Investigational Devices – Review, Approval, and Use

1.0 Policy
It is the policy of West Virginia University (WVU) Institutional Review Board (IRB) that all investigational device use be reviewed and approved by the IRB in accordance with applicable laws and regulations.

2.0 Definitions
2.1 Investigational Device: Any healthcare product that does not achieve its primary intended purposes by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

2.2 Investigational Device Exemption (IDE): A FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

2.3 Non-significant Risk (NSR) Device Study: A study of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.

2.4 Significant Risk (SR) Device Study: A study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and a) is intended as an implant; b) is used in supporting or sustaining human life or otherwise prevents impairment of human health; c) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or d) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.
2.5 Treatment IDE: A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.

2.6 Unanticipated Adverse Device Effect: any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem to participants or others associated with a device that relates to the rights, safety, or welfare of participants.

3.0 Investigator Responsibilities:

3.1 The Investigator will provide all information regarding the use of investigational devices as required in the IRB guidelines. This will include the identification of the IDE number, if applicable.

3.2 When an IDE is required, the Investigator will also complete the FDA's Investigator's Agreement form for submission to the FDA. A copy of this form must be submitted with the initial IRB application.

3.3 The initial submission will also include all correspondence from the sponsor and/or FDA in regards to the determination of the device as being a non-significant (NSR) or a significant risk device (SR). If the sponsor considers that a study is NSR, the Investigator should provide the IRB an explanation of the determination and any other information that may assist the IRB in evaluating the risk of the study. The Investigator should provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the IRB deems necessary to make its decision. The Investigator should inform the IRB whether other IRBs have reviewed the proposed study and what determination was made. The Investigator must also inform the IRB of the FDA's assessment of the device's risk if such an assessment has been made.

3.4 The Principal Investigator (PI) is responsible for the submission to the IRB of the sponsor's report of prior investigations for the IDE.

3.5 Additionally, the Investigator will provide a description of the component, ingredient, property, principle of operation and each anticipated change in the device during the course of the research.

3.6 The Investigator will complete the informed consent process.

3.7 The Investigator will maintain all case report forms and records as required by the sponsor, Institution, and/or FDA.
3.8 The Investigator is responsible for the accountability, storage, dispensing, tracking, and oversight of the FDA-regulated devices in accordance with applicable institutional, State, and Federal laws and regulations.

3.9 The Investigator will complete and submit continuing reviews at the established review intervals imposed by the IRB. At the time of continuing review, the Investigator will provide the following information in the form of a summary:

- The clinical indications for the use of the investigational device with each participant;
- Adverse events or unanticipated problems to research participants or others that are possibly related to the use of the investigational device and
- Clinical outcomes of each participant, if known.

3.10 The Investigator will notify the IRB of any amendments, unanticipated device effects, serious adverse events or unanticipated problems to participants or others, that may occur while conducting the research or follow-up.

3.11 The Investigator will assure that adverse device effects or unanticipated problems to participants or others are reported to the IRB as required under policies for reporting Adverse Events (AE’s) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO’s) (Policy #7.002).

3.12 The Investigator will assure the device is only used under his/her direct supervision and will discard or ship all unused devices back to the sponsor as specified by the sponsor.

3.13 The Investigator will notify the IRB of study closure or completion of the study and return all unused products per the sponsor's instructions.

3.14 The Investigator will submit the final report as required within three months of termination or completion of study.

4.0 IRB Committee Responsibilities

4.1 Device studies that are exempt from the IDE requirement must go to full committee for initial evaluation. Such device studies are not eligible for waiver of consent. The IRB will complete the IRB checklist for drugs or devices without an IND or IDE as part of its review of studies involving drugs or devices without an IND or IDE.

4.2 Both significant and non-significant risk device studies must go to full Committee for quorum review and approval. The IRB Committee is responsible for reviewing and determining whether it is in agreement with the sponsor's determination of
non-significant risk. See section 3.3 above for information to be submitted by the Investigator that may assist the IRB in evaluating the risk of the study. The IRB may also consult with the FDA for its opinion. The risk determination should be based on the proposed use of the device in an investigation, and not on the device alone. In deciding if a study poses a SR, an IRB must consider the nature of the harm that may result from the use of the device.

Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device. Two examples follow:

- The study of a pacemaker that is a modification of a commercially-available pacemaker poses a SR because the use of any pacemaker presents a potential for serious harm to the subjects. This is true even though the modified pacemaker may pose less risk, or only slightly greater risk, in comparison to the commercially-available model. The amount of potential reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing whether the study can be approved.

- The study of an extended wear contact lens is considered SR because wearing the lens continuously overnight while sleeping presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR.

4.3 When the sponsor and the IRB agree that the investigational device is of non-significant risk, the initial review and approval by the IRB may proceed under full IRB Committee review. Once the SR/NSR decision has been reached, the IRB should consider whether the study should be approved or not. The criteria for deciding if SR and NSR studies should be approved are the same as any other FDA regulated study. To assure that the risks to the subject are reasonable in relation to the anticipated benefits, the risks and benefits of the investigation should be compared to the risks and benefits of alternative devices or procedures. This differs from the judgment about whether a study poses a SR or NSR which is based solely upon the seriousness of the harm that may result from the use of the device.

Research involving the use of a Non-significant Risk (NSR) device must be conducted in accordance with the “abbreviated” requirements of the FDA as described in the FDA regulations 21 CFR § 812.2(b).
4.4 When the sponsor determines the investigational device to be of a non-significant risk and the WVU IRB disagrees, the proposed research is to be deferred by the full IRB Committee. The IRB will draft a letter of deferral and request that the Investigator contact the sponsor and notify them of the Committee’s determination. The sponsor or the Investigator may withdraw the study and not submit the investigational device to the FDA for consideration of an IDE.

It is the Investigator’s responsibility to notify the Sponsor of the SR decision made by the IRB Committee if this occurs.

4.5 In the event that the FDA rules that the investigational device is a significant risk device after the sponsor and the WVU IRB have determined the investigational device to be a non-significant risk device, the IRB will suspend the currently approved study detailing criteria for suspension.

- The study may not reopen until an IDE is granted by the FDA and the study is reviewed by the full Committee with appropriate changes to the IRB application, protocol and/or informed consent documents.

- The Committee must direct the Investigator on the issue of re-consenting participants, if appropriate.

4.6 The IRB must be confident that the investigator understands all relevant federal and local policies and procedures related to the use of medical devices. The IRB will request that the investigator who will utilize the device meet with the IRB staff for a session on the “Rules and Regulations Concerning Use of Medical Devices” unless the IRB is satisfied that the physician is experienced and knowledgeable. It is expected that all members of the physician’s team who will be playing a major role in the use of the HUD will also plan to attend this session if determined necessary by the IRB. After completing the course successfully, the IRB staff will notify the IRB that the physician is qualified to conduct the studies with the medical device. When West Virginia University or an individual assumes the sponsor function, the individual assuming responsibility of the sponsor function must provide evidence to the convened IRB that he/she is knowledgeable about the additional regulatory requirements of sponsor and has followed them.

4.7 The IRB will request that the investigator provide information on the use of the medical device at the time of continuing review unless a serious adverse device effect occurs prior to that time. The IRB may determine that a continuing protocol be submitted at three-month intervals or even sooner if there are concerns about human subject safety. The IRB will also request information on the number of times the device has been used, any problems associated with its use, any information received by the sponsor or the FDA concerning the use of the device at any other sites. The IRB may, at its discretion, decide after reviewing one or more continuing requests, decide that an interval different from
the initial interval (i.e., annually, semiannually, monthly, etc) would be more appropriate for a particular protocol.

5.0 Exemptions from IDE requirements
A device can be exempt from the FDA IDE requirements. A claim that the device is exempt must reference the FDA exemption category being claimed. There are seven FDA exemption categories that may be claimed. The first two categories pertain to devices that were either manufactured before 1976 or similar products manufactured after 1976. Categories 3 and 4 are the most commonly applied for exemptions. Categories 5 and 6 are pertinent to the use of devices in animals. Category 7 pertains to custom devices and is rarely utilized. Full information regarding the seven exemption categories that may be claimed can be found in FDA regulations 21 CFR §812.2(c).

