POLICY STATEMENT: It is WellStar’s policy that all research projects involving WellStar team members, services, facilities, or records, and:

1. Conducted by WellStar team members,
2. Conducted by WellStar Graduate Medical Education faculty, resident employees, or
3. Conducted at WellStar facilities or using WellStar data

will be submitted through the WellStar Research Institute and reviewed and approved by the Institutional Review Board (IRB). The IRB shall have the authority to approve, approve with modifications, disapprove, place restrictions to a project including the informed consent process; require periodic reports from the project investigator; oversee the conduct of the project and informed consent; and suspend or terminate approval of the project.

PURPOSE: WellStar Health System recognizes that in conducting research, investigations or clinical trials involving human subjects the first responsibility is to the health and well-being of the individual research subject. The WellStar Research Institute has been established to administratively coordinate research activities and human subjects protections, including the WellStar Institutional Review Board.

DEFINITIONS: This policy has been adopted in compliance with Federal Regulations regarding the use of human subjects in research projects. The Code of Federal Regulations defines research as “...a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)); this Policy reflects the basic guidelines of that Code and the guidelines contained in the Belmont Report and the Declaration of Helsinki. Additionally, this policy has been adopted in compliance with Federal Regulations regarding clinical investigations. The Code of Federal Regulations defines a clinical investigation as “...any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but 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.'

AUTHORITY: The Institutional Review Board (IRB) has been established under the authority of the WellStar Health System. The Administration of WellStar Health System can decline to implement a project that the IRB has approved but cannot implement one that has been disapproved or terminated. The WellStar Research Institute has been established to support compliance with the WellStar Federal Wide Assurance (FWA00004294) designation.

IRB MEMBERSHIP:

Composition
1. The IRB shall be in compliance with the CFR guidelines set forth in 45 CFR 46.107 and 21 CFR 56.107 in that it shall consist of at least five members of varying backgrounds including both male and female members, members with primarily scientific and non-scientific backgrounds determined by their degree(s) earned, and members not affiliated with the institution and representing the community. Documentation of these qualifications shall be maintained in the member’s file and a resume kept in the IRB Member file; for non-affiliated members, a resume shall be provided and maintained in the IRB Member file. All IRB files will be maintained at the WellStar Research Institute.

2. The IRB may invite individuals with specific expertise as required by the projects under consideration, but these persons shall not vote.
3. Members with interests in projects under review and project investigators will present information to the Board and respond to questions but will not participate in the original or continuing review or vote on project actions.
   a. In compliance with OHRP/FDA guidelines these members will not be counted for purposes of maintaining a quorum in these instances.
   b. Conflicts of Interest for Board members shall be queried at the start of each meeting. If a conflict is disclosed, any member with such a conflict will be recused.

**IRB Chair**
The IRB Chairperson manages the IRB and the matters brought before it according to FDA and DHHS regulations pertaining to the rights and welfare of research subjects. The IRB Chairperson is responsible for conducting meetings in an efficient and orderly fashion with respect given to the opinions of all members. Robert’s Rules of Order may be used as a guidebook for conducting the meeting. Should an IRB Chairperson not be available to conduct panel business, he/she may designate an IRB staff member or senior board member to assume his/her responsibilities during the period of absence.

The Chairmanship of the IRB shall be an Institutional Official appointment with an open-ended term of service subject to yearly reappointment by the Institutional Official. In addition to conducting meetings, the IRB Chair shall primarily be responsible for:
   a. institutional compliance with applicable federal, state and local regulations governing the conduct of human subject research
   b. compliance with the federal mandate for ensuring continuing IRB education and development activities.

**IRB Appointment, Term, and Training**
1. Members shall be recruited from both WellStar team members and individuals who are unaffiliated with WellStar Health System
   a. Persons agreeing to serve on the IRB shall be appointed by the Institutional Official to a one-year term with automatic renewal unless otherwise requested.
   b. Members shall be expected to attend each regularly scheduled meeting, and an attendance and sign-in record shall be kept.
      (i) Non-medical staff and non-employee members shall be offered an honorarium per attended meeting.
      (ii) Alternate members as allowed for in 45 CFR 46 and 21 CFR 56 can be designated for a specific member. All training requirements apply.

