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Section: Corporate	**Policy Number:** HS-120.11	**Last Reviewed Date:** 1/15/2026
Title: Institutional Review Board (IRB)		**Page:** 1 of 32

CORPORATE ENTITY:

- ☒ All
- ☐ Alliance, Inc.
- ☐ Family Services, Inc.
- ☐ Mosaic Community Services, Inc.
- ☐ Non-Contracted Services, LLC
- ☐ Sheppard and Enoch Pratt Foundation, Inc.
- ☐ Sheppard Pratt Health System, Inc.
- ☐ Sheppard Pratt Physicians, P.A
- ☐ Sheppard Pratt Properties, LLC
- ☐ Way Station, Inc.
- ☐ Other: _____

DEPARTMENT:

- ☐ Administrative
- ☐ All
- ☐ Clinical
- ☒ Compliance
- ☐ Corporate Governance
- ☐ Environmental Services
- ☐ Facilities Engineering
- ☐ Finance
- ☐ Food Services
- ☐ Health Information Management
- ☐ Human Resources/Occupational Health
- ☐ Infection Control
- ☐ Information Technology
- ☐ External Affairs
- ☐ Medical Staff
- ☐ Public Safety
- ☐ Transportation

PROGRAM AND SERVICES:

- ☐ Care Coordination & In-Home Services
- ☐ Community & Family Supports
- ☐ Crisis & Admission
- ☐ Developmental Disability Services
- ☐ Employment & Job Training
- ☐ Housing & Homelessness Services
- ☐ Inpatient & Specialty Services
- ☐ Residential & Structured Day Services
- ☐ Schools & School-Based Services
- ☐ Therapy & Medication Management
- ☒ Not Program Related

PURPOSE:

To outline the policies and procedures of the Sheppard Pratt Institutional Review Board (IRB).

POLICY STATEMENT:

It is the policy of Sheppard Pratt to ensure that all research is undertaken in compliance with the requirements of federal, state, and local law guided by the principles of respect for persons, beneficence, and justice by the Board of Trustees of Sheppard Pratt Health System, Inc. and, at the request of Sheppard and Enoch Pratt Foundation, Inc., at all of the affiliates of Sheppard and Enoch Pratt Foundation, Inc. (hereinafter, "Sheppard Pratt"). The IRB is guided by the institution's commitment to protect the rights and welfare of research participants from undue risks and unreasonable invasions of privacy as well as the applicable legal and regulatory requirements which form the basis of the institution's research policies.

For purposes of this policy and associated activities, "human subjects research" is systematic investigation designed to develop or contribute to generalizable knowledge involving humans as participants as further refined in 45 CFR 46 and the Guidelines/Procedures outlined below. All human subjects research conducted by or at Sheppard Pratt must be approved or granted an exemption by an IRB. Human subjects research reviewed and approved or exempted by an IRB may be subject to further review and disapproval by other review bodies or officials.

These policies and guidelines/procedures (hereinafter, the "Policies") and, in the case of certain research, the requirements of 45 CFR 46, 21 CFR 50, 21 CFR 56 and other regulations related to the conduct of human subjects research (hereinafter, the "Regulations") are used by the Sheppard Pratt IRB (hereinafter, the "IRB") in carrying out its responsibilities in accordance with a Federal Wide Assurance (FWA 00008047) under the designated IRB Organization (IORG0003087) and internal IRB (IRB00004510). The primary responsibilities of the IRB are to

oversee human subjects research that is subject to federal regulations. These Policies may be changed as deemed necessary by the IRB and revisions will be considered at least annually.

These policies apply to all studies submitted to the Sheppard Pratt IRB on or after January 19, 2019. Studies that were submitted to the IRB before that date are not subject to these policies and the 2018 revised OHRP common rule and are subject to the IRB policies approved in August 2018 and the provisions of the pre-2018 OHRP common rule.

DEFINITIONS:

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. Internal operational activities such as quality improvement activities or demonstrations that are not systematic investigations designed to develop or contribute to generalizable knowledge do not constitute research for purposes of this policy.

Human subject – a living individual about whom an investigator (whether professional or student) conducting research:

I. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or
II. Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Employees or agents – staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. Employees or agents refer to individuals who:

I. Act on behalf of the institution,
II. Exercise institutional authority or responsibility; or
III. Perform institutionally designated activities

Engaged – considered engaged in non-exempt human subjects' research when its employees or agents for the purposes of the research project obtain the following:

I. Data about the subjects of the research through intervention or interaction with them.
II. Identifiable private information about the subjects of the research; or
III. The informed consent of human subjects for the research. (45CFR 46 Engaged in Research Guidance; 10/16/2008)

GUIDELINES:

I. Composition of the IRB and Reporting Relationships
    A. Membership
        1. The IRB shall consist of at least five (5) members appointed by the Institutional Official of the Sheppard Pratt Health System, Inc., representing a diversity of backgrounds including experience and expertise to adequately review the proposed research activities. Membership shall also be composed of the following:

i. One (1) member shall be the Chair. This member shall lead IRB meetings and serve in the administrative leadership capacity as outlined in the Policies.
ii. One (1) member shall be the Vice-Chair. This member shall participate in leadership of the IRB. This member shall stand in for the Chair in instances where the Chair is recused from a review or otherwise unable to serve in the Chair role.
iii. At least one (1) member of the IRB shall not otherwise be or have been professionally associated with the Institution, nor a member of the immediate family of a person who is or has been professionally affiliated with the Institution.
iv. At least one (1) member of the IRB shall have a background or profession in a non-scientific area. A background in a non-scientific area is defined as training or occupation which would incline the member to view research activities from the perspective of someone outside of a behavioral or biomedical scientific discipline.
v. At least one (1) member of the IRB shall have a background or profession in a scientific area. A background in a scientific area is defined as training or occupation which would incline the member to view research activities from the perspective of someone within a behavioral or biomedical scientific discipline.

2. Members may serve in more than one role with the exception of the mutually exclusive non-scientist and scientist roles.
3. The IRB shall not allow any member to participate in the initial or continuing review of any project on which the member has a conflicting interest, except to provide information requested by the IRB. Members shall report any potential broad conflict of interest upon appointment via the conflict-of-interest form. Any study-specific conflict of interest shall be disclosed by the member prior to the study review and a determination made by the Chair regarding what level of participation is appropriate in accordance with Section XI (Conflict of Interest) of this policy.
4. The IRB shall maintain a membership roster showing each member's name, earned degrees, expertise, professional certifications or licenses, professional or vocational status, representative capacity, relationship to Sheppard Pratt, race, gender, and term of appointment.
5. A curriculum vitae or résumé and education records for each member will be kept on file.