The exemption category most commonly claimed is 21 CFR §812(c)(3). In addition to the sponsor’s compliance with applicable requirements in 21 CFR §809.10(c), the device testing must comply with the following:
- 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 of the diagnosis by another, medically established diagnostic product or procedure.

Another common exemption category claimed is 21 CFR §812(c)(4). To qualify for this exemption, the device testing must not be for the purposes of determining safety and effectiveness and must not put subjects at risk. The device testing must be limited to the following:
- Consumer preference testing;
- Testing of a modification; or
- Testing of a combination of two or more devices in commercial distribution.

It is the sponsor’s responsibility to provide sufficient justification to support the exemption category being claimed.

An exemption from the IDE requirement is not an exemption from the requirement for prospective IRB review or informed consent.

Research with the use of an investigational device must be conducted under all WVU IRB applicable policies and procedures.
6.0 Advertising or Recruitment for Studies that Involve an IDE

Advertisements or recruiting tools must not include the term "new treatment", without explaining that the IDE is "investigational, meaning non-FDA approved". A phrase such as "receive new treatment" implies that all study subjects will be receiving newly marketed products of proven worth. It is not a treatment since its effectiveness has not been proven or established. The term "new" is misleading as it gives the participant hope of a new intervention when the outcome is unknown. This could be viewed as coercive.

In addition, advertisements or recruiting tools must not include the promise of "free medical treatment" when the intent is only to say that participants will not be charged for taking part in the investigation or experimental intervention (e.g. device). The use of the word "free" could be viewed as coercive as it may entice someone to participate in a study for the perceived benefits.

7.0 Informed Consent in Research that Involves an IDE

Informed consent must meet the requirements outlined in the IRB Informed Consent policies and procedures (See Policies 4.001 to 4.009). In addition,

No claims are to be made which state or imply, directly or indirectly, that the IDE is safe or effective for the purposes under investigation or that the device is in any way superior to any other device;

The informed consent document must contain a statement that the IDE is "investigational, meaning non-FDA approved";

The informed consent document must contain a statement that the FDA may have access to the participant's medical records as they pertain to the study; and

The Investigator must ensure that throughout the consenting process and study participation the participant understands that the IDE is experimental, and that its benefits for the condition under study are unproven.

8.0 Additional Reporting Requirements

Devices may have an unanticipated adverse device effect to participants or others. An investigator must submit to the sponsor and to the WVU IRB a report of any unanticipated adverse device effect to participants or others occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. Should the IRB determine that the new information gained in the adverse effect report changes its risk assessment, the IRB has the ability to reconsider its prior NSR decision and ask for FDA review.

A sponsor must immediately conduct an evaluation of any unanticipated adverse device effect to participants or others.

- A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects must terminate or suspend all investigations or parts
of investigations presenting that risk as soon as possible. Termination or suspension must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect.

- If the device is a significant risk device, a sponsor may not resume a terminated or suspended investigation without IRB and FDA approval. If the device is not a significant risk device, a sponsor may not resume a terminated or suspended investigation without IRB approval and, if the investigation was terminated or suspended for an unanticipated adverse device effect that presented an unreasonable risk to participants or others, FDA approval.

Within 3 months after termination or completion of the investigation or the Investigator's part of the investigation, the Investigator must submit a final report to the sponsor and the WVU IRB.
Investigational Unlicensed Test Article

1.0 Definitions

1.1 Case Histories: These include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including progress notes of the physician, the subject’s hospital chart(s), and the nurses’ notes.

1.2 Food and Drug Administration (FDA): The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation’s food supply, cosmetics, and products that emit radiation. The FDA is responsible for advancing the public health by helping to speed innovations that make medicines and food more effective, safer, and more affordable. The FDA is also responsible for helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

1.3 Investigational Use: A substance in any clinical stage of evaluation which has not been released by the FDA for general use or cleared for sale in interstate commerce. An investigational drugs may also be defined by one of the following:

- A drug in any of the clinical stages of evaluation (Phase I, II, and III) which has not been released by the FDA for general use or cleared for sale in interstate commerce.

