5.1 Criteria for WVU IRB Approval

The WVU IRB must determine that the following requirements are satisfied to approve human subjects research:

1. Risks to participants are minimized:
   a. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and
   b. Whenever appropriate, by using procedures currently being performed on the participants for diagnostic or treatment purposes

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the WVU IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the participant(s) would receive even if not participating in the research). The WVU IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall with the purview of its responsibility.

3. The selection of participants is equitable. The WVU IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the unique problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, following, and to the extent required by the Federal Regulations.

5. Informed consent will be appropriately documented, following, and to the extent required by the Federal Regulations.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the project to protect the rights and welfare of these participants.

The following criteria must be satisfied for each review (initial, continuing, and modifications) for both expedited review and review by the convened WVU IRB.

5.1.1 Risk/Benefit Assessment

The goal of the assessment is to ensure that the risks to research participants posed by
participation in the research are justified by the anticipated benefits to the participants or society.

Toward that end, the WVU IRB must:

- Judge whether the anticipated benefit, either of new knowledge or improved health for the research participants justifies asking any person to undertake the risks;
- Disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of the proposed research – one of the significant responsibilities of the WVU IRB – involves a series of steps:

1. **Identify the risks** associated with the research, as distinguished from the risks of standard procedures the participants would receive even if not participating in research;
2. **Determine whether the risks will be minimized** to the fullest extent possible;
3. **Identify the probable benefits** to be derived from the research;
4. **Determine whether the risks are reasonable in relation to the benefits** to participants if any, and assess the importance of the knowledge to be gained;
5. **Ensure that potential participants will be provided with an accurate and fair description** of the risks or discomforts and the anticipated benefits.

Risks to participants are minimized:

1. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and
2. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

Risks to participants are reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the WVU IRB should consider only those risks and benefits that may result from the research - as distinguished from risks and benefits of procedures participants would receive even if not participating in the research.

The WVU IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

5.1.1.1 Scientific Merit

To assess the risk and benefits of the proposed research, the WVU IRB must determine that:

- The research uses procedures consistent with sound research design;
- The research design is sound enough to expect the research to answer its proposed question reasonably; and
- The knowledge expected to result from this research is sufficiently essential to justify
the risk

The WVU IRB may rely on its knowledge and disciplinary expertise, or the WVU IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency or departmental review to make a determination. When a scientific review is conducted by an individual or entity external to the WVU IRB, documentation must be provided to the WEV IRB addressing the above items.

Departmental scientific review is documented by the administrative official responsible for the PI’s research unit providing a signature.

5.1.1.2 Adequate Resources

To approve research, the WVU IRB determines that research studies have the resources necessary to protect participants, such as:

- Adequate time for the researchers to conduct and complete the research
- Adequate number of qualified staff
- Adequate facilities
- Access to a population that will allow recruitment of the necessary number of participants
- Availability of medical or psychosocial resources that participants might need as a consequence of the research

5.1.2 Equitable Selection of Participants

The WVU IRB determines that the selection of participants is equitable concerning gender, age, class, etc. by viewing the submitted WVU IRB application, protocol, and/or other research project materials. The WVU IRB will not approve a project that does not provide adequately for the equitable selection of participants or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research. In making this determination, the WVU IRB evaluates:

1. The purpose of the research;
2. The setting in which the research occurs;
3. The scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
4. The scientific and ethical justification for excluding classes of persons who might benefit from the research;
5. And the inclusion and exclusion criteria.

At the time of the continuing review, the WVU IRB will determine that the PI has followed the participant selection criteria that he/she initially established at the time of the initial WVU IRB review and approval.
5.1.2.1 Recruitment of Participants

The PI will provide the WVU IRB with all recruiting materials to be used in identifying participants, including recruitment methods, advertisements, and payment arrangements. See Section 3.7.7 for a discussion of WVU IRB review of advertisements. See Section 3.7.8 for a discussion of WVU IRB review of payments.