2. Members can be removed at the discretion of the Institutional Official.

3. New members, when appointed, shall be required to have completed Human Protections Training (e.g. NIH, CITI, etc.) and receive initial orientation through the WellStar Research Institute.
   a. Continuing education shall also be provided by the WellStar Research Institute and shall consist of reference materials, publications and journals, professional meetings, training materials, on-line NIH and OHRP modules, and in-house/system education courses as variously specified.
   b. Six continuing education contact hours are expected to be completed every year to continue IRB Membership in good standing
      a. Initial review of IRB submissions and materials and preliminary disposition and recommendation for IRB action.
      b. Development, preparation and distribution of meeting agenda and materials.
      c. Documentation, correspondence, and follow-up activities as required.

**Administrative Infrastructure – WellStar Research Institute (WRI)**
1. The Director of Research/Human Protections Administrator will be an experienced research professional with oversight on a day-to-day basis or the administration and operations of the WRI.
2. The Director of Research/Human Protections Administrator will be held to the same training requirements as IRB Members including timeliness of initial training and continuing education.
3. The WellStar Research Institute shall provide the supportive administrative services as required by the IRB and which include:
   a. Initial review of IRB submissions and materials and preliminary disposition and recommendation for IRB action.
   b. Development, preparation and distribution of meeting agenda and materials.
   c. Documentation, correspondence, and follow-up activities as required.
d. Development and maintenance of IRB activity and research project files.

**IRB REVIEW:**

**Submission**
The following documents will be submitted to the WellStar Research Institute for prospective approval of all human subjects research (expect research exempt from federal regulations) conducted at WellStar Health System:

- a) IRB Intake Form
- b) Protocol
- c) Informed Consent Form (ICF)
- d) Authorization to Use and Disclose Protected Health Information (may be included with ICF or separate)
- e) Investigator Brochure, if applicable
- f) Recruitment Materials and other information to be given to subjects

**Initial Review—Full Board**
All proposed projects that involve human subjects and that satisfy the definition of research must be reviewed prior to the activity beginning. This review is called “initial review.” The types of initial review are expedited and full. Full Board review of research is exercised when the research does not meet the criteria for expedited review or otherwise is determined to necessitate review at the convened full board meeting of the IRB membership.

The IRB conducts all full board review processes in accordance with 45 CFR 46 and 21 CFR 56. The convened IRB may be a forum for discussion and reviewer guidance of protocols which would otherwise be exempt such as student or resident research. Such discussion does not change the review levels of such protocols without a vote by the convened IRB. In order to conduct research via Full Board review, the IRB must meet the requirements described in **IRB COMPOSITION.**

**Initial Review—Expedited Review**
Identification of research projects that qualify for expedited review will be made by the IRB administrative staff. Expedited research projects will be reviewed by the Chairperson of the IRB or by an experienced member of the IRB designated by the Chairperson. Only projects involving no more than minimal risk are considered for expedited review. The reviewer makes the final decision as to whether or not the protocol meets the applicability criteria and qualifies for the category or categories noted (or another one or more of the 7 categories) and can decide to refer the review to the full board. Investigators must submit sufficient information to ensure that the IRB criteria for approval are met, including but not limited to the application, scientific rationale, research protocol, consent form and any other necessary information. At initial review, the expedited review type applies to research projects that:

i. pose no more than minimal risk, AND
ii. involve one or more research activities authorized by 45 CFR 46.110 and 21 CFR 56.110 as qualifying for expedited review.