B. Appointment
1. Members of the IRB shall be appointed for three (3) year terms by the Institutional Official of the Sheppard Pratt Health System, Inc. at the request of the IRB via the IRB Chair. Members may succeed themselves.
2. Every effort will to be made to ensure that IRB membership is diverse, such as that the committee does not consists entirely of men or entirely of women. However, no selection shall be made on solely the basis of a specific group, such as gender.
3. A member may be appointed as an alternate to another member with similar expertise. Alternate members shall be permitted to attend all meetings but shall not count toward quorum or vote unless they serve

in the alternate voting member role for a given study. Meeting minutes shall reflect attendance and identify when an alternate member is serving as the designated voting member for a study.

4. The Chair of the IRB shall be appointed from among the IRB members by the Institutional Official of Sheppard Pratt Health System, Inc. The Chair of the IRB serves at the pleasure of the Institutional Official of Sheppard Pratt Health System. The Institutional Official of Sheppard Pratt Health System may, at any time, remove the Chair of the IRB by designating in writing to the IRB a new Chair either from among the other members of the IRB, or by substituting a new member to serve as Chair. The IRB may select from among its members a Vice-Chair.
5. Other personnel and/or subject matter experts may be requested to participate on an ad hoc basis in the deliberations of the IRB for items of relevance to their responsibilities or expertise. Such personnel and experts shall not be considered voting members of the IRB.

C. Compensation: Members of the IRB shall not receive compensation for their services beyond their salaried employment, if applicable, with Sheppard Pratt.

D. Liability: Members of the IRB shall be covered by the liability insurance of Sheppard Pratt as agents of Sheppard Pratt with respect to actions and decisions falling within the scope of their responsibilities. This classification of non-affiliated members does not render them affiliated for purposes of quorum requirements.

E. Reporting Relationships
   1. The IRB provides reports to the Institutional Official of the Sheppard Pratt Health System, Inc.
   2. The IRB shall work in cooperation with other Sheppard Pratt committees as requested and deemed appropriate.
   3. The IRB shall conduct study reviews, privacy waiver reviews, compliance monitoring and reporting, associated activities.

II. Education and Training

A. Member Education
   1. Members of the IRB shall complete an educational course about research ethics and human subjects research protection. Ongoing education for members shall be performed in conjunction with meetings. Records of ongoing education shall be recorded in the meeting minutes along with any associated materials as attachments to meeting in IRBNet

B. Study Personnel Education
   1. Principal Investigators shall complete an educational course about research ethics and human subjects research protections prior to initial submission and at least every three years.
   2. Principal Investigators shall ensure that study personnel complete an educational course and human subjects research protections prior to initial submission and every three years within the continuing review report period.
      i. The PI is responsible for maintaining records for study personnel education and shall provide records upon request to the IRB or associated auditing personnel.

C. Additional Research Personnel Qualifications

1. The IRB shall rely upon the institution's employment practices and documents to ensure that research personnel have the following as appropriate: credentialing, appointments, background checks, and insurance coverage. Records shall be made available upon request to the IRB or associated auditing personnel.

III. Purview
   A. Except as provided in the subparagraphs in this Section, the IRB shall have responsibility for the approval or disapproval of all research involving human participants at Sheppard Pratt and/or conducted by employees or agents of Sheppard Pratt. The IRB will not have oversight of studies which have been deferred to another IRB.
   B. The IRB shall have ongoing supervision of all protocols that it has approved. If a protocol must be changed, revisions must be submitted to the IRB via IRBNet and approved before the protocol change is implemented, except where an emergency change is required to eliminate an immediate hazard.
      1. Any change that increases the risk to participants must be reviewed by the full IRB committee.
      2. Any emergency change shall be immediately reported to the IRB. In addition, following any emergency change the investigator shall submit periodic status reports concerning the study to the Chair of the IRB. The IRB shall determine the frequency of such reports in each case.
      3. Based upon its determination that a study is not proceeding in a satisfactory manner, the IRB may, at any time, suspend or terminate the study.
      4. When the IRB is serving in the role of single IRB for a multi-site study, the IRB shall arrange communications with investigators and external entities per established agreements for the study.
   C. Privacy and Confidentiality
      1. The IRB is responsible for reviewing any requests for access to protected health information (PHI) for purposes other than treatment, payment, health care operations, or other purpose permitted or required by law.
         i. The Privacy Officer may be invited to provide guidance to the committee when regulatory interpretation expertise is required as determined by the IRB Chair.
      2. The IRB shall be guided by the Sheppard Pratt policy HS# 120.8 (Participation of Employees as Research Participants)

IV. Meetings
   A. Scheduling and Requirements
      1. Meetings shall be scheduled monthly or as deemed necessary to meet the needs of the IRB by the Chair to review:
         i. New research proposals
         ii. Applicable modifications pertaining to approved studies
         iii. Continuing review reports pertaining to approved studies
         iv. Other proposals associated with oversight of research activities.
   B. Materials shall be available to members of the IRB within a reasonable time in advance of meetings convened.
   C. Quorum: A quorum shall consist of a majority of the members of the IRB, including at least one member who is a licensed practitioner with medical staff

privileges at Sheppard Pratt and one member whose primary concerns are in non-scientific areas. Members participating in person or via a web-based platform or telephone shall constitute a quorum. All persons counting towards the quorum must be able to interact verbally in the meeting discussion. No person who will be a primary or secondary investigator in a study shall participate in the review of the study as a committee member.

1. Only those members who are participating in a meeting shall be counted towards a quorum. A meeting may be held by any method that permits all participants at the same time to hear and be heard by each other and are in possession of all relevant written materials.

D. Conflict of Interest: Any IRB member with a conflict of interest, financial or otherwise, with respect to any protocol shall recuse him or herself from deliberation and voting with respect to such protocol or may be recused as determined by the Chair in consultation with other IRB members. The Vice-Chair or other committee member may assume the responsibilities of the Chair in the absence of the Chair or when the Chair is the principal investigator or is otherwise disqualified. The IRB may request participation from the recused member for clarifications. A recused member shall not be counted in ascertaining a quorum.