5.1.3 Informed Consent

The WVU IRB will ensure that informed consent will be sought from each prospective participant or the participant’s legally authorized representative, following, and to the extent required by 45 CFR 46.116 and 21 CFR 50.20. Also, the Committee will ensure that informed consent will be appropriately documented following, and to the extent required by 45 CFR 46.117 and 21 CFR 60.27. See Section 5 for detailed policies on informed consent.

5.1.4 Safety Monitoring

For all research that is more than minimal risk, the PI may submit a safety monitoring plan. The initial plan submitted to the WVU IRB should describe the procedures for safety monitoring, reporting of unanticipated problems involving risks to participants or others, descriptions of interim safety reviews, and the procedures planned for transmitting the results to the WVU IRB. This description should include information regarding an independent Data and Safety Monitoring Board (DSMB) if one exists, or an explanation of why an independent data safety monitor is not necessary.

The WVU IRB determines that the safety monitoring plan makes adequate provision for monitoring the reactions of participants and the collection of data to ensure the safety of participants. The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the research project. The method and degree of monitoring needed are related to the degree of risk involved. Monitoring may be conducted in various ways or by multiple individuals or groups, depending on the size and scope of the research effort. These exist on a continuum from monitoring by the principal PI in a small, low-risk project to the establishment of an independent data and safety monitoring board for a large phase III clinical trial.

The factors the WVU IRB will consider in determining whether the safety monitoring plan is adequate for the research are as follows:

1. Monitoring is commensurate with the nature, complexity, size, and risk involved.
2. Monitoring is timely. Frequency should be commensurate with risk. Conclusions are reported to the WVU IRB.
3. For low-risk studies, continuous, close monitoring by the project PI or an independent individual may be an adequate and appropriate format for monitoring, with prompt reporting of problems to the IR, sponsor, and regulatory bodies, as appropriate.
4. For an individual Safety Monitor, the plan must include:
   a. Parameters to be assessed
   b. A mechanism to assess the critical efficacy endpoints at intervals to determine when to continue, modify or stop a project
   c. Frequency of monitoring
d. Procedures for reporting to the WVU IRB

5. For a Data Safety Monitoring Board, the plan must include:
   a. The name of the Data Safety Monitoring Board
   b. Where appropriate, the Board is independent of the sponsor
   c. Availability of written reports
   d. Composition of the monitoring group (if a group is to be used). Experts in all scientific disciplines need to interpret the data and ensure patient safety should be included. Examples include clinical trial experts, biostatisticians, bioethicists, and clinicians knowledgeable about the disease and treatment under the project.
   e. Frequency and content of meeting reports
   f. The frequency and character of monitoring meetings (e.g., open or closed, public or private)

   In general, it is desirable for a Data, and Safety Monitoring Board (DSMB) to be established by the project sponsor for research that is blinded, involves multiple sites, involves vulnerable participants, or employs high-risk interventions. For some research projects, the National Institutes of Health (NIH) require a DSMB. The WVU IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed.

   When DSMBs are used, WVU IRBs conducting a continuing review of research may rely on a current statement from the DSMB indicating that it has and will continue to review project-wide AEs, interim findings, and recent literature that may be relevant to the research, instead of requiring that this information be submitted directly to the WVU IRB. After the Board has determined whether a Data Safety Monitoring Plan is required for a given sponsored research project, the Office of Sponsored Programs will be contacted with this information and the timelines involved.

5.1.5 Privacy and Confidentiality

The WVU IRB will determine whether adequate procedures are in place to protect the privacy of participants and to maintain the confidentiality of the data.

5.1.5.1 Privacy

The WVU IRB must determine whether the activities in the research constitute an invasion of privacy. To make that determination, the WVU IRB must obtain information regarding how the PIs access participants and participants’ private, identifiable information. The WVU IRB must also consider the participant’s expectations of privacy in the situation. PIs must have appropriate authorization to access the participants or the participants’ information.