**Continuing Review**
All human subjects research is subject to continuing review of research based on the level of risk as assessed by the IRB at the time of initial review. The IRB considers the same criteria for consideration of approval under continuing review as under initial review in accordance with 45 CFR 46.111 and 21 CFR 56.111, including, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB maintains written records indicating the results of continuing review, including the date of the most recent continuing review, the results, and the action taken. At initial review and at continuing review (or otherwise as warranted), the IRB will plan for continuing review of research at intervals appropriate to the degree of risk but not less than once per year, and will exercise the authority to observe or have a third party observe the consent process and the research, as appropriate (given the level or risk, experience of the investigator, vulnerability of subjects, or other concerns) per 45 CFR 46.109 and 21 CFR 56.109.

For research receiving full board review, the length of approval is calculated from the date of the full board review. The IRB will provide a recommendation for length of approval; if other than annual continuing review will be required. The appropriate length of approval is considered as part of the full board discussion of known or potential risks and requires a majority vote from a quorum of IRB Members. For research approved via expedited initial review, the Chair or designee primary reviewer suggests length of approval.

**Exempt determinations**
Exempt Research is “exempted” from federal regulations outlined in 45 CFR 46; which means that the research is not subject to a formal informed consent process or to continuing review by the IRB. However, determinations of exemption must be made by an assigned member of the WellStar Research Institute.
The WellStar Research Institute makes all determinations of exemption. Identification of research projects that qualify for exemption will be made by the Human Protections Administrator or their designee. Exempt research projects will be reviewed by an assigned member of the WellStar Research Institute.

Principal Investigators requesting exemption for their research projects, as permitted in IRB Forms and Guidelines for Human Subjects Research, shall submit no packet, but shall submit a letter to the IRB through the WellStar Research Institute requesting exemption, and including sufficient documentation so that a determination on the request for exemption can be made.

If such request for exemption is denied, and the Principal Investigator desires to proceed with the research project, the Principal Investigator shall submit the IRB Forms and Guidelines for Human Subjects Research as provided in Section 1.

**Review of amendments**

Federal regulations require that amendments to research activities not be initiated without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (in which case the investigator must promptly report the amendment to the IRB). Investigators must report planned amendment in the conduct of research and receive IRB approval PRIOR to implementing these changes. At the time a study receives IRB approval principal investigators receive a letter of approval that outlines the requirement to submit any changes in their research project to the IRB for prior review and approval. Amendments that were unplanned and involved deviations from the protocol in order to minimize or eliminate a serious hazard are unanticipated problems that involve risk to subjects or others. See Reporting-Unanticipated problems.

Amendments include, but are not limited to, procedural changes to a protocol, requesting additional subjects beyond the approved number, changes in protocol or investigational drug brochure, and any changes in informed consent materials or advertisements.

**Special Protections**

Due to the vulnerable nature of certain study populations and the additional regulatory requirements stipulated in 45 CFR 46 and 21 CFR 56 subparts B, C, and D, the IRB will not review/approve studies involving the following populations as subjects:

- a) pregnant women including their fetuses and neonates
- b) prisoners
- c) children including wards

**INFORMED CONSENT**

Informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. It is both an initial and ongoing process, not just a form or document, which enables prospective and current research subjects to voluntarily decide whether or not to participate as a research subject, or to continue participation.

With few exceptions (other than research determined to be exempt), no investigator may involve a human being as a subject in research at WellStar unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative PRIOR to participation and appropriately documented the informed consent process.

The process of informed consent to participate in a clinical trial or research project includes at a minimum:

- a. A full description of the nature of the trial/project, procedures to be followed and expected treatment;
- b. A full description of expected benefits, potential risks and discomforts, and alternatives that might also prove advantageous;
- c. Comprehensive information related to the right to refuse to participate in the trial or project and that this refusal will not compromise access to services otherwise available;
- d. The opportunity for the subject to ask questions and have those questions answered to their satisfaction;
- e. The name of the person who provided the consent information; and
- f. The date the consent form was signed.

