedure

Emergency Use of Unapproved Medical Devices

An **unapproved medical device** is a device that is used for a purpose or condition for which the device requires, but does not have, an approved application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360(e)].
An unapproved device may be used in human subjects only if it is approved for clinical testing under an approved application for an Investigational Device Exemption (IDE) under section 520(g) of the Act [21 U.S.C. 360(j)(g)] and 21 CFR part 812. Medical devices that have not received marketing clearance under section 510(k) of the FD&C Act are also considered unapproved devices which require an IDE.
The Food and Drug Administration (FDA) recognizes that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but an IDE for the device does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE. Using its enforcement discretion, FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies in writing to the FDA and the IRB that an emergency actually existed.

Requirements for Emergency Use

Each of the following conditions must exist to justify emergency use:

- the subject is in a life-threatening condition that needs immediate treatment;
- no generally acceptable alternative for treating the subject is available; and
- because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

FDA expects the physician to determine whether these criteria have been met, to assess the potential for benefits from the unapproved use of the device, and to have substantial reason to believe that benefits will exist. The physician may not conclude that an "emergency" exists in advance of the time when treatment may be needed based solely on the expectation that IDE approval procedures may require more time than is available. Physicians should be aware that FDA expects them to exercise reasonable foresight with respect to potential emergencies and to make appropriate arrangements under the IDE procedures far enough in advance to avoid creating a situation in which such arrangements are impracticable.

In the event that a device is to be used in circumstances meeting the criteria listed above, the device developer should notify the Center for Devices and Radiological Health (CDRH), Program Operation Staff by telephone (301-594-1190) immediately after shipment is made. [Note: an unapproved device may not be shipped in anticipation of an emergency.] Nights and weekends, contact the FDA Office of Emergency Operations (HFA-615) 301-443-1240.

FDA would expect the physician to follow as many subject protection procedures as possible. These include:

- obtaining an independent assessment in writing, documented in the subject/subject's medical record by an uninvolved physician;
- obtaining informed consent from the subject or a legal representative;
- notifying institutional officials as specified by institutional policies;
- notifying the Institutional Review Board (IRB); and
- obtaining authorization from the IDE holder, if an approved IDE for the device exists.

After-Use Procedure

After an unapproved device is used in an emergency, the physician should:

- report to the IRB within five days [21 CFR 56.104(c)] and otherwise comply with provisions of the IRB regulations [21 CFR part 56];
- evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and

- if an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff 301-594-1190) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

Subsequent emergency use of the device may not occur unless the physician or another person obtains approval of an IDE for the device and its use. If an IDE application for subsequent use has been filed with FDA and FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist. Developers of devices that could be used in emergencies should anticipate the likelihood of emergency use and should obtain an approved IDE for such uses.

Exemption from Informed Consent Requirement

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing in the subject/subject's medical record all of the following [21 CFR 50.23(a)]:

- The subject is confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- Time is not sufficient to obtain consent from the subject's legal representative.
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

## L. Other Types of IDE's

There may be circumstances under which a health care provider may wish to use an unapproved device to save the life of a patient or to help a patient suffering from a serious disease or condition for which there no other alternative therapy exists.

Patients/physicians faced with these circumstances may have access to investigational devices under one of four main mechanisms by which FDA may make an unapproved device available:

- Compassionate Use
- Emergency Use
- Humanitarian Use
- Treatment Use
- Continued Access

IRB procedures for each of these IDEs are found in appendices at the end of this procedure

## M. Investigators as sponsors

If an investigator is the developer of the drug, biologic or medical device, and no commercial manufacturer is involved, then the investigator is also the sponsor for the purposes of designing and organizing clinical trials.