In developing strategies for the protection of participants’ privacy, consideration should be given to:

1. Methods used to identify and contact potential participants
2. Settings in which an individual will be interacting with an PI
3. Appropriateness of all personnel present for research activities
4. Methods used to obtain information about participants and the nature of the requested information

5. Information that is obtained about individuals other than the “target participants,” and whether such individuals meet the regulatory definition of “human participant” (i.e., a participant provides information about a family member for a survey)

5.1.5.2 Confidentiality

Confidentiality and anonymity are not the same. If anyone, including the PI, can readily ascertain the identity of the participants from the data, then the research is not anonymous, and the WVU IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure.

At the time of the initial review, the WVU IRB ensures that the privacy and confidentiality of research participants are protected. The WVU IRB assesses whether there are adequate provisions to protect participant privacy and maintain confidentiality. The WVU IRB does this through the evaluation of the methods used to obtain information:

- About participants;
- About individuals who may be recruited to participate in studies;
- The use of personally identifiable records; and
- The methods to protect the confidentiality of the research data.

The PI will provide the information regarding the privacy and confidentiality of research participants at the time of initial review through the completion of the application, any necessary HIPAA Forms, research protocol, and/or other submitted, relevant materials.

The WVU IRB will review all information received from the PI and determine whether or not the privacy and confidentiality of research participants are sufficiently protected. In some cases, the WVU IRB may also require that a Certificate of Confidentiality be obtained from the NIH to protect research data.

In reviewing confidentiality protections, the WVU IRB will consider the nature, probability, and magnitude of harms that would be likely to result from disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

5.1.6 Vulnerable Populations

At the time of the initial review, the WVU IRB will consider the scientific and ethical reasons for including vulnerable participants in research. The WVU IRB may determine and require that, when appropriate, additional safeguards are put into place for vulnerable participants, such as those without decision-making capacity.
5.2 Additional Considerations for WVU IRB Approval

5.2.1 Determination of Risk

At the time of initial and continuing review, the WVU IRB will make a determination regarding the risks associated with the research protocols. Risks associated with the research will be classified as either "minimal" or "greater than minimal." The meeting minutes will reflect the Committee’s determination regarding risk levels.

5.2.2 Period of Approval

At the time of the initial review and for continuing review, the WVU IRB will make a determination regarding the frequency of review of the research protocols. All protocols will be reviewed by the WVU IRB at intervals appropriate to the degree of risk but no less than once per year. In some circumstances, a shorter review interval (i.e., biannually, quarterly, or after the accrual of a specific number of participants) may be required (see below). The meeting minutes will reflect the WVU IRB's determination regarding review frequency.

New Common Rule

*IRB can override this default and conduct continuing review but must justify and document the reason.

Expedited reviews for WVU studies will be every two (2) years.

Exempt reviews will be every five (5) years.

5.2.2.1 Review More Often than Annually

Unless waived by the WVU IRB, research that meets any of the following criteria will require review more than annually:

1. Significant risk to research participants (i.e., death, permanent or long-lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants.

2. The involvement of especially vulnerable populations likely to be a participant to coercion (i.e., terminally ill).

3. A history of serious or continuing non-compliance on the part of the PI.

The following factors will also be considered when determining which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to participants.

2. The likely medical condition of the proposed participants.

3. The overall qualifications of the PI and other members of the research team.

4. The specific experience of the responsible PI and other members of the research team in conducting similar research.

5. The nature and frequency of adverse events observed in similar research at this and
other institutions.

6. The novelty of the research making unanticipated adverse events more likely.

7. Any other factors that the WVU IRB deems relevant.

In specifying an approval period of less than one year, the WVU IRB may define the period with either a time interval or a maximum number of participants either studied or enrolled. If a maximum number of participants enrolled is used to define the approval period, it is understood that the approval period in no case can exceed one year and that the number of participants enrolled determines the approval period only when that number of participants enrolled in less than one year. If the WVU IRB specifies an approval period of less than one year, the reason for more frequent review must be documented in the minutes.