2. An Informed Consent Template is provided each investigator modeled on the requirements of 45 CFR 46,
21 CFR 56, and WellStar policies and including:

a. The registration of relevant trials on clintrials.org

b. A transparent statement regarding the potential for loss of insurance coverage and the resultant financial responsibility of the subject

3. When research studies/clinical trials are complete, the Principal Investigator will do everything possible to eradicate any confusion, misinformation, stress, physical discomfort, or other harmful consequences the subject may have experienced as a result of participation in the research.

a. The IRB will not allow discriminant financial coverage for research-related injuries or any other study costs incurred by the subject.

b. Full information regarding any financial responsibility of the subject will be disclosed before the subject is enrolled.

**IRB OPERATIONS:**

1. Meetings shall be held monthly at a regularly scheduled time.

2. Meeting notification and materials will be sent to all members prior to each meeting in sufficient time for review.

   a. All members will receive information sufficient to provide an overview of each of the agenda items. Documentation of new projects will include at a minimum an informed consent and protocol summary as well as supporting information as defined in the "Forms and Guidelines." Complete documentation will be available to all members, if requested, through the Research Department.

   b. Criteria for IRB approval, referencing 45 CFR 46.111 and 21 CFR 56.111, shall be distributed as part of the material when new projects are reviewed.

   c. Principal investigators, or a designate pre-authorized by the IRB, are required to attend each IRB meeting at which their projects are initially reviewed.

   d. A simple majority of IRB members with at least one IRB member having primary interests and educational training in science and at least one IRB member whose primary interest and educational training are in a non-scientific area shall be considered a quorum for voting purposes and for sustaining an action.

      (i) These members must be physically present at the meeting site or as allowed by regulatory oversight.

      (ii) The action of a simple majority of the members present and eligible to vote shall be the action of the IRB.

3. Research projects which are disapproved, terminated, or suspended by the IRB shall not be continued until IRB approval is re-established.

   a. The IRB shall notify the investigator and the hospital administration of these actions and the supporting rationale.

   b. If a project has not received initial approval the investigator may request re-review upon resolving the issues raised in the IRB deliberations.

4. At the request of a principal investigator who is a member of the medical staff or a team member of WellStar, the IRB will review studies whose primary location will not be WellStar if the anticipated location does not have a designated IRB.

   a. If a new location, a site visit by the Research Department will be made to the proposed study location to ensure that the study can be conducted in compliance with appropriate policies and guidelines.

   b. If the study location is a separate institutional facility, a cooperative agreement will be completed between WellStar and the study location detailing the structure of the research to be conducted and the rights and responsibilities of both parties.

5. Principal Investigators shall comply with all applicable federal, state and local laws, rules and regulations in the conduct of research projects as set forth in 21 CFR 20, 21 CFR 50, 21 CFR 56, and 45 CFR 46 and Good Clinical Practice ("GCP").

   a. Qualifications of the PI will be established as part of the submission
(i) Certification of approved training will be required for new investigators doing research; such training can be sponsor-designated or part of the CITI or NIH series.
(ii) Investigators shall also be required to remain in compliance with WellStar education policies.

6. The IRB shall set a fee for the initial and continuing review of research projects which are externally funded. This fee can be waived at the discretion of the IRB Chairman if so requested by the investigator.

IRB RECORDS:

1. The IRB operates under the principles and policies set forth in these Policies and Procedures and in compliance with applicable local, state and federal regulations.

2. The WellStar Research Institute shall maintain a current roster of IRB members.
   a. The IRB shall be registered at OHRP/FDA as required by the FWA.
   b. The IRB roster will include members’ names, specialty, affiliation, primary interest, and earned degrees to ensure appropriate representation is documented.

3. The minutes of each IRB meeting shall be prepared by the WellStar Research Institute and shall include: a listing of members present with special notation of the individual representing the mandated non-scientist, absent and excused; a summary of the discussion for each agenda item; a record of decisions taken with documentation of appropriate rationale; a record of pending issues; and a record of voting for each issue giving a total tally of members voting for, against and abstaining:
   a. The minutes shall reflect the abstention of members during voting regarding projects in which they have a personal involvement including the nature of the involvement.
   b. An approved copy of the minutes shall be provided to the Medical Staff Office and a copy maintained in the WRI files.