E. Voting: Each IRB member shall have one vote for rendering decisions. At a meeting, the approval of any matter shall require the vote of a majority of those present and constituting a quorum. Personnel who are not IRB members but who are participating on an ad hoc basis in deliberations as outlined in Section I., B., 3 shall not vote.

F. Minutes: Minutes shall be kept of all meetings and actions of the IRB and shall be available to all members of the IRB and others as deemed appropriate per applicable agreements and regulations.

1. Minutes which include redaction of any confidential or privileged information, shall be available for inspection by any individual within 30 days following a written request.
2. Minutes shall include the following:
    i. A list of members participating and their representative capacity
    ii. Guests attending and their representative capacity
    iii. Recusals
    iv. A summary of the discussion of controverted issues and their resolution
    v. A record of voting including the number for (approve), opposed (not approved), and abstained on each protocol,
    vi. A record of the continuing review schedule, if applicable. time frame
    vii. A record of IRB decisions
3. Minutes shall also include any actions taken since the last meeting such as expedited review of minor changes to approved protocols.
4. For any study application received on or after 1/19/2019, the new regulations will apply. For any study application received prior to 1/19/2019, the review processes may be grandfathered into prior regulations or transitioned to the new regulations, a determination shall be made regarding which regulations will apply and then documented in the minutes.

5. The minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol undergoing full continuing review by the convened IRB.
6. Record Retention: The IRB shall retain the records required by this policy for at least 3 years and records relating to research which is conducted for at least 3 years after completion of the research study and/or retained for at least 3 years after study subjects have reached the age of 18 years. All records shall be accessible for inspection by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (45 CFR 46.115).

V. IRB Submission and Review Procedures
   A. A submission to the IRB must be made on IRBNet and must include:
      1. A fully completed Application Form which includes the risk level of the study (minimal risk or more than minimal risk).
         i. Minimal risk is defined as the probability and magnitude of harm or discomfort is not greater than that ordinarily encountered in daily life or during routine examinations or tests.
      2. Signed Financial Disclosure Form(s)
         i. Forms must be submitted by the Principal Investigator, Co-Investigator (if there is a co-investigator for the study), and any other study personnel that may have financial relationship(s) associated with study funding or sponsorship.
         ii. If the study is unfunded, then the financial disclosure form does not need to be completed
      3. A fully completed written protocol with respect to the proposed study.
         i. The IRB may refer Investigators to the protocol content guidelines regarding applicable elements as deemed appropriate.
      4. Informed Consent Document(s) and Assent Document(s) when applicable.
         i. Waiver request or explanation of alternative consent procedures may be submitted when an alternative to written consent is proposed.
      5. A Certificate of completion of human participants' protection training by the Principal Investigator and other research staff as noted in the Education section of this policy.
      6. For those proposed studies that will be performed at a clinical program or on an inpatient unit, the IRB may require the approval of the clinical director of the program where the study is to take place.
      7. An IRBNet submission must be signed via the IRBNet signature function by the Sheppard Pratt Principal Investigator or designee. Other study personnel may be asked to sign based on the study documents submitted. The submission must be signed by all required parties before IRB approval can be granted.
      8. The IRB Chair or designee shall determine whether the proposed investigation requires Full IRB review, is eligible for Expedited Review, or is Exempt from review as provided in Section IV. B, or is "not research" and does not fall under the purview of the IRB.

9. If the IRB has any question regarding the proposed investigation, or desires any further information, it may request that the investigator provide the necessary information or materials as written amendments or supplements to the original submission. The investigator may also be asked to attend the meeting of the IRB, but any modifications of or supplements to the proposal must be submitted in writing.
10. Submissions for which additional information or modifications are requested following pre-review or review in order for the study to proceed will remain active in the IRB study list on IRBNet for a period of at least 90 days. If a revised submission is not made within 90 days, the IRB may close out the study. Once closed, resubmission to the IRB under a new study number will be required to proceed with review.

B. Types of Review
    1. Full Review
        i. Any non-exempt protocol not eligible for Expedited Review, and any protocol eligible for Expedited Review for which there is a question raised in the Expedited Review process, shall be submitted to Full Review. Full Review shall be conducted by at least a quorum of the members of the IRB, and shall be conducted pursuant to the processes and based upon all of the criteria set forth in these guidelines
        ii. Primary Reviewer: The IRB Chair or IRB member designated by the IRB Chair may act as primary reviewer for an initial proposal, continuing review, study modification, report of an unanticipated problem, or report of a serious adverse event. All materials related to the submission shall be available to the primary reviewer and the other members of the committee, unless the member has a conflict of interest.
    2. Expedited Review
        i. Under the expedited review process, an initial or continuing review may be carried out by the IRB Chair, Vice-Chair, or by one or more experienced reviewers designated by the IRB Chair from among the members of the IRB for certain kinds of research, minor changes in approved research, and for exempt research for which Limited IRB Review is a condition of exemption.
        ii. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the Full Review process.
        iii. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

iv. Expedited review by the designated member may be performed with respect to the Eligible Expedited Review Categories and Continuing Review Categories listed below.

a. Eligible Expedited Review Categories

i. Investigations involving minimal risk and procedures on the Federal guidance list of research categories which may be reviewed by an expedited process as follows:

1. Clinical studies of drugs or medical devices where an investigational new drug application is not required; or where an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the device is being used according to the approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture according to the following:
    a. For healthy, non-pregnant adults who weigh at least 110 lbs. (The amounts drawn may not exceed 550 ml over an 8-week period and may not be drawn more than 2 times a week.)
    b. For other adults and children, considerations are made for age, weight, and health; collection procedure; amount; and frequency of collection. (The amounts drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and may not be drawn more than 2 times per week.)
3. Prospective collection of biological specimens by non-invasive means.
4. Collection of data through non-invasive procedures routinely employed in clinical practice (excluding procedures involving general anesthesia or sedation, x-rays, microwaves, medical device studies intended to evaluate safety/effectiveness of the device, or medical device studies using cleared device for new indications).
5. Collection of materials that have been or will be collected solely for non-research purposes where the research is not considered exempt.

6. Collection of data through voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies where the research is not considered exempt.

ii. Minor changes proposed in previously approved research during the established approval period of one year or less. Changes for this category include, but are not limited to the following:
1. Changes to studies that meet the criteria for expedited review per the criteria noted above.
2. Changes that do not change the risks and benefits for which the reviewer can make the determinations required for approval.

v. Documents associated with studies undergoing expedited review will be available to IRB members.

vi. The IRB will keep members advised of research proposals that have been approved under the expedited procedures via report at convened meetings.