5.2.3 Independent Verification That No Material Changes Have Occurred

The WVU IRB recognizes that protecting the rights and welfare of participants sometimes requires that the WVU IRB verify independently, utilizing sources other than the PI that no material changes occurred during the WVU IRB-designated approval period. Independent verification from sources other than the PI may be necessary at times, for example, in cooperative studies, or other multi-center research.

The WVU IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

1. Protocols where concern about possible material changes occurring without WVU IRB approval have been raised based on information provided in continuing review reports or from other sources.

2. Protocols conducted by Principal PIs who have previously failed to comply with federal regulations and/or the requirements or determinations of the WVU IRB.

3. Protocols participant to internal audit.

4. Whenever else, the IRD deems verification from outside sources is relevant.

The following factors will also be considered when determining which studies require independent verification:

1. The probability and magnitude of anticipated risks to participants.

2. The likely medical condition of the proposed participants.

3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making determinations about independent verification, the WVU IRB may prospectively require that such verification take place at predetermined intervals during the approval period or may retrospectively require such verification at the time of continuing review, review of amendments, and/or unanticipated problems.

If any material changes have occurred without WVU IRB review and approval, the WVU IRB will decide the corrective action to be taken.
5.2.4 Consent Monitoring

In reviewing the adequacy of informed consent procedures for the proposed research, the WVU IRB may determine that special monitoring of the consent process by an impartial observer (consent monitor) is required to reduce the possibility of coercion and undue influence.

Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action where the WVU IRB has identified problems associated with a particular PI or a research project.

5.2.5 PI Conflicts of Interest

The research application asks protocol-specific questions regarding conflict of interest for the PIs and key personnel. As part of its review process, the WVU IRB and the CIRC (Conflict of Interest Research Committee) will make a determination as to whether a conflict of interest exists concerning the research under review. If a conflict of interest exists, final WVU IRB approval of a protocol cannot be given until an approved conflict management plan that adequately protects the human participants in the protocol is in place (see Section 14 for a detailed discussion of Conflict of Interest).

5.2.7 Advertisements

The WVU IRB will review:

- The information contained in the advertisement
- The mode of its communication
- The final copy of printed advertisements
- The final audio/video taped advertisements
- The final version of emails and social media postings

The WVU IRB will also review the recruitment material to assure that it is accurate and not coercive or unduly optimistic, creating undue influence on the participant to participate, which includes, but is not limited to:

1. Statements implying a certainty of a favorable outcome or other benefits beyond what was included in the consent document and the protocol.
2. Claims, either explicitly or implicitly, that the drug, biologic, or device was safe or effective for the purposes under investigation.
3. Claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic, or device.
4. Claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are consistent with the FDA labeling.
5. Using terms like "new treatment," "new medication," or "new drug" without explaining that the test article was investigational.
6. Promising "free medical treatment" when the intent was only to say participants will
not be charged for taking part in the investigation.

7. Emphasis on payment or the amount to be paid, such as bold or underlined text, larger fonts, or different colored text printed on media.

8. The inclusion of exculpatory language. Any advertisement to recruit participants should be limited to the information the prospective participant(s) need to determine their eligibility and interest.

9. Advertisements cannot include an offer of compensation by the sponsor for participation in a trial that involves a coupon for a discount on the purchase price of the product once it has been approved for marketing.

When appropriately worded, the following items must be included in the recruitment advertisements:

1. The name and address of the clinical PI and/or the research facility.
2. The condition being studied and/or the purpose of the research.
3. In summary form, the criteria that will be used to determine eligibility for the project.
4. The time or other commitment required of the participants.
5. The location of the research and the person or office to contact for further information.
6. A clear statement that this is research and not treatment.
7. A brief list of potential benefits (i.e., no-cost health exam).
8. A statement that WVU IRB approval is on file. Exempt studies should have a statement that WVU IRB acknowledgment is on file.

5.2.8 Payment to Research Participants

Payment to research participants may be an incentive for participation or a way to reimburse a participant for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, PIs must take care to avoid coercion of participants.

Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the project. PIs who wish to pay research participants must indicate in their research protocol application the justification for such payment. Such justification should:

1. Substantiate that proposed statements are reasonable and commensurate with the expected contributions of the participant;
2. State the terms of the participant participation agreement and the amount of payment in the informed consent form; and
3. Substantiate that participant payments are fair and appropriate and that they do not constitute (or appear to constitute) undue pressure on the veteran patient to volunteer for the research project.

The WVU IRB must review both the amount of payment and the proposed method of
disbursement to assure that neither entails problems of coercion or undue influence. The WVU pre-
paid card payment system must be used. Refer to the WVU Procurement website for the policy.

Credit for payment should accrue and should not be contingent upon the participant completing
the entire project. The WVU IRB does not allow the entire payment to be contingent upon
completion of the entire project. Any amount paid as a bonus for completion of the entire project
should not be so great that it becomes coercive.

The consent form must describe the terms of payment and the conditions under which
participants would receive partial payment or no payments (e.g., if they withdraw from the project
before their participation is completed).

The consent form must inform participants that they will be asked to provide their Social
Security Number and verification of U.S Citizenship or Permanent Resident Status to receive
payment. For confidential projects, only the participant name and address are required, the PI must
keep an identity secure.

5.2.9 Compliance with all Applicable State and Local Laws

The WVU IRB follows and must adhere to applicable state and local laws in the jurisdictions
where the research is taking place. The HRPP and the WVU IRB rely on the WVU General Counsel
for the interpretation and application of West Virginia State law and the laws of any other
jurisdiction where research is conducted as they apply to human participants research.

All consent forms must be consistent with applicable state and local laws.

5.2.10 Deception in Research

Deception occurs as a result of PIs providing false or incomplete information to participants. The WVU
IRB accepts the need for certain types of behavioral and social science studies to employ strategies that
include deception. Employment of such strategies must, however, be justified. In general, deception is not
acceptable if, in the judgment of the WVU IRB, the participant may have declined to participate had they
been informed of the real purpose of the research. Studies that use deception as part of their experimental
design must meet all the requirements of 45 CFR §46.116(d), described below, and include a post-project
debriefing unless the WVU IRB grants an exception. If such an exception is requested, this will require a
full board review.

If a project includes the use of deception, the PI must:

Justify the deception (e.g., why the project could not be conducted without deception);

Describe the manner of deception (e.g., the participants are not informed of the real intent of the project)
and/or how the deception will take place (e.g. an associate will simulate an accident);

Note whether the deception results in any increased risk to participants (e.g. associates engage in a staged
altercation, which could result in emotional upset) or the effect of the deception on a participant’s
willingness to participate in research;
Describe how any additional risks would be minimized; and

Offer the participant the option to withdraw their data from the project in the debriefing script.

5.2.11 Incidental Medical Findings during Research Studies

An incidental finding (IF) is defined as an unexpected finding concerning an individual research participant that has potential health or reproductive importance discovered in the course of conducting research, but that is beyond the aims of the project. IFs are an increasingly common byproduct of research using powerful technologies that generate "extra" data, particularly in imaging studies and genetic studies.

Since it is not the purpose of the research to look for incidental findings, the researcher may not be capable of verifying that a potential IF is clinically essential. In the case of imaging studies, the parameters of the project may not be optimal for detecting or verifying potential lesions. Before a participant is informed about an IF, it is necessary that the PI establish whether the IF is medically essential. To accomplish this, it may be necessary to consult with a radiologist in the case of imaging studies. In the case of a genetic IF, verification from a genetics laboratory approved to perform clinical tests under the Clinical Laboratory Improvements Amendments (CLIA) may be required.