- When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, an Investigational New Drug (IND) or Investigational Device Exemption (IDE) may be required. If an IND or an IDE is required, it is the investigator's responsibility to submit the appropriate application to the FDA, obtain the necessary documentation, and provide this documentation to the IRB as a part of the approval process.
- An IND may not be necessary if all of the conditions stated in 21 CFR 312.2(b)(1) have been met. If the PI does not already have an IND, the PI will be notified in writing that IRB approval is pending receipt of an IND. If there is a debate regarding the need for an IND, the IRB will require that the PI contact the Food and Drug Administration (FDA) to obtain written documentation that an IND is not necessary.
- The IRB will review protocols involving investigational devices to determine if the device is exempt from IDE regulations. If not exempt, the IRB will then determine if the device is a “Significant-Risk device” (SR) or a “Non-Significant Risk”(NSR) device. If the IRB determines that the research involves a SR device, an IDE is necessary. If the PI does not already have an IDE, the PI will be notified in writing that IRB approval is pending receipt of an IDE.

Sponsors also have important administrative and reporting requirements above and beyond those of investigators.

The sponsor must declare any individual financial conflict(s) of interests in the research and develop a management plan that is approved by the University.

Multi site trials:

Should an investigator associated with WSU sponsor a multi-site study, that investigator is required to meet all the responsibilities of a sponsor as determined by DHHS guidance.

At the time of initial review the IRB will assess the procedures for dissemination of protocol information (e.g. unanticipated problems involving risks to subjects or others, protocol modifications, interim findings) to all participating sites. In addition the PI must ensure that investigators at other research sites submit and follow requirements directed by their local IRBs.

IRB policies and procedures from each approving institution will be followed by researchers at that site. All required reports will be provided to the local IRB as per their policy. The coordinating PI at WSU will be responsible for providing local information as well as unanticipated problems involving risks to subjects or others, protocol modifications, or interim findings that may affect the WSU IRB's continuing approval of the research.

## Appendix - IRB Procedures for Device Use
## Compassionate, Emergency, Humanitarian, Treatment

### A. Compassionate Use of Devices

1. FDA Requirements

Compassionate Use (or Single Patient/Small Group Access)

2. IRB Process

NOTE: The researcher at WSU should not submit an application to the IRB prior to a patient being identified and the sponsor having submitted a new IDE submission to the FDA for that particular patient.

a. The Principal Investigator either through the sponsor or directly with the FDA must submit an IDE supplement requesting approval for a protocol deviation under section §812.35(a) in order to treat the patient under Compassionate Use. The FDA review time for IDE submissions is 30 days from the date of their receipt of the submission so please plan accordingly.

b. The IDE supplement should include:
   - A description of the patient's condition and the circumstances necessitating treatment;
   - A discussion of why alternatives therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition;
   - An identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient; and
   - The patient protection measures that will be followed. (Informed consent, concurrence of IRB chairperson, clearance from the institution, independent assessment from uninvolved physician, authorization from IDE sponsor)

c. Submit the following items to the IRB:

   - Cover letter stating request for compassionate use of a device.
   - Copy of IDE supplement to FDA for compassionate use
   - Copy of consent form from sponsor to be used to consent subject
   - Copy of protocol currently being used in ongoing clinical trial
   - IDE# (This must be a different IDE # from the IDE# for the ongoing clinical trial)

## B. Emergency Use of Devices

1. FDA Requirements

Emergency Use

2. IRB Process

a. The Principal Investigator should communicate with the sponsor (device manufacturer) and the FDA to confirm that all FDA requirements are being met for emergency use.
b. If Emergency Use is approved by the Sponsor/ FDA consent should be obtained from the patient using a consent form provided by the sponsor.
c. If the patient is unable to give consent, the physician must provide written documentation from him/her and another physician not involved in the clinical trial, verifying the following criteria:
    - The subject is confronted by a life-threatening situation necessitating the use of the test article.
    - Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject
    - Time is not sufficient to obtain consent from the subject's legal representative
    - No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
d. The device may then be given to the patient.
e. The Principal Investigator must notify the IRB-HSR in writing within 5 working days stating that he/she has used the Emergency Use provision. A copy of the consent form or the documentation verifying consent could not be obtained should be attached A form for IRB notification can be found on the WSU IRB web site.
f. Following the next IRB meeting the Principal Investigator will receive notification from the IRB verifying that the board concurred with the emergency use.

