1 PURPOSE
   1.1 This policy establishes the definitions followed by the human research protection program.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Addition of definition for a “systematic investigation”; replaces version dated 1/18/2013.
   2.2 Addition of definition for “clinical trial”; replaces version dated 4/1/2013.
   2.3 Addition of definition for “prisoner”; replaces version dated 8/5/13.

3 POLICY
   3.1 Adverse Event: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Include both physical and psychological harms.
   3.2 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.
   3.3 Approved: An approval is granted by the IRB if the research activity meets the criteria for approval as defined in 45 CFR 46.111 as applicable and no changes to the research application are recommended.
   3.4 Clinical Trial: A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious, and effective.
   3.5 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual’s Immediate Family have any of the following:
      3.5.1 Involvement in the design, conduct, or reporting of the research.
      3.5.2 Membership in the same Department (or in case of Department of Medicine, same Division) as the principal investigator on the study.
      3.5.3 Ownership interest, stock options, or other ownership interest Related to the Research of any value exclusive of interests in publicly-traded, diversified mutual funds.
      3.5.4 Compensation Related to the Research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research.
      3.5.5 Proprietary interest Related to the Research including, but not limited to, a patent, trademark, copyright or licensing agreement.
      3.5.6 Board or executive relationship Related to the Research, regardless of compensation.
      3.5.7 Any other reason for which the member or consultant believes that he or she cannot provide an independent review.
   3.6 Continuing Non-Compliance: A pattern of Non-Compliance that indicates a deficiency likely to result in further Non-Compliance or a circumstance in which an investigator fails to cooperate with investigating or correcting Non-Compliance.
   3.7 Deferred: The research does not meet the criteria for approval, lacks sufficient information to conduct an adequate review, or the IRB recommends revisions to the IRB Application, Protocol, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit analysis without the completed revisions.
   3.8 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct a Non-Committee Review.
   3.9 Disapproved: A study is found to be unethical, without scientific or scholarly merit and/or does not meet the criteria for approval.
3.10 **Enrollment:** A subject is considered enrolled in a study when any of the following conditions apply: 1) the subject or legally authorized representative gives consent to participate and signs a consent document; 2) in cases where written consent is waived, the subject gives verbal consent to participate in the study OR completes a research task (e.g. completion of a questionnaire, interview or survey); or 3) data on subject is collected as part of chart review for use in data analyses.

3.11 **Experienced IRB Member:** An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

3.12 **Expiration Date:** The first date that the protocol is no longer approved. The date after the end date of the approval period.

3.13 **External Adverse Event:** Adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.

3.14 **Finding of Non-Compliance:** Non-Compliance in fact.

3.15 **Generalizable knowledge:** Knowledge created to share with other people beyond an internal group, for example through publication or an article in a journal, presentation at a local or national conference or preparation of a thesis or dissertation. The process of making knowledge generalizable would include the following concepts or methods:

3.15.1 The knowledge contributes to a theoretical framework of an established body of knowledge.

3.15.2 The primary beneficiaries of the knowledge are other researchers, scholars, and practitioners in the field of study.

3.15.3 The results are expected to be generalized or applied to a larger population beyond the site or data collection.

3.15.4 The results are intended to be replicated in other settings.

3.16 **Human Research:** Any activity that either: 1

3.16.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

3.16.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.17 **Human Subject as Defined by DHHS:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

3.17.1 **Intervention:** Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.17.2 **Interaction:** Communication or interpersonal contact between investigator and subject.

3.17.3 **Private Information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

3.17.4 **Identifiable Information:** Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

3.18 **Human Subject as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

3.19 **Immediate Family:** Spouse, domestic partner; and dependent children.

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1 The terms “Human Subject Research,” “Research Involving Human Subjects,” “Human Subject Research,” “Research Involving Human Subjects,” “Clinical Research,” “Clinical Investigation,” “Clinical Study” and similar phrases are considered to be synonyms for the term **Human Research**.
3.20 **Internal Adverse Event**: Adverse events that are experienced by subjects enrolled by the investigator at his/her institution.

3.21 **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of healthy persons or during the performance of routine physical or psychological examinations or tests in healthy persons.

3.22 **Modifications Required**: The IRB Staff communicates in writing the modifications required by the IRB to a protocol. The investigator must complete the requirements, and the protocol must then be reviewed at the appropriate level.

3.23 **Non-Committee Review**: Any of the following:

3.23.1 Determination of whether an activity is Human Research.

3.23.2 Determination of whether Human Research is exempt from regulation.

3.23.3 Reviews of non-exempt research using the expedited procedure.

3.24 **Non-Compliance**: Conducting research in a manner that disregards or violates federal regulations, failure to follow the requirements and determinations of the IRB, or institutional policies and procedures applicable to human research that can be characterized by severity of the event and the pattern of like or similar events. Non-Compliance with IRB and/or federal requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more Serious Non-Compliance violations, which pose risk to subjects or others and/or violations of their rights and welfare.

3.25 **Organizational Official**: Director, Office of Research and Technology Development

3.26 **Prisoner**: An individual involuntarily confined or detained in a penal institution and encompasses individuals sentenced to such an institution under criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

3.27 **Related to the Research**: A financial interest is Related to the Research when the interest is in the:

3.27.1 Sponsor of the research;

3.27.2 A competitor of the sponsor of the research;

3.27.3 The product or service being tested; or

3.27.4 A competitor of the product or service being tested.

3.28 **Research as Defined by DHHS**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.29 **Research as Defined by FDA**: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

3.29.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

3.29.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

3.29.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.30 **Restricted**: Applies to investigators or research staff members who are delinquent in meeting IRB requirements.

3.31 **Serious Adverse Event**: Any adverse event that results in death, is life-threatening, results in inpatient hospitalization or prolongation of existing hospitalization, results in a persistent or significant disability/incapacity, results in a congenital anomaly/birth defect or based upon
appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

3.32 **Serious Non-Compliance**: **Non-Compliance** that may: adversely affect subject safety or the safety of others; increase risks to subjects; violate the rights and welfare of participants (any of which may also be an unanticipated problem). **Serious Non-Compliance** may affect the subject’s willingness to participate in research or may affect the integrity of the data (which may also be scientific misconduct).

3.33 **Suspension of IRB Approval**: An action of the IRB, IRB designee, or **Organizational Official** to temporarily or permanently withdraw IRB approval of some or all research procedures short of a **Termination of IRB Approval**. Suspended studies remain open and are subject to continuing review.

3.34 **Systematic Investigation**: An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question. Examples of *systematic investigations* include: surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, cognitive and perceptual experiments, and medical chart review studies.

3.35 **Tabled**: A study is unable to be reviewed at the meeting due to lack of time, lack of quorum, lack of IRB expertise and/or other extenuating circumstances.

3.36 **Termination of IRB Approval**: An action of the IRB or **Organizational Official** to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.37 **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 associated with a device that relates to the rights, safety, or welfare of subjects.

3.38 **Unanticipated Problem Involving Risks to Subjects or Others**: Any information that is (1) unanticipated and (2) indicates that subjects or others are at increased risk of harm.

### 4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline or a hyperlink to this policy.

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined/hyperlinked terms.

### 5 PROCEDURE

5.1 None

### 6 MATERIALS

6.1 None

### 7 REFERENCES

7.1 45 CFR §46.102.

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)