There are specific research areas that have reported high rates of incidental findings. Among these are genetic family studies where genetic variants may be identified that may cause or increase susceptibility to phenotypic disease or disability, or where the researchers may discover misattributed paternity or other misattributed lineage. Another area would be MRI studies of the brain or elsewhere in the body where masses, various anatomical malformations, evidence of cranial bleed or stroke, evidence of infection, evidence of injury, and evidence of dementia may be discovered. An area of increasing IFs is that of CT colonography research where anatomical malformations, masses, aneurysms, evidence of infection, and evidence of injury or trauma may be seen.

The reanalysis of archived data is an overlooked source of IFs. Archived data may consist of genetic data or imaging data that may yield the evidence of IFs, when reevaluated in the future. In some cases, archived data is truly anonymous, and the participant cannot be identified. In other cases, however, the identity of the participant can be ascertained, and the participant may be contacted, if necessary. If the IFs are such that potential clinical benefits to participants are likely, all reasonable effort should be made to contact participants.

These are not the only sources of incidental findings. Social and behavioral research may reveal evidence of alcoholism, drug abuse, mistreatment, or mental illness when these are not the objectives of the project. In many cases, if these findings are discovered, the PI must report the evidence to local authorities.
In summary, any type of research may reveal incidental findings that might or might not affect the health and welfare of the potential participant and must, therefore, be considered by the PI and the WVU IRB. Since this is the case, the policy for West Virginia University must be broad enough to cover most of the possibilities, but not be so cumbersome as to be useless.

The first question that must be asked is: should all incidental findings be discussed with the participants? Although some institutions take this stance, it appears that most do not. Because the disclosure of IFs can potentially save lives but also cause alarm and other potential harm, the decision on whether or not to disclose them to research participants constitutes a significant dilemma. Researchers often stumble upon unexpected findings but have no idea whether to share this information with research participants. The information may prove highly significant or a false alarm. Current best practice distinguishes among three categories of IFs to determine if and when they should be disclosed.

IFs with substantial net benefits – ones revealing a condition likely to be life-threatening or revealing a condition likely to be grave that can be avoided should be offered to research participants as soon as practical.

IFs that offer possible net benefits – ones that may offer more benefit than burden to the research participant may be disclosed at the researcher’s discretion.

IFs that are unlikely not to have any net benefit, or whose net benefit cannot be determined, should not be offered to the research participant because disclosure may well present more burden than good.

In the case of an IF with suspected or known substantial net benefits, the following should be followed prior to the participant leaving the facility. If the IF involves a medical condition and if the researcher is not a clinician or qualified to interpret the IF, a knowledgeable physician should be contacted immediately to review the finding to determine the likelihood of net benefit. The participant should be informed by the PI (if he/she is qualified) or by the physician that was contacted by the nature of the finding. If warranted, and the participant agrees, the contacted physician should directly examine the participant. The participant should be informed that any medical information found will be sent to his/her physician (unless the participant objects).

If the participant indicates that he/she does not wish to be informed of the incidental findings, even if it is high health importance and utility, and such findings are discovered, additional considerations may be warranted. It is the policy of WVU that, without revealing the information, the researcher should attempt to confirm that the research participant indeed wants to refuse even information that may have “life or death” consequences to him/her.

If the participant indicates that he/she does not wish to be informed, the wishes of the participant should be honored. If this occurs, a notation should be made a permanent part of the participant's research record and should also be transmitted to the WVU IRB in a timely fashion.
The notification of the personal physician is the extent of West Virginia University’s responsibility in the matter. If the IF is one in which possible net benefit to the participant, the PI should consult with an appropriate clinician if the PI does not possess the necessary expertise. If it is decided that the participant should be informed, this should be done as soon as practically possible; medical information should be sent to the participant's physician (unless the participant objects). The participant should be directly informed about any non-medical information.

The researcher should send a letter detailing the procedure, with a copy being sent to the WVU OHRP.

The policy of informing (or not informing) potential participants in the event of IFs should be included in all informed consent documents in which IFs are a possibility.

It is recommended that policy, based on the above general rules, be created for separate units.