3. Exempt from Review

i. The IRB, not the investigator, shall make the determination regarding the applicability of exemption. The IRB Chair or designee may make this determination on behalf of the IRB.

ii. Records of exemption determinations will be maintained on IRBNet. Investigators should submit sufficient information to allow the IRB Chair or designee to make the appropriate determination.

iii. Research shall be classified as Exempt if it meets one or more of the requirements listed in the Federal Regulations as follows:
a. Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of the comparison among instructional techniques, curricula, or classroom management methods
b. Research that only includes interactions involving educational tests, survey procedures, interview procedures,

or observation of public behavior if at least one of the following criteria is met

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identified linked to the subjects
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identified linked to the subjects, and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

c. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the humans subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
    iv. For the purposes of his provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has not reason to think that the

subjects will find the interventions offensive or embarrassing.

v. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature of purposes of the research.

d. Secondary research for which consent is not required includes research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met
    i. The identifiable private information or identifiable biospecimens are publicly available.
    ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will no re-identify subjects.
    iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b) or
    iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government collects information obtained for non-research purposes.
e. Research and demonstration projects that are conducted or supported by a Federal department or agency or otherwise subject to the approval of department or agency heads.
f. Taste and food quality evaluation and consumer acceptance studies
g. Storage or maintenance for secondary research for which broad consent is required including storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if the IRB conducts a limited IRB review and makes the determinations that the consent is obtained in accordance with the general requirements for informed consent, consent or waiver of consent is appropriately documented,

and there is adequate provision to protect subject privacy and confidentiality of data.

h. Secondary research for which broad consent is required including research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the general requirements for informed consent.
    ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the standards for documentation of informed consent.
    iii. The IRB conducts a limited IRB review and makes the determinations that there is adequate provision to protect subject privacy and confidentiality of data the research to be conducted is within the scope of the broad consent, and the investigator does not include returning individual research results to subjects as part of the study plan. Note: This provision does not prevent an investigator from abiding by any legal requirements to return individual reach results.

4. Limited Review
    i. Under some of the categories that qualify a study for exemption, the research is required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens. Categories of studies subject to limited review are:
        a. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
            i. This category does not apply to the following:
                1. Research involving prisoners as subjects except for research aimed at involving a broader subject population that only incidentally includes prisoners.
                2. Research involving children as subjects
    ii. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention

and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

a. This category does not apply to the following:
    i. Research involving prisoners as subjects except for research aimed at involving a broader subject population that only incidentally includes prisoners.
    ii. Research involving children as subjects
    iii. Research involving deceiving the subjects regarding the nature or purpose of the research unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research
b. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

iii. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use.

iv. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with general requirements for informed consent;
b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the standards for documentation of informed consent;
c. The IRB conducts a limited IRB review and makes the determination that there are adequate provisions to protect subject privacy and confidentiality of data and makes the determination that the research to be conducted is within the scope of the broad consent; and
d. The investigator does not include returning individual research results to subjects as part of the study plan. Note: This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

VI. Criteria for IRB Approval of Research

A. In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
    1. Risks to participants are minimized:
        i. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
        ii. Whenever appropriate, by using procedures already 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 IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
    3. Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons.
    4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, as outlined below in Section VII of this document.
    5. Informed consent will be appropriately documented as outlined in Section X.
    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.

B. For purposes of conducting limited reviews in which broad consent is obtained, the IRB need not make the determinations above and shall make the following determinations:
    1. Broad consent for storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with and in the scope of the general requirements for informed consent
        i. Broad consent is appropriately documented or waiver of documentation is appropriate in accordance with requirements for documentation the standards for documentation of informed consent AND
        ii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are

stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data

iii. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included to protect the rights and welfare of the subjects

2. Broad consent for the use of identifiable private information or identifiable biospecimens for secondary research use is obtained in accordance with the general requirements for informed consent
    i. Broad consent is appropriately documented or waiver of documentation is appropriate in accordance with the standards for documentation of informed consent AND
    ii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data AND
    iii. The investigator does not include returning individual research results to subjects as part of the study plan. (This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.)

C. Vulnerable populations:
    1. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.
        i. When determining applicability and criteria for approval for studies involving populations addressed in 45 CFR 46 Subparts B, C (Prisoners), and D (Children) the IRB must apply the following:
            a. Subpart C provision of additional protections for research involving prisoners as subjects: The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
            b. Subpart D provision of additional protections for children involved as subjects in research: The exemptions including normal educational practices in accordance with regulation, secondary research for which consent is not required, research demonstration projects, storage or maintenance for secondary research for which broad consent is required, secondary research for which broad consent is required may be applied to research subject to subpart D if the conditions of the exemption are met.
    2. In reviewing research proposals where participants are not competent to give consent (either because of age or disability) and informed consent may be given by a proxy decision maker, the following shall apply:
        i. If the research involves mental health treatment, participants who are not able to give consent will be limited to:
            a. Minors whose parents or court appointed guardian will give informed consent

b. Adults who have a court appointed guardian who is authorized to and will give informed consent
c. For studies that will result in the patient receiving treatment, adults who have previously executed an advanced directive appointing a health care agent who is authorized to and will give informed consent, or
d. For studies that may not result in the patient receiving treatment, adults who have previously executed an advanced directive appointing a health care agent who is authorized to and will give informed consent for research.

ii. If the research does not involve mental health treatment, any participant who is not competent to consent may participate if consent is given by a proxy decision maker (i.e., surrogate decision makers listed in Maryland Health General Article 5-605) and if the following criteria are met by the proposal.
    a. Wherever research involves proxy decision makers, the following guidelines shall apply:
        i. Studies involving solely non-therapeutic procedures (i.e., research not designed to directly benefit the participants participating in the research, but rather designed solely to answer a scientific question to benefit the public at large or some commercial interest):
            1. Research will be limited to studies with no more than minimal risk and
            2. Risks are minimized and justified by scientific value.
        ii. Studies involving therapeutic procedures (research designed to study a therapeutic procedure which offers the possibility of direct therapeutic benefit to each participant participating in the study): Research will be allowed if the procedures meet the following guidelines:
            1. Procedures are consistent with competent medical care for all participants; and
            2. Risks are justified by a prospect of direct benefit.
        iii. Procedures for both therapeutic and non-therapeutic studies are consistent with sound scientific design.

iii. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45§46.404 or 45§46.405.
    a. Where research is covered by 45§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

b. Where parental consent as proxy consent for minors is not feasible due to custody or other legal factors, the IRB must apply the conditions of the relevant Sheppard Pratt risk management policy.