The FDA allows for only one emergency use of a test article without prospective IRB approval. See FDA Requirements above for additional information. If you expect to have an additional patient who will need the same test article- please begin work on submitting a protocol to the IRB.

## C. Humanitarian Use Device

### 1. FDA Requirement

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 4000 individuals in the United States per year. The sponsor must get a HDE designation from the FDA's Office of Orphan Products Development. The Federal Food, Drug, and Cosmetic Act and the HDE regulation do not require informed consent because a HDE provides for marketing approval, and so use of the device does not constitute research or an investigation that would normally require informed consent. The sponsor may provide the patient with patient labeling to assist the patient in making an informed decision about the use of the device. Even though the device is not considered investigational, IRB review is required. The initial review must by done by full board, although continuations may be done by expedited review.

Additional information may be found at

- 21CFR814 Subpart H
- Humanitarian Device Exemption
- Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answersm

### 2. Emergency Use of a Humanitarian Use Device

For additional information on the emergency use of a HUD see: HUD Emergency Use

### 3. IRB Process

a. The Principal Investigator needs to submit the following documentation to the IRB for full board review:

- Cover letter requesting IRB HDE approval. This letter must include the maximum # of subjects planned to use the device and a statement that the device will only be used according to the indications approved under the HDE.
- The name, address, phone number and e-mail address of the principal investigator, co-investigators (if applicable), and the study coordinator (if applicable).
- Investigational Brochure or equivalent documentation for device.
- HDE #

- A research consent form is not required by the FDA for use of a Humanitarian Use Device. However, patient information concerning the device is generally available to present to the patient, and this should also be submitted to the IRB. If a patient packet of information is not available, a consent document should be prepared and be submitted. The consent document should address the following:
  - What is a humanitarian use device?
  - What humanitarian use device will be used with this patient?
  - What will be involved with the use of this device?
  - Possible risks, side effects or discomforts associated with the use of the device
  - Possible benefits associated with the use of the device
  - Any alternate treatments or procedures that may be available
  - Who will be charged for the costs of the device and the associated procedures

b. The protocol is processed like any other new approval by the full board except that a protocol, consent form, Investigator's Agreement and Human Subject Protection Training are NOT required.

c. Continuing review is required for Humanitarian Use Devices, and may be done either by the full board or by expedited review. Review should include the risk and benefit information available and any Medical Device Reporting reports.

d. Any medical device reporting (MDR) reports submitted to the FDA must also be submitted to the IRB.

## D. Treatment Use of Devices

1. FDA Requirements

Additional information may be found on the FDA website.
"Treatment Use" is described in the federal regulations to facilitate broader availability of promising new therapies to desperately ill patients as early in the development process as possible. Under these regulations, patients faced with a serious or life-threatening disease/condition for which no alternative exists may receive investigational therapy outside of the controlled clinical trial.
Treatment Use may be considered when:

- The drug/device is intended to treat or diagnosis a serious or immediately life-threatening disease or condition
- There is no comparable or satisfactory alternative drug/device available to treat or diagnose the disease or condition in the intended patient population.
- The drug/device is under investigation in a controlled clinical trial for the same use under an approved Investigational Device Exemption (IDE) or

Investigational New Drug (IND) application, or all clinical trials have been completed; AND

- The sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the investigational drug/device with due diligence.

2. IRB Process

- The Principal Investigator either through the sponsor or directly with the FDA must obtain a "Treatment Use IND/IDE"
- The Principal Investigator then submits a new protocol application to the IRB for a Full Board study.
- The IRB strongly encourages the investigator to contact the IRB staff prior to writing and submitting application documents to verify that the protocol meets the criteria for a treatment use protocol.