IRB INITIAL REVIEW

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to protecting the rights and welfare of human research subjects by outlining policy and delineating responsibility and procedures of the Institutional Review Board (IRB; also previously and elsewhere referred to as the Subcommittee on Human Studies).

It is the policy of the BVAMC HRPP to ensure that the applicable Federal, state, and local regulations are carried out in protecting the rights and welfare of subjects who voluntarily participate in investigational studies within this Medical Center. This Standard Operating Procedure (SOP) provides written policies and procedures for the information provided to the IRB for the initial review of research, for conducting initial reviews of research proposals and for communicating its findings and actions to the BVAMC Director, Research and Development (R&D) Committee, and the investigator.

2. RESPONSIBILITIES

The BVAMC Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the BVAMC.

The BVAMC R&D Committee is responsible for approval or disapproval of the actions of each IRB.

The IRB of record for BVAMC is currently BVAMC, but is expected to be either the affiliate IRB at UAB or the Central IRB (CIRB). They are responsible for the initial review and subsequent continuing reviews of investigational studies involving human participants. Each of these IRB’s approve, disapprove, modify, restricts suspend, or terminate studies involving human subjects. Within the review process, the committee is responsible for safe-guarding human studies in the areas of informed consent, voluntary participation, confidentiality, and ensures that human experimentation is performed under stipulation and procedures of the written protocol as approved.

Principal Investigators are responsible for submitting the research proposal to the IRB for evaluation and decision before initiation. Under no circumstances may an investigator begin a study involving human participation without approval from the IRB of record for BVAMC, (VA, UAB or CIRB) and the R&D Committee. Research cannot be initiated until the
investigator receives a letter from the ACOS/R indicating all approvals have been obtained and the proposed study may begin.

3. **DEFINITIONS**

See HRPP SOP#24 – HRPP Definitions

4. **PROCEDURES**

a. **General Procedures.** Unless determined to be exempt (HRPP SOP #5), all human subject research conducted at the BVAMC or by BVAMC employees must be prospectively reviewed, as described below, and approved by one of the IRB’s of Record. No research may be initiated or continued at the BVAMC or by BVAMC employees without prospective approval by one of these IRB’s. Regardless of the type of review (approval as exempt, expedited or reviewed at a convened meeting), the investigator and the BVAMC Research office is notified in writing of the IRB’s determination. If an investigator is unsure whether IRB review is required, he/she may consult with the IRB office, Chair or Vice Chair and may be asked to submit a detailed letter explaining his/her plans requesting a determination from the IRB on whether or not the study meets the regulatory definition of human research. The IRB Chair will notify the investigator in writing whether or not the research meets the criteria to be reviewed by the IRB and whether the project is research, and/or human research. If a study is submitted for review and the IRB tables the study and requests substantive modifications or clarifications that were directly relevant to the regulatory criteria for approval, the changes must be reviewed and approved by the convened IRB. If a protocol is submitted for review and the Chair or the IRB members believe that there is insufficient information to enable an appropriate review, the study is tabled and a written request for additional information is sent to the Principal Investigator. The investigator may wish to attend an IRB meeting to discuss the protocol with IRB members or may respond in writing.

b. **Documents Required for Initial Review (See Initial Submission Checklist, Attachment A).** Prior to the convened meeting, all members of either IRB shall be provided with sufficient information to substantially and meaningfully evaluate the proposed research and determine appropriate action during the convened meeting. The list of documents that the investigator must submit for initial review is listed below in the Checklist of Documents for Initial Review. The investigator must submit all materials to the IRB office one calendar week prior to the next IRB meeting. The agenda and all supporting documentation to be reviewed are made available to all IRB members ideally within 4 days, in advance of the meeting.

In addition to the agenda and the previous minutes, all members receive the following for each study considered for initial review:

- Abstract and Protocol including a DHHS approved protocol if one exists
- Initial application form
- If multi-site study, materials required as a multi-site study (see section below)
- Informed Consent Document or waiver
• The complete DHHS approved sample consent form if one exists
• Any relevant grant application if applicable
• HIPAA Authorization (VA Form 10-0493) or request for HIPAA waiver (Separate from the ICF)
• Inclusion and Exclusion criteria for subject enrollment
• Investigational Drug Information Record (10-9012), if applicable
• Investigators’ Financial Disclosure and Conflict of Interest Forms
• Recruitment or advertising material(s), if applicable
• Checklist for Reviewing Privacy, Confidentiality and Information Security in Research
• Clinical Trial data sheet, if applicable
• Other materials needed to support the agenda
• If not already on file in the IRB office, a copy of the curriculum vitae and certificates of completion on the protection of human subjects in research and Good Clinical Practices (and other required training in HRPP SOP #12) for Investigators and Co-investigators
• Subject surveys or questionnaires, if not a standardized rating scale, if applicable
• Investigator’s Brochure or equivalent material (package insert), if drug is involved
• Full sponsor protocol, if applicable