4. All IRB documentation shall be maintained by the WellStar Research Institute and shall include complete files on each research project presented, including protocols, consents, amendments, adverse events, investigator updates, all correspondence and any financial or contractual information.
   a. The final version of the informed consent as approved by the IRB may reflect the version date on each page but shall bear a dated stamp from the IRB.
   b. Once a project has been reviewed and approved by the IRB, even without implementation, it will be considered an active project and subject to IRB continuing review and guidelines.
   c. Each research project shall be collected in a separate file and maintained in an active grouping for at least three years following termination of that project.
      (i) Research files shall be maintained at least seven years by the facility following the initial three-year post-termination phase but may be stored in an inactive grouping location.
      (ii) Research files may be shredded or otherwise destroyed consistent with the facility's 10-year retention policy.

5. All other documentation pertaining to the IRB and the research program shall be maintained by the WRI and shall include meeting minutes, general correspondence, financial records, and reference and education materials. Access to such records shall be limited to as provided for in CFR and applicable federal and legal guidelines.

6. The WRI will conduct periodic auditing of active projects to ensure appropriate informed consent documentation and documentation of adverse events and report such findings to the IRB. The WRI will perform specific audits as requested by the IRB.

IRB COMMUNICATION:

1. Investigators are required to report to the IRB adverse events associated with research projects in which they are participating.
2. If the event occurs within the investigator’s own study patient population and:
(i) the patient is enrolled from WellStar and
(ii) the event is life-threatening and
(iii) related to study participation

It should be reported within 24 hours.

3. Other events occurring within the investigator's own study patient population should be reported to the IRB within three days. Events occurring due to disease state or progression are not reportable unless they are serious and unexpected.

   a. If an event occurs within the investigator's own study patient population but the patient has not been enrolled from WellStar, the event should be reported to the IRB at the same time as it is reported to the sponsor or the separate IRB.
   
   b. All other events as reported by the sponsor should be forwarded to the IRB within one month and will be included in the materials submitted to the IRB as an agenda item for the next monthly meeting.
       (i) As part of such documentation the investigator should include a written statement evaluating the event in terms of its relation to participation in the research project.
       (ii) The investigator should also state whether the event has altered the risk to benefit ratio and whether a consent revision is required.

Communication Steps

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<td>1.4 Confirm IRB approval of the research project and Informed Consent Form and communicate same to WRI staff prior to initiation of study.</td>
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**REPORTING**

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**Special circumstance and determinations – Emergency Use, Expanded and Compassionate Access, Humanitarian Use, Medical Device Risk Determination:**