D. Local context, particularly for multi-site studies.
   1. The IRB shall consider logistics, applicable state and local laws, and other issues that may be relevant for all study sites. Input from local sites regarding consent and protocol modifications to address these issues shall be considered in the context of applicable institutional agreements as well as legal and regulatory requirements.

E. For investigational drug studies (i.e., studies which involve an FDA-approved pharmaceutical or studies which have an IND number from the FDA), the following must be considered:
   1. A provision for supplying the pharmacy with all pertinent drug information, provision for inclusion of medication information in the participant's medical record, provision for the storage, labeling and dispensing of investigational drugs by, or under procedures approved by the pharmacy.
   2. Except as noted in the waiver sections of this policy below informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form. The consent form may be either of the following:
      i. A written consent document that embodies the elements of informed consent required by the FDA regulations. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
      ii. A short form written consent document stating that the elements of informed consent required by the FDA regulations have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.
   3. Waiver of consent may be applied when the following conditions are met:
      i. The clinical investigation involves no more than minimal risk as defined in the FDA regulations to the subjects;
      ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

iii. The clinical investigation could not practicably be carried out without the waiver or alteration; and
iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4. Exception to the limitations on consent waivers for emergencies may be made if the conditions found under the FDA regulations are met.

VII. Decisions

A. The IRB may take the following actions in response to a submitted study, modification of an approved study, or continuing review of an approved study:

1. Approve
   i. The IRB may approve as submitted. The IRBNet action ("APPROVE") shall be recorded for the minutes in IRBNet.
   ii. The IRB may approve with conditions. The IRBNet action ("APPROVED WITH CONDITIONS") and specific notes indicating the conditions that must be satisfied to secure approval shall be recorded for the minutes in IRBNet.
      a. Approval with Conditions is defined as a determination that, at the time when the IRB reviews and votes to approve a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the investigator
         i. Make specified changes to the research protocol or informed consent document(s)
         ii. Confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted or
         iii. Submit additional documents such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations.
   iii. The IRB may designate the IRB chairperson or qualified designee to review responsive materials from the investigator and determine that the conditions have been satisfied to approve on behalf of the IRB.
2. Disapprove
   i. The IRB may disapprove the study, modification, or continuing review as submitted. The IRBNet action ("NOT APPROVE") shall be recorded for the minutes in IRBNet
3. Require modifications
   i. If the IRB is unable to approve the research because it cannot make the determinations required for approval, the IRB may require modifications to secure approval or defer for further review after required modifications are submitted. The IRBNet action (e.g., "MODIFICATIONS REQUIRED", "INFORMATION REQUIRED", "TABLED WITHOUT ACTION") and specific notes indicating the requested information or modifications shall be recorded for the minutes in IRBNet.
4. Other administrative actions as deemed appropriate.

5. The IRB may suspend or terminate any study if the IRB determines that risks, non-compliance, or related concerns warrant such action. The rationale and action shall be documented in the meeting minutes.

B. The Chair or designee of the IRB shall notify the investigator via published letter in IRBNet of the decision of the IRB.
    1. If the IRB decides approval cannot be granted until modifications or conditions have been addressed, which have not been accepted in writing by the investigator, or if the IRB decides to disapprove an investigation, it shall include in its notification a statement of the reasons for the decision.
    2. If the IRB decides on approval, it shall include the approval expiration date as determined by the review interval set by the IRB and notification that any modifications must be submitted to the IRB and approved prior to implementation of the changes.
    3. The PI will also be notified about the requirements for reporting events.

C. Appeals: Decisions of the IRB which are not acceptable to the investigator or a member of the IRB may be appealed in writing to the Institutional Official of the Sheppard Pratt Health System. The Institutional Official may not override the IRB disapproval, but may propose modifications or conditions for IRB consideration, or recommend IRB reconsideration for specific reasons.

VIII. Responsibilities of the Principal Investigator

A. The principal investigator shall:
    1. Conduct research in accordance with the ethical principles in the Belmont Report and supervise the research process.
    2. Assure that all investigators and key study personnel are properly trained, qualified, and have appropriate resources to conduct the research as well as remain up-to-date on federal regulations. The PI is responsible for maintaining records for study personnel and shall provide records upon request to the IRB or associated auditing personnel.
    3. Provide the IRB with all required materials in accordance with this policy and applicable regulations.
    4. Not initiate any part of the study until the protocol has been fully approved. The investigator shall not modify the study or the protocol without the consent of the IRB. Modifications cannot be implemented until it is approved. The protocol shall be implemented only in accordance with the modifications or conditions approved by the IRB.
    5. Provide the IRB with required reports for continuing review in accordance with the requirements of the IRB.
    6. Assure that the IRB is informed of any updates or modifications prior to their implementation and in compliance with all federal, state, and local regulations and policies.
    7. Ensure participant privacy and confidentiality according to HIPAA and/or FERPA guidelines as applicable, institutional regulations, and IRB policies and procedures
    8. Ensure adequate provisions for the monitoring of participants to reduce risk and promote compliance with applicable regulations and policies regarding the safety and welfare of participants.

9. Inform the IRB in accordance with the requirements of the IRB via IRBNet of the following:
    i. Serious Adverse Event
    ii. Major Deviation
    iii. Unanticipated Problem
    iv. Unexpected Adverse Event
10. Make the records of the study procedures available to the IRB Committee upon request including eligibility of participants' checklist documents, informed consent documents, and the current status of the study project

B. For investigational drug studies as defined by FDA regulations, the principal investigator shall:
    1. Ensure that the clinical investigation is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products, or agreement for clinical investigations of medical devices, the investigational plan, and applicable regulations
    2. Oversee drugs, biological products, and devices under investigation in accordance with all applicable federal, state and local regulations.
    3. Ensure that all investigational drugs include to evidence of collaboration with the hospital pharmacy, supplying the pharmacy with all pertinent drug information including but not limited to the proposed label, drug name, drug dosage form, dosage ranges, indications, contraindications, potential adverse reactions and side effects.
    4. Ensure that all investigational drugs shall be stored, labeled and dispensed by the pharmacy or in accordance with arrangements which have been approved by the pharmacy.
    5. Maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects or for device studies the type and quantity of the device, dates of receipt, and batch numbers or code marks.
    6. Prepare and maintain adequate and accurate case reports forms 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
    7. Sign an investigator statement (Form FDA-1572) with the IND sponsor, if applicable
    8. As applicable, permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall not supply an investigational device to any person unauthorized.