c. Initial Review Requirements: In order to judge if criteria are met each IRB needs the following detailed information to be included in the protocol and/or the initial application form (whether it is a sponsored study or investigator initiated), and the IRB documents its consideration of these elements in the Protocol/Risk Assessment Checklist
  1. Title of the study
  2. Principal Investigator
  3. All co-investigators
  4. Sponsor of the study
  5. Research setting
  6. Purpose of the study including hypothesis to be tested
  7. Background, including results of relevant research, gaps in the current knowledge.
  8. Whether prospective participants would be vulnerable to coercion or undue influence.
  9. Potential benefits to the research subject and the knowledge to be gained. Choose from the following:
     • Prospect for direct benefit to participants [include knowledge to be gained],
     • Little prospect for benefit to participants, but likely to yield generalizable knowledge,
     • No prospect for direct benefit to participants, but likely to yield generalizable knowledge,
     • No prospect for direct benefit to participants, and unlikely to yield generalizable knowledge
  10. Definition of population to which study is directed and justification
  11. Number of the subjects that will be recruited for study
  12. Subject inclusion/selection criteria
13. Subject exclusion criteria
14. Subject exit criteria
15. Justification for use of special subject populations who may present informed consent issues (for example, incompetent patients, elderly, etc.) and reason for inclusion
16. Scientific and ethical justification for excluding classes (gender, race, etc) of persons who might benefit from the research
17. Appropriateness of Impact of Study design on risk
18. Description of procedures to be performed and whether any of the procedures are part of the usual or standard of care or are the procedures designed strictly for research purposes?
19. Description of the anticipated data and how the data will be analyzed to test the specific hypotheses
20. Risks (physical, psychological, social, and economic) and steps taken to minimize these risks (all four types of risk must be stated in consent form)
21. Provisions for managing adverse reactions and safety monitoring, including the identification of a qualified clinician responsible for all study-related healthcare decisions
22. Planned procedure for obtaining informed consent (including the circumstances surrounding consent procedures) to include: setting, subject autonomy concerns, language difficulties, cultural differences, educational capabilities, and vulnerable populations, when applicable. Also include the procedures for documentation of Informed Consent.
23. Compensation for participation, if offered, the amount and timing (include when participant will be paid i.e., after each visit, at end of study, etc.)
24. Plans for protection of patient confidentiality and privacy. The provisions to protect privacy may include use of a private office for interviewing, removing identifiable information, coding data, securing or limiting access to data, and obtaining Federal Certificate of Confidentiality. Also, a description of the use of personally identifiable records, the methods to protect the confidentiality of research data, and whether or not there is a Federal Certificate of Confidentiality in place, should be included in the Informed Consent. The following issues must be addressed:
   a) Will the investigator collect individually identifiable information that may be transferred or transmitted to the Sponsor or outside the VA Medical Center?
   b) Clearly delineate how the data will be secured and stored.
   c) Will the data be re-used? If so what protection will be in place until it is re-used?
   d) PI must acknowledge in the Initial Review Application adherence to VA guidelines on retention and destruction of VA research data.
25. Methods used to identify and recruit patients. These provisions include a description of the methods used to obtain information about subjects and/or those individuals who may be recruited to participate in studies. The methods may include surveys, questionnaires, interview, direct observation, rating scales, record review, tests, etc.
26. Safeguards to prevent coercion or undue influence for study participants.
27. Resources

28. Safeguards to protect the rights and welfare of mentally disabled and/or decisionally impaired subjects (vulnerable patient populations)

28. All Birmingham VA Medical Center (BVAMC) policies and regulations and all other VHA policies regarding research involving controlled substances/drugs will be followed.

29. References

**d. Collaborative Research:**

1. **IRB of Record Approval.** Each institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted at that institution.
   
   i. Each collaborating institution engaged in human subjects’ research must obtain approval from its IRB of Record and hold a FWA or another assurance acceptable to VA, e.g. DoD assurance.
   
   ii. VA investigators must submit a protocol or other documentation to their VA IRV of Record that delineates which research activities will be conducted by VA.
   
   iii. Each institution engaged in the collaborative research must use the informed consent document and HIPAA authorization required by their respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subject at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed at VA and which will be performed at other institutions.

   1. The VA informed consent document must clearly state when procedures mentioned at other institutions are part of the VA’s portion of the study.

   2. The informed consent document and HIPAA authorization must be consistent and include information describing the following:

      a. PHI to be collected and/or used by the VA research team;
      b. PHI to be disclosed to the other institutions; and
      c. Purpose for which the PHI may be used.