- A new dosage form or method of administration.

- A commercially available drug which contains a new component such as an excipient or coating.

- A new combination of two or more commercially available drugs.

- A combination of commercially available drugs in new proportions.
1.4 **Investigational Biologic:** Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries which has not been released by the FDA for general use or cleared for sale in interstate commerce. Biological products are made from living organisms derived from living material – human, plant, animal, or microorganism.

1.5 **Investigational Device:** Any healthcare product that does not achieve its primary intended purposes by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

1.6 **Investigational or unlicensed test articles:** A new drug or biologic that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. Test articles may include:
- Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
- Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency of administration).

1.7 **Investigational New Drug (IND):** FDA granting of permission that a new drug, agent, or biologic may be used in humans prior to FDA review of clinical data that has determined that a particular product is safe and effective for a specific use. The FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

Some uses of drugs are exempt from the requirement for an IND. These are summarized in 21 CFR 312.2(b) Exemption. They include use of drugs lawfully marketed in the United States some uses not intended to be reported to the FDA in support of a New Drug Application.

1.8 **Investigational Device Exemption:** A FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device. Additional information on IDEs is presented in Policy #3C.005.

1.9 **Sponsor-investigator:** An individual who both initiates and actually conducts, alone or with others, a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a participant). The term does not include any person other than an individual (e.g.,
it does not include a corporation or agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

1.10 **Drugs or devices without an IND or IDE:** For those studies that do not require an IND or IDE, the IRB must determine that the IRB is in compliance with relevant federal regulations. The IRB must complete all questions in Document 210 bb, “Checklist for drugs or devices without an IND or IDE”.

2.0 **Policy**

It is the policy of West Virginia University Institutional Review Board (IRB) that the use of all Investigational Agents be reviewed and approved for use in accordance with the federal regulations. The relevant federal regulations for drugs are 21 CFR § 312 and §314; for devices, 21 CFR §812 and §814. For biologics, the regulations are 21 CFR §600 and §601.

The West Virginia University IRB will not approve any protocol involving an investigational drug or an investigational device without an IND # (for drugs) and/or IDE # (for devices), unless the FDA approved exemptions to these requirements are met. The IRB requires that the investigator provide a valid IND # or a valid IDE # prior to initial evaluation of the protocol. The investigator must submit evidence from the sponsor of a valid IND when the protocol is initially submitted.

Investigators must list all drugs being used in the research.
- For each drug, the investigator must:
  - Provide the IND number.
  - Indicate that the drug is exempt from the requirement for an IND number.
- For each drug with an IND number, the investigator must provide verification of the IND number in terms of one of the following:
  - Commercial sponsor protocol with the IND number.
  - Communication from the commercial sponsor.
  - Communication from the FDA.
  - The investigator brochure is not to be used to determine validity of an IND.

The investigators must list all medical devices being evaluated for safety or efficacy in the research.
- For each device the investigator must:
  - Provide the IDE number.
  - Indicate that the device meets the abbreviated requirements for an IDE (non-significant risk device.)
  - Indicate that the device is exempt from the requirement for an IDE number.
- For each device with an IDE number, have the investigator provide verification of the IDE number in terms of one of the following:
  - Commercial sponsor protocol with the IND number.
  - Communication from the commercial sponsor.
  - Communication from the FDA.
The investigator brochure is not to be used to determine validity of an IDE number.

When research involves a drug with an IND or device with an IDE, it is the responsibility of the Office of Research Integrity and Compliance staff to confirm that the IND or IDE number is valid. The IRB staff should compare the IND or IDE to the sponsor protocol, written communication from the sponsor, or written communication from the FDA. The investigator brochure is not to be used to determine validity of an IND or IDE numbers.

The investigator has clearly defined responsibilities for conducting drug, device, or investigational biologics based on FDA regulations. The investigator needs to be familiar with all appropriate federal regulations. For this reason, relevant FDA regulations are provided in the following sections.

When West Virginia University or an individual assumes the sponsor function, the individual assuming responsibility of the sponsor function must provide evidence to the convened IRB that he/she is knowledgeable about the additional regulatory requirements of the sponsor and has followed them.