C. For double-blind medication trials, the investigator shall provide evidence that the pharmacy staff or other Sheppard Pratt personnel have available to them a procedure for immediate breaking of the code in the event of an emergency.

D. For multi-site studies where the Principal Investigator is from Sheppard Pratt and Sheppard Pratt is the reviewing IRB, additional investigator roles including the following:
    1. Maintain a current roster of the PI and other research personnel involved in the study at relying on site

2. Determine any special local considerations that must be considered by the relying site such as local requirements for ancillary human research protection reviews (pharmacy, nursing, radiation safety, etc.)
3. Oversee the relying site(s) as outlined in institutional agreements and in accordance with applicable federal and local laws (e.g., assuring that the site(s) maintain adequate staff, resources, clinical and pharmacy practices, federal assurances, as well as evidence of training for the relying site PI and research personnel at the relying site PI and research personnel at the relying site).
4. Promptly provide the relying site PI with the following:
    i. Current approved protocol and consent documents
    ii. Approved modifications, amendments or changes to the protocol
    iii. Approval of continuing reviews, reviews of unanticipated problems
    iv. Any other information required by the reviewing IRB to be provided to the relying site PI and IRB

E. For clinical trials, clinical trial consent forms must be posted on the publicly available federal website. One consent form for each clinical trial must be posted on the federal website after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject. A federal department or agency may permit or require redactions.

IX. Study Announcements

A. Announcements and print advertisements should present a balanced picture of what the research entails and must not overstate direct benefit to volunteers.
    1. Announcements should include the elements recommended in the announcements form found in the IRBNet library. It is recognized that the applicability of the items in the announcement may vary depending on the nature of the study and channel of distribution such as for verbal presentations or social media, in which case it may not be feasible to include all of the suggested elements.

B. Announcements should not include the following elements:
    1. Language extolling the importance of the study or exaggerating claims about the benefits of participation
    2. An emphasis on monetary compensation for participation.
        i. The IRB will not require the announcements to be vetted by the Sheppard Pratt Marketing Department, but may recommend that investigators coordinate with the Marketing Department about the content and formatting of the announcement and the representation of the study's association with Sheppard Pratt
        ii. The IRB shall consider the applicability of the recommended announcement elements, risks of the study, appropriateness of the announcement content, and the context of the planned distribution of the materials.

X. Informed Consent

A. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

B. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider where or not to participate and minimize the possibility of coercion or undue influence.
C. Each protocol submitted for approval shall describe the process by which the investigator intends to explain the investigational research to the potential participants, to assess and record the participant's capacity to consent, and to obtain their agreement to participate. Potential subjects must be provided with the information that a "reasonable person" would want to have in order to make an informed decision and subjects must be provided with an opportunity to discuss that information.
D. Informed consent as a whole must present information in sufficient detail and organized in such a way that does not merely provide lists of isolated facts but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate.
E. The informed consent document must begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be organized and presented in a way that facilitates comprehension. This concise explanation should include the following:
    1. The fact that consent is being sought for research and that participation is voluntary;
    2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
    3. The reasonably foreseeable risks or discomforts to the prospective subject;
    4. The benefits to the prospective subject or to others that may reasonably be expected from the research; and
    5. Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject.
F. The basic elements of the consent form are as follows:
    1. A statement that the study involves research and an explanation of the purposes of the research
    2. A statement that participation is voluntary, refusal to participate will involve no penalty or low of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
    3. The exact name of the approved protocol
    4. The name of the principal investigator and contact information for that individual including institutional affiliation.
    5. Contact information regarding whom to contact for answers to questions related to the research, whom to contact in the event of a research-related injury and participants rights including study contact and the IRB contact information
    6. The name of the sponsor or funding source of the study, if any
    7. A description of the expected duration of the participant's participation

8. Identification of any procedures that are experimental
9. A description of any benefits, if any, to be expected by the participant
10. A description of the potential discomforts and foreseeable risks to the participant and the precautions which will be taken to minimize those risks
11. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant
12. For more than minimal risk studies: An explanation as to whether any compensation for participation will be provided, and whether any medical treatment will be available if injury occurs, and who will be expected to pay for it
13. A statement concerning the participant's rights to privacy and/or confidentiality and the steps which will be taken to preserve privacy and confidentiality and an authorization to use or disclose health information as required for research purposes;
14. The name of the person who provided this information to the participant and the date the form was signed.
15. Signature lines for the individual giving informed consent and for the person leading the informed consent discussion.
16. Informed consent shall be documented by the use of a written informed consent form approved by the IRB (Electronic signatures are allowed for consent documentation). A written copy must be given to the person signing the consent form upon request.
17. A description of the procedures to be followed for a study involving identifiable private information or identifiable biospecimens including one of the following as applicable:
    i. Identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from the subject; or,
    ii. The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.
    iii. Whether the subject will or will not share in the commercial profit if biospecimens are to be used for commercial profit.
    iv. Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
    v. Whether the research project will or might include whole genome sequencing.
18. If appropriate or potentially material to the participant's decision making, the following information shall be included in the informed consent:
    i. A statement that the particular treatment or procedure may involve risks, which currently are unforeseeable
    ii. Any additional costs to the subject that may result from participation in the research
    iii. A statement of the source of funding for the study, the payment arrangements for the investigators, and how any conflict of interest is being managed

iv. A description of any anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
v. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the participant in the event of withdrawal of participation.
vi. The approximate number of subjects in the study