1. Emergency Use guidelines as defined by the FDA will be accepted by the IRB and notification to the IRB of such activity should occur within 24 hours and be accompanied by appropriate documentation.
   a. Investigators anticipating additional accrual of patients for a research protocol implemented under the Emergency Use guidelines should submit the protocol for full review at the next regularly scheduled IRB meeting.
   b. Patients enrolled in protocols under Emergency Use guidelines shall not be considered evaluable study subjects unless specifically approved by the IRB.
2. All “expanded access” and/or “compassionate use” protocols as defined in FDA regulations will be required to complete the full board review process.
3. All Humanitarian Use Device/Humanitarian Device Exemption protocols will be required to complete the full board review process and be subject to annual continuing review.
4. Research studies intending to evaluate safety and/or effectiveness of an investigational device must be conducted in compliance with 21 CFR 812. The IRB is responsible for verifying that studies involving investigational devices have a valid Investigational Device Exemption (IDE) issued by the FDA, qualify for an IDE exemption, or qualify for an abbreviated IDE. When an IDE is required, the IRB must make a Significant Risk/Non-Significant Risk determination regarding the device, unless this determination has already been made by the FDA. Requests for determination of Significant vs Non-Significant Risk devices as outlined in the FDA guidelines will be considered by the Board as part of the full protocol review process. It is the responsibility of the investigator to supply appropriate documentation to the Board so that a determination can be made. Such documentation should include prior pre-clinical testing results, any FDA determinations, any product specifications, and human subjects results, and any supporting extra-disciplinary specifications and expert testimony.
PROCEDURES
1. Protocols for all research projects shall be submitted to the WellStar Research Institute using the standard e-packet entitled IRB Forms and Guidelines for Human Subjects Research. All non-exempt research involving human subjects shall be coordinated through the Research Department prior to actual IRB submission as outlined in the submission application.
2. Specific information regarding deadlines, copies, etc. are detailed in the packet and should be followed.
3. Each research project shall have a qualified designated Principal Investigator who is either a member of the Medical Staff, medical or pharmacy resident, or an employee of the hospital (system). Principal Investigators, or a designee pre-authorized by the IRB, are required to attend each IRB meeting, or meetings, when their research projects are being reviewed.
4. Correspondence pertaining to the IRB shall be between the Principal Investigator or a designate authorized by the IRB and the IRB. Materials intended for subject use or education may be accepted rather approved at the determination of the IRB if such materials are not subject to revision by the investigator or IRB.
5. The "Financial Disclosure Form" shall be completed and submitted at the time of initial application.
6. No research project may be implemented until the research project has been approved by the IRB. Preliminary pre-review budgeting, development of interdepartmental support resources, and sponsor review requirements should be coordinated through the Research Department.
7. Projects may need to be reviewed by WellStar departments, individuals or committees prior to or following IRB review. Investigators should consult with the Research Office to make this determination.
8. If Expedited Review is requested, a cover letter to the IRB so stating should be included with the submission to the WellStar Research Institute. The appropriate documentation from the "Forms and Guidelines" should be included.
9. Review for Continuation of research projects is required at least annually. Principal Investigators are responsible to provide the required information and will be notified and supplied with the continuation Forms in time to satisfy this requirement.

REPORTING:

Federal agencies
The IRB will report, within 30 days of identifying a reportable event, the following to relevant regulatory and oversight agencies [in accordance with 45 CFR 46.103(a), 21CFR56.108(b), and 21 CFR 56.113] for non-exempt research, regardless of funding:

a. unanticipated problems involving risks to subjects or others;
b. serious and/or continuing noncompliance with the requirements or determinations of the IRB; and
c. suspension or termination of previously approved research.

Unanticipated problems
Consistent with federal regulations, WellStar requires reporting to the IRB of unanticipated problems posing risks to participants or others. This policy applies to both behavioral research and biomedical research and includes (but is not limited to) the reporting of adverse events, protocol deviations/violations, and confidentiality breaches.

While there are many unique terms to define a given type of reportable events (e.g., serious adverse event, adverse event, adverse experience, etc.), the IRB uses the following single definition for an IRB-reportable event:

Unanticipated Problem: An unanticipated problem involving risk to participants or others is defined by meeting ALL 3 of the following criteria:

a. Was not anticipated or foreseen;
b. Involves risk or harm to participants or others; AND
c. Was probably or definitely related to, or caused by, the research activity in the judgment of the investigator.

Procedures for reporting of unanticipated problems involving adverse effects, serious adverse events, emergency use, obtaining informed consent, etc. are set forth in Federal regulations and E6 Good Clinical Practice copies of which are available through the WellStar Research Institute. It is the responsibility of the Principal Investigator to be familiar with and comply with all such reporting requirements. Each new Principal Investigator shall be provided, upon request, with a copy of these policies and procedures and with any other documentation pertaining to the specific research study and IRB operations.

INSTITUTIONAL COORDINATION:
1. Principal Investigators are responsible for ensuring that all appropriate interdepartmental arrangements have been made. Upon request, the WellStar Research Institute will assist in this activity.
   a. The investigator may be required to provide assurance that specific coordination has occurred within the institution ensuring that the research will be conducted in compliance with WellStar policies and guidelines.

2. Interdepartmental arrangements may include coordination with Laboratory and Pharmacy when non-standard procedures are required or investigational drugs are used; coordination with medical records when records reviews are necessary; coordination with patient care services when non-standard clinical practices or training is required, or coordination with patient accounts when patients are not to be billed for research-related procedures.