3.0 Investigator responsibilities for drug studies
An investigator is responsible for: (21 CFR §312.60)

• Ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations.

• Protecting the rights, safety, and welfare of subjects under the investigator’s care.

• The control of drugs under investigation.

An investigator shall administer the drug only to participants under the investigator’s personal supervision or under the supervision of a sub-investigator responsible to the investigator (21 CFR §312.61).

The investigator shall not supply the investigational drug to any person not authorized under this part to receive it (21 CFR §312.61).

An investigator is required to maintain adequate records for the disposition of the drug, including dates, quantity, and use by participants (21 CFR §312.62).

If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.

An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each
individual administered the investigational drug or employed as a control in the investigation (21 CFR §312.62).

The case history for each individual shall document that informed consent was obtained prior to participation in the study.

An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified (21 CFR §312.62).

The investigator shall furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained. The sponsor is required under §312.33 to submit annual reports to FDA on the progress of the clinical investigation.

An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately (21 CFR §312.64).

An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator’s participation in the investigation.

The clinical investigator shall provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under part 54 of this chapter. The clinical investigator shall promptly update this information if any relevant changes occur during the course of the investigation and for one year following the completion of the study (21 CFR §312.64).

An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study (21 CFR §312.66).

The investigator shall also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human participants or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human participants.

An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 21 CFR §312.62.
The investigator is not required to divulge participant names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution (21 CFR §312.69).

4.0 Investigator responsibilities for device studies.
See Policy #3C.005 for a thorough discussion of the use of experimental devices.
Investigational Drugs – Storing, Handling, and Dispensing

1.0 Policy
It is the policy of the West Virginia University Institutional Review Board (IRB) that all investigational drugs, agents, and/or biologics used in human subjects research be stored, handled, and dispensed in accordance with governing regulations and Institutional policy.

2.0 Storage of Investigational Drugs, Agents, or Biologics
2.1 It is the responsibility of the investigator to comply with all institutional, state, and Federal regulations in regards to storage of investigational drugs, agents, or biologics.

2.2 Investigational drugs, agents, or biologics used in the context of research may be stored in areas, other than the West Virginia University Hospitals, Inc. (WVUH) Department of Pharmaceutical Services, under the direct supervision of the investigator and in accordance with the sponsor, if applicable.

All investigational drugs in use at West Virginia University Hospitals, Inc. and the Cancer Center are received, stored, distributed, and controlled by the Department of Pharmaceutical Services and are used only under the direct supervision of the authorized principal investigator(s).

Controlled substances must be stored by the WVUH inpatient or outpatient pharmacy.

2.3 Investigational agent storage facilities outside of the WVUH inpatient or outpatient pharmacy must be in compliance with institutional, state, Federal (FDA), and Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirements. The WVUH Department of Pharmaceutical Services will inspect the storage facility on a quarterly basis.
3.0 Dispensing of Investigational Drugs, Agents, or Biologics

3.1 All investigational drugs, agents, or biologics administered to inpatients should be dispensed through the WVUH Department of Pharmaceutical Services.

3.2 If the WVUH inpatient or outpatient pharmacy is not utilized for the dispensing of investigational drugs, agents, or biologics, it is the responsibility of the Investigator to assure that dispensing is in accordance with all Institutional, State, Federal, and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requirements.

3.3 The WVUH inpatient or outpatient pharmacy must prepare and dispense controlled substances for all inpatients and outpatients.

3.4 Intravenous drugs must be prepared by the WVUH Department of Pharmaceutical Services. The WVUH Department of Pharmaceutical Services must prepare and dispense such medications for all inpatients and outpatients.

3.5 Compounding of oral medications must be handled by the WVUH inpatient or outpatient pharmacy. The WVUH inpatient or outpatient pharmacy must prepare and dispense such medications for all inpatients and outpatients.

4.0 Investigation Issues
Investigations of issues related to the potential mishandling of investigational drugs, agents, or biologics will be conducted by the IRB.

5.0 Investigator Requirement
Investigators who control their own investigational drugs are required to take the CITI GCP (Good Clinical Practice) Continuing Education course, or equivalent training.