19. The following items are required to comply with the Health Insurance Portability and Accountability Act (HIPAA) for authorization to use or disclose protected health information (PHI) for research. These items must be included in the informed consent document.
    i. A description of the protected health information to be used or disclosed
    ii. The name or other specific identification of who is authorized to use or disclose the protected health information. Examples: "Sheppard Pratt" or "Dr. XXX."
    iii. The name or other specific identification of the person or organization to which the disclosure may be made and the purpose of the disclosure.
    iv. An expiration date or an expiration event. The statement "does not expire" is sufficient.
    v. A statement that the patient has the right to revoke the authorization in writing, and how this revocation may affect continued participation in the study.
    vi. A statement that information that is disclosed in accordance with the authorization may be disclosed further by the recipient, and that the information may no longer be protected by federal privacy rules regarding protected health information.
20. In order for a patient to be determined to be competent to give informed consent for participation in a research project, it must be the judgment of the investigator that:
    i. The patient knows he/she has a choice to make.
    ii. The patient is able to understand the risks, the available options and their advantages and disadvantages.
    iii. The patient is able to understand the Informed Consent, the nature of his/her participation in the research project, and his/her right to discontinue participation. The evidence upon which a determination of competence is based should be permanently maintained with the consent document.
21. When a participant is not competent to give consent, informed consent may be given by a proxy decision maker in accordance with applicable laws, regulations, and Sheppard Pratt policy.
22. In studies of inpatients which require the obtaining of signed informed consent, either the attending doctor or the primary clinician must give approval for a given patient's participation in the project before the patient may be invited to take part or, where appropriate, before the guardian is approached for permission.

G. When using a "short form" to document consent, the informed consent must begin with a concise and focused presentation of the key information to assist a

prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

H. Broad consent may be obtained in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Elements that must still be included are:
    1. General description of the types of research that may be conducted.
    2. A description of the identifiable information or identifiable biospecimens that might be used in future research; whether sharing might occur; and the types of institutions or researchers that might conduct research.
    3. A description of the length of time that the identifiable information or identifiable biospecimens may be stored, maintained and used.
    4. Unless subjects provide details about specific studies, a statement is required that subjects will not be informed of the purposes or details of any specific research studies that might be subsequently conducted, and, that they might have chosen not to consent to some studies.
    5. Unless it is known that clinically relevant research results will under all circumstances be disclosed to subjects, a statement is required that research results may not be disclosed to subjects.
    6. Contact information to be provided for questions about rights, questions about storage and use, and in the event of research-related harm.
    7. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable. biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual.
    8. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements of broad consent.

XI. Procedures for Obtaining PHI for research purposes without individual authorization

A. In the case of research in which HIPAA protected health information is to be collected from existing patient records, if the researcher does not propose to obtain individual authorizations from each patient whose existing patient record is to be reviewed, the researcher must apply to the IRB for a waiver or exception from the usual informed consent/authorization requirements, as required by the HIPAA regulations. Any studies for which student education records will be accessed must comply with the FERPA regulations.

B. The following representations must be made and substantiated in writing via the form provided in the Sheppard Pratt IRBNet Library by the researcher in order for the IRB to waive or modify the authorization requirement:
    1. Access to protected health information is necessary to prepare a research protocol or to complete a research project and the research should not practicably be conducted without this protected health information and without the waiver or alteration of the participant authorization requirement.
    2. If protected health information is to be copied or abstracted, an adequate plan is in place to protect the security and confidentiality of the copied or abstracted protected health information. No protected

health information will be removed from the patient record by the researcher in the course of the review.
3. An adequate plan is in place to protect patient identifiers from improper use and disclosure.
4. An adequate plan exists for destroying the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
5. The protected health information will not be reused or disclosed to any other persons or entity except as required by law; or for authorized oversight of the research study.
6. For research that involves using identifiable private information or identifiable biospecimens, it is a requirement that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

C. The approval issued by the IRB shall be considered to encompass the formal waiver approval and the attestation made by the investigator on the waiver request form which must include the following information.
1. A brief description of the protected health information for which use or access has been determined to be necessary.
2. A finding that the specific protected health information needed for the research study, and its use, involves no more than minimal risk to the privacy of individuals.
3. A statement that the representations and criteria above have been satisfied, and
4. A description of the review and approval procedure utilized by the IRB, the date of action, and signature by the IRB chair or designee.

D. Waiver of documentation of consent if the subjects are members of a distinct cultural group or community in which signing forms are not the norm may be allowed. This is restricted to minimal risk research and requires an appropriate alternative method for recording that informed consent was obtained.

E. An exception to a waiver may be granted in accordance with Sheppard Pratt Privacy Policy # 340.

XII. Continuing Review

A. For continuing review, the IRB shall conduct ongoing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year. The intervals for Continuing Review shall be established by the IRB at the time of the initial approval of the investigation.

B. Unless the IRB determines otherwise, continuing IRB review is not required in the following circumstances:
1. Research eligible for expedited review in accordance with the federal code
2. Research reviewed by the IRB in accordance with the limited IRB review requirements
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study
    i. Data analysis, including analysis of identifiable private information or identifiable biospecimens.

ii. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

C. For studies for which continuing review is not required, investigators are not required to provide annual confirmation to the IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. However, the following reporting requirements remain.
    1. Such studies must report unanticipated problems and proposed study changes to the IRB.
    2. Such studies may be queried by the IRB about whether the study is still active
D. In reviewing proposals, the IRB also shall include considerations of the criteria for review section of this policy. If continuing review is not required (e.g. for studies eligible for expedited review) and continuing review is requested nonetheless, IRB records must reflect why continuing review has been requested.
E. The procedures for continuing review by the convened IRB may include a primary reviewer system.
F. In conducting continuing review of research, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including:
    1. A brief summary of the protocol.
    2. The number of participants accrued.
    3. A summary of adverse events and any unanticipated problems involving risks to participants or others and any withdrawal of participants from the research or complaints about the research since the last IRB review.
    4. A summary of any relevant recent literature, interim findings related to safety and adverse events, and amendments or modifications to the research since the last review.
    5. Any other relevant information, including findings from the Data Safety Monitoring Board, where applicable or other information about risks associated with the research.
    6. A copy of the current informed consent document and any newly proposed consent document.
    7. A copy of the protocol if modifications are proposed at the time of continuing review.
G. When reviewing the current informed consent document(s), the IRB should ensure the following:
    1. The currently approved or proposed consent document is still accurate and complete.
    2. Any significant new findings that may relate to the participant's willingness to continue participation are provided to the participant in accordance with the regulations.
H. Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.
I. As in the initial review of a study, the IRB may take any of the following actions in the continuing review:

1. Approve the study
    i. as submitted, or
    ii. with conditions
2. Require modifications to secure approval and defer or table the research study for further review at a future date after the required modifications are submitted.
    i. The HHS regulations at 45 CFR 46 make no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval. If the IRB has not conducted a continuing review and re-approved the research – with or without conditions- by the expiration date, all research activities involving human research subjects must stop after IRB approval has expired, unless it is determined to be in the best interest of already enrolled subjects to continue participation in research. Initially the decision may be made by the investigator, but the investigator must as soon as possible submit a request for confirmation that the IRB agrees with this determination.
3. Disapprove of the study

J. Failure of an investigator to submit required continuing or interim reports shall suspend automatically IRB approval of the research unless continuation for enrolled participants is determined to be in the best interest of the participants by the IRB. The IRB Chair or designee shall give written notice of the suspension to the investigator via IRBNet communication.