5.3 WVU Specimen Bank Policy

For purposes of this policy, the term "tissue" includes any cell tissue, fluid, or excreta from which measures of normal or pathologic human physiologic function can be obtained. The term, "tissue" includes, but is not limited to pathological specimens, diagnostic specimens, hair and nail clippings, deciduous and permanent teeth, dental plaque and calculus, sweat, uncanulated saliva, placenta removed at delivery, amniotic fluid, cerebrospinal fluid, genetic material, urine, blood, and other bodily fluids. First-trimester fetal tissue may include additional guidelines.

5.3.1 Policy

Research using human tissue can be conducted, using the normal established guidelines for WVU IRB review, as long as all tissue collected is either used for the project described or discarded. If any tissue collected as part of an approved protocol, normal operating room procedure, or from a non-university affiliated institution will be banked for future research investigations at West Virginia University or its affiliates, the PI must first register the tissue bank and then conform to the guidelines outlined in this policy for tissue banking. The policy is not directed at tissue banks that exist for other than research purposes, e.g., quality improvement or state reporting.

5.3.2 Tissue Bank Registration

PIs intending to create an on-site database or tissue bank using clinical health information or authorized tissue specimens must complete a Tissue and Data Repository form. The form can be found on the WVU OHPR website. The approved form should be submitted with the protocol application.

It is expected that proper informed consent from family members to have the decedent's tissue stored will be obtained and submitted with the registration application.
5.3.2.1 Requirements for Tissue Banking Approval

All WVU Tissue Banks must have biosafety approval from the Institutional Biosafety Committee (IBC) before the WVU IRB will approve the protocol.

Storage of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined through the IBC Guidelines.

Disposal of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined through the IBC Guidelines. This identification number assigned by the tissue bank will be the only method of linking the specimen, the Specimen Record, and the Donor Record. The Donor Record and the Specimen Record will be housed in separate files.

The Specimen Record. The Specimen Record includes demographic and medical information from the patient's medical or research record, which does not identify the patient. Variables like age (< 90), medical diagnosis, and laboratory values can be included in the Specimen Record. Variables like date of birth, hospital record number, or phone number cannot be included in the Specimen Record.

The Donor Record. Any information identifying the donor, including a copy of the approved consent agreement signed by the donor, shall be kept in the Donor Record.

Deposits of banked specimens must conform to the WVU IRB-approved guidelines for conducting research on human tissue. All specimens in a tissue bank must be accompanied by a copy of the consent agreement signed by the donor.

Removal of banked specimens or portions of banked specimens must conform to the WVU IRB guidelines for conducting research on human tissue. No tissue can be removed for research purposes without an approved WVU IRB research protocol or WVU IRB acknowledgment of a protocol involving de-identified samples.

All tissue deposited and/or removed from a tissue bank must be logged using a Tissue Bank Log which will include date and time of deposit or removal, specimen number, the approved WVU IRB protocol number, name(s) of PI(s) making the deposit or withdrawal, and name of the tissue bank personnel responsible for completing the transaction.

5.3.2.2 Monitoring of WVU IRB Approved Tissue Banks

The WVU IRB has the authority to suspend or terminate any or all research being conducted through a tissue bank that is not in compliance with WVU IRB Guidelines. Tissue banks subject to periodic audits.

5.3.2.3 Pre-Existing Specimens

The WVU IRB acknowledges that there may be specimens that were collected before the development and enforcement of the approved policy for conducting research on human tissue and that records accompanying these specimens may not comply with these WVU IRB Guidelines. Whenever possible, it is the duty of the tissue bank to bring records from pre-existing specimens into compliance with WVU IRB Guidelines (i.e., obtaining copies of consent forms to accompany specimens, separating the
Specimen Record from the Donor Record, completing a Tissue Bank Development Application to register an on-site Tissue Bank)

5.3.2.4 Grandfather Clause for Tissue Banks

All tissue deposited or removed from a tissue bank after 1 January 2011 must conform to the WVU IRB Guidelines for Tissue Banking. Any tissue banked after 1 January 2011 must conform to the WVU IRB Guidelines for removal of tissue from a tissue bank. As it may be impractical to obtain consent for many specimens deposited before 1 January 2011, the tissue bank will not be required to demonstrate evidence of informed consent for specimens collected before this date.