3. Investigators shall be able to demonstrate familiarity with the appropriate rules, regulations and procedures governing the ethical conduct of research. This documentation can consist of historical review, evidence of completion of a training program or a detailed operational implementation plan concerning the proposed research project.

**PRIVACY BOARD:**

1. The Institutional Review Board shall also advise and inform the WellStar Privacy Board (PB) as described in the 45 CFR Parts 160 and 164 Privacy Rule Provisions Related to Research.
   a. Requests for authorizations for uses and disclosures related for research will be reviewed.
   b. Waiver of authorizations for research and activities preparatory to research will be reviewed.
   c. Other authorizations and requirements to include PHI identifiers, access and accounting for disclosures for research will be monitored by the IRB/PB.

2. Minutes of actions of the Privacy Board will be kept separately from minutes of the IRB and these minutes shall include full documentation of Board composition, discussion voting as required in full for IRB minutes.

**FINANCIAL ACCOUNTABILITY:**

1. The financial components of each research project shall be initially reviewed by the WellStar Research Institute at the time of project submission.
   a. All financial and accounting policies and procedures as mandated by the WellStar Health System shall be applied and followed in addition to the site-specific policies as outlined following. WellStar Health System policies supersede local policies when the two are in conflict but should be complementary.
   b. Non-WellStar employee investigators conducting studies not utilizing significant WellStar resources, facilities or staff are required to complete the Financial Disclosure information but can administrate project funding without WellStar Research Institute involvement. In the event subject payments or contracted services from WellStar are included in the protocol a contract shall be developed between WellStar and the investigator by the Research Department with the assistance of WellStar personnel and advisors. The Financial Disclosure information shall include research-related clinical and patient care costs that are to be reimbursed by the study.
   c. Investigators who are WellStar employees or whose projects will be implemented with a significant involvement of WellStar resources, facilities or staff are required to coordinate contracting, budgeting, receipt and dispersal of funding through the WellStar Research Institute.
   d. Investigators implementing studies in collaboration with another institution for a project in which WellStar receives funding as a subcontractor, will be required to coordinate contracting, budgeting, receipt and dispersal of funding through the WellStar Research Institute.

2. When the WellStar Research Institute is to administer funding, the WellStar Research Institute and the investigator shall together develop a line item budget guideline that details categories of allowable expenditures. This line item guideline shall at a minimum include all patient-related and hospital-service-related costs that are to be reimbursed by the study.

3. For each project for which the WellStar Research Institute is to administer funding, the WellStar Research Institute and the investigator shall develop a mechanism by which patient-care costs and hospital service costs will be reimbursed in compliance with applicable federal and state guidelines.

4. When the WellStar Research Institute is to administer funding, study payments will be deposited into a pre-designated revenue account by the WellStar Research Institute.
   a. Deposits to the account will be done with funds supplied by the investigator with documentation as
to their source.
b. Investigator-requested payments and transfers will be made from that account upon receipt of adequate documentation.
c. Each research project shall be assigned a separate account number.
d. The investigator will be provided an accounting of study funds upon request but not less than annually.

5. The WellStar Research Institute shall initially review all legal documentation related to research activities including, but not limited to, study contracts, letters of indemnification, confidentiality agreements and cooperative agreements. Following initial review, the WellStar Research Institute will either recommend signature to the appropriate WellStar authority or recommend WellStar legal review and document same.

6. Decisions regarding financial conflicts of interest shall be made by the Chairman, the Board and the WellStar administration.

7. Review and decisions regarding fraud and misconduct of research shall be undertaken by the Chairman, the Board and the WellStar administration and medical staff. Sanctions with be consistent with WellStar and medical staff policy.

8. The WellStar Research Institute, along with the designated FWA administrative official, shall be responsible for reporting, as required, for all research activities.

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This replaces all previous [SPP/APP/DPP] and all previous [SPP/APP/DPP] shall automatically terminate upon the effective date set forth above.