K. In unusual circumstances, provisions for verification of adherence to the research protocol obtained from other sources than the researcher may be obtained by the IRB; these provisions shall be specified at the time of initial or continuing review if the IRB members deem external verification appropriate.

XIII. Reporting Serious Adverse and Other Events to the IRB

A. Serious adverse events and the other types of events described in this Section must be reported to the IRB as delineated below.

B. Serious adverse events:
1. A Serious Adverse Event (SAE) is defined as a clinical event that takes place in the course of the study that:
    i. Results in the patient's death; is life threatening (i.e. the patient was at actual risk of death);
    ii. Requires inpatient hospitalization or prolongation of an existing hospitalization; results in persistent or significant disability/incapacity; OR
    iii. Is a congenital anomaly/birth defect. (Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events; 1/15/2007).
2. Serious adverse events must be reported to the IRB. An event is reportable as a serious adverse event regardless of whether it is perceived to be related or not to the patient's study participation.
3. Serious adverse events must be reported immediately to the IRB via IRBNet. In most cases, immediately it is defined as within 72 hours after the serious adverse event becomes known to the research staff.

4. Serious adverse events will be reported at each IRB meeting by the designated IRB member who receives and reviews IRB reports. The adverse events reports will also be reviewed by the IRB at the time of the annual continuing review. The IRB will review the adverse events reports to determine if there are implications for the protocol or the consent form.

C. Unanticipated problems involving risks to human participants:
   1. An Unanticipated Problem for purposes of reporting to the Sheppard Pratt IRB is any incident, experience or outcome that meets ALL of the following criteria:
      i. Unexpected given the research procedures that are described in the protocol and related documents and the characteristics of the subject population AND
      ii. Related or possibly related to a subject's participation in the research AND
      iii. Suggests that the research placed subjects or others at a greater risk of harm related to the research than was previously known or recognized.
   2. When unanticipated problems involving risks to human participants arise, the principal investigator shall notify the IRB via IRBNet. All unanticipated problems involving risks to subjects or others must be reported to the IRB within ten (10) working days of discovery.
   3. The Chair shall send a copy of the notification and action of the IRB to the Secretary of Health and Human Services in accordance with federal guidance and regulations when these problems are deemed unexpected AND related or possibly related to research AND place participants or others at greater risk of harm than previously known or recognized or was considered a serious adverse event within 30 days.

D. Unexpected adverse events:
   1. An Unexpected Adverse Event for purposes of reporting to the Sheppard Pratt IRB is any adverse event occurring in a research protocol and for which the nature, severity, or frequency is not consistent with either of the following:
      i. The known or foreseeable risk of adverse events associated with the research procedures that are described in the protocol or related documents and other relevant sources of information OR
      ii. The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing profile for the adverse event.
   2. All unexpected adverse events involving risks to subjects or others must be reported to the IRB via IRBNet within ten (10) working days of discovery.

E. Major deviations:
   1. A Major Deviation for purposes of reporting to the Sheppard Pratt IRB is any change, divergence, or departure from study design or procedures that:
      i. Is under the investigator's oversight and responsibility without prior IRB approval that affects the risks and benefits of the study,

subject safety, the integrity of study data, and/or subjects' willingness to participate in the study

2. All major deviations must be reported to the IRB via IRBNet within ten (10) working days of discovery.

XIV. Conflict of Interest

A. Underlying Principle

1. The federal Department of Health and Human Services regulations protecting human research participants are based on the ethical principles of respect for persons, beneficence, and justice. These principles should not be compromised by financial relationships or interests which create potential or actual Conflicts of Interest. Disclosure of financial relationships and interests enables the IRB to evaluate their potential impact on the implementation and evaluation of proposed research.

B. Implementation

1. The Principal Investigator must disclose to the IRB the funding source for each funded study using the disclosure form provided in the Sheppard Pratt IRBNet Library in keeping with Policy Number: HS-120.10 Sheppard Pratt Conflict of Interest Policy for Public Health Service-Funded Research.
    i. In the event that a financial relationship or interest is disclosed, the IRB will evaluate its impact on:
        a. The design of the study
        b. The risks to which participants may be submitted
        c. The selection of participants
        d. The process of soliciting informed consent
        e. The evaluation of the study results
2. IRB members must disclose any financial relationships, one time only, using the IRB Member Disclosure Form, which must be supplemented within 30 days in the event of a significant change in financial relationships or interests. It is incumbent upon each IRB member to disclose any potential conflict of interest relevant to a study that is being reviewed to the chair prior to the time the study is reviewed.

C. The evaluation process may include seeking supplemental information and the IRB Committee may engage the assistance of resources such as a Conflict-of-Interest Officer or General Counsel.

1. In the event that the IRB Committee determines that, as a result of a financial relationship or interest, there is any reasonable possibility of a Conflict of Interest, including bias, coercion or undue influence, the IRB will take appropriate action, which may include:
    i. Refusal to approve the study; or
    ii. Attachment to its approval of conditions intended to eliminate or mitigate the Conflict of Interest, such as separation of responsibilities, additional oversight or monitoring, or reduction or elimination of financial interest; or
    iii. Requiring disclosure of the Conflict of Interest to parties who might be affected by the Conflict of Interest, if, in the judgment of

the IRB Committee, the information would meaningfully add to the protection of the rights and welfare of participants

As of July 2018, this policy replaces Clinical Manual Policy #CM-410.3 Institutional Review Board (IRB)

REFERENCES:

CM 520.9 - Use of Investigational New Drugs
HS 120.8 - Participation of Employees as Research Subjects
HS 120.10 - Sheppard Pratt Conflict of Interest Policy for Public Health Service-Funded Research