5.3.3 Approval of Tissue Banking Protocols

Collection and placement of human tissue into a bank for research purposes can occur after completion and approval of a protocol application. To establish an on-site Tissue Bank, the approved Tissue Bank Development Application must be attached to the WVU IRB protocol application. Human tissue, accompanied by a copy of an approved consent agreement signed by the donor, can be placed into an approved tissue bank for general research purposes.

Human tissue can be deposited as part of an approved protocol:

- Following standard operating or delivery room procedures;

- Following standard diagnostic and treatment procedures (e.g., dental extraction, collection of bodily fluids); and

- From a non-affiliated institution(s) that conforms to comparable standards for the protection of human participants.

An approved protocol is needed if human tissue is to be placed into a bank as part of an approved tissue bank protocol for general research purposes other than that outlined in the submitted protocol. A separate consent form obtaining approval of the donor must be obtained.

**Surgical Consent Form** – If human tissue obtained through standard operating or delivery room (non-research) procedures is to be placed into a bank for potential research purposes, a separate consent form obtaining the approval of the donor must be obtained in addition to the standard operating room consent form.

**Non-Surgical Consent Form** – If tissue obtained for purposes of standard medical or dental diagnostic and treatment (non-research) procedures is to be placed into a bank for potential research purposes, a separate consent form must be approved by the WVU IRB for this purpose.

For example, if a blood sample is obtained for standard clinical diagnostic purposes and then discarded without identifiers, no consent is required, unless the blood is analyzed as part of a research project before being discarded, in which case a standard approved consent form is required. If the remaining blood or
components of blood from a standard clinical diagnostic test are banked for potential research use, a
signed consent form is required.

Center for Organ Recover and Education (CORE) – if CORE is involved, their consent form may be
substituted.

5.3.4 Tissue Acquired from Non-Affiliated Institutions

If identifiable human tissue is acquired from an institution, laboratory, or company not affiliated with
West Virginia University for tissue banking for research, the tissue must be accompanied by an approved
consent agreement signed by the tissue donor.

The approved consent agreement must contain comparable language to the approved WVU tissue banking
language, assuring that the tissue can be used without additional consent as long as donor confidentiality
is maintained, that tissue can be used with participant identification with the additional consent, and that
financial considerations regarding the cost and potential financial advantage to institutions are
enumerated.

5.3.5 Removal of Tissues from an Approved Bank for Research Purposes

Human tissue can be removed from an approved tissue bank for research purposes with an approved
protocol, using the established guidelines for Not Human Participant Research (NHSR), exempt,
expedited, or full board review. All researchers must obtain WVU IRB approval for each research project
using tissue from a Tissue Bank.

NHSR – If human tissue is de-identified (stripped of all 18 Protected Health Information Identifiers) so
that the researcher cannot trace the tissue back to the donor, then it is not human participants’ research
(NHSR). The researcher must submit an NHSR application to the WVU IRB for acknowledgment.

Exempt Research – if identifiable human tissue is removed from a bank for research purposes, but the
researcher records the data without identifiers, the project qualifies as "exempt research."

Expedited or Full Board Review – if identifiable human tissue is removed from a bank for research
purposes and information is provided to the PI in such a manner that human participants can be or are
identified. The researcher uses the identifiers; the research project must follow the procedures for
Expedited Review or Full Board Review.

Tissue Sent to a Non-Affiliated Institution – If identifiable human tissue is removed from an approved
bank at West Virginia University and sent to an institution, laboratory, or company not affiliated with
West Virginia University for purposes of research, the PI must conform to the WVU IRB Guidelines for
the Protection of Human Participants by obtaining approval from their institution.
A HIPAA Data Use Agreement for Limited Data Sets form must be submitted, following approval from the WVU Legal Counsel.