2. **Waivers.** PHI obtained in research for which the IRB of Record has waived the requirements to obtain a HIPAA authorization and a signed informed consent document may not be disclosed outside VA unless the VA facility Privacy Officer ensures and documents VA’s authority to disclose the PHI to another institution. A waiver of HIPAA authorization is not sufficient to fulfill the requirements of other applicable privacy regulations such as the Privacy Act of 1974 (5 U.S.C. 552a).

3. **Research Data.** The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, and how the data are to be transmitted. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.
i. Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1.

ii. All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, VA Handbook 6500, and VHA Handbook 1605.1.

4. **Written agreements.** Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a CRADA or a Data Use Agreement (DUA)) that addresses such issues as the responsibilities of each party, the ownership of the data, and the reuse of the data for other research. 

   **NOTE:** Any reuse must be consistent with the protocol, the informed consent documents, and the HIPAA authorization.

e. **Documents required for collaborative research:** Research that is being conducted with external sites must provide IRB with the following information (or process to provide the information) on the application form.

   1. Whether the external site had an IRB and if so, whether it had approved the research or relied upon BVAMC’s IRB or CIRB.
   2. Copies of Approval letters from the external organizations’ IRB and R&D Committee of each site involved (if applicable)
   3. Contact information for each site
   4. If the lead investigator is at BVAMC they must provide the IRB with a plan to manage information from all of the external sites such as; unanticipated problems involving risks to participants or others, protocol modifications, interim results if any, and personnel information and training as appropriate. If BVAMC is the lead and the research is transnational research, all BVAMC HRPP Sop’s to protect participants must be adhered to in addition to local and state regulations/SOPs.

f. **Criteria for IRB Approval:** Research with human subjects must be performed under stipulation and procedures of a written protocol, which has successfully met the test of peer review and has been approved by the IRB. The IRB systematically evaluates the likelihood and magnitude of risks and potential benefits and knowledge to be gained with each individual study. Specifically, the IRB evaluates and identifies the risks that may result from the research and the steps taken to minimize risks and determines if potential gain outweigh potential risks, in a research protocol. As part of the IRB assessment and review a determination is made of how often to review the study and its progress. This determination is based on the risk assessment, informed consent, and data safety monitoring and other assessments as deemed necessary by the IRB. These reviews, known as continuing review, can be conducted as often as every 3 months or at 6 months but must be conducted at least annually (See SOP #6 IRB Continuing Review). The investigator is notified in writing of the date for continuing review of each study submitted to the IRB.

Criteria for IRB approval include a determination and documentation of its consideration on the checklist that:

1. Risks to subjects are minimized, including physical, psychological, social, or economic. For example, risks can be minimized by using procedures that:
a) Are consistent with sound research,
b) Do not unnecessarily expose participants to risk,
c) Are already being performed on the participants for diagnostic or treatment purposes, and
d) Mitigate or reduce the risk.

2. The rights and welfare of human subjects will, in every case, supersede the interest of the investigator in experimentation.

3. Risks to subjects are reasonable in relation to anticipated benefit to subjects (if any) and the importance of the knowledge to be gained that may be expected to result from the research.

4. All known risks are included in the Consent Form, and sponsors and PIs have not used language that inappropriately minimizes risks and exaggerates potential benefits. The IRB distinguishes the risk of research activities from the risk of therapeutic activities (where applicable). See HRPP SOP #7 Research Informed Consent.

5. Selection of subjects is equitable, which includes the consideration of the following: purposes and setting of the research, the purposed recruitment plan, and the scientific and ethical justification for including vulnerable populations or for excluding classes of persons who might benefit from the research. See HRPP SOP #7 and SOP #8.

6. Informed Consent is adequate and is appropriately documented. A significant part of the initial review process focuses on the Consent Form. Research with human subjects must be done with proper informed consent. Informed Consent requires that the person consenting be given sufficient details in language that the person can understand with enough time to arrive at a decision in his/her best interest. The language of the information in the document should neither be exculpatory or coercive. Additional elements of information may be required to be included in an Informed Consent when the opinions of the sponsor, the PI, or the IRB deem it necessary or appropriate. See HRPP SOP # 7 Research Informed Consent for more detail.

7. When provisions for monitoring data safety monitoring plans are adequate, by the use of data monitoring boards or other independent monitoring teams as is deemed necessary. Additionally, members consider if adequate provisions are in place for monitoring research data collected (e.g., SAEs/AE’s and UAP’s) events at the BVAMC and sponsor reports of events at other sites, serious and unexpected events, subject enrollment and withdrawal etc.) to ensure the safety of subjects. Written agreements such as a CRADA or data use agreement may be necessary to ensure that BVAMC IRB is receiving data and safety monitoring reports that ensure and address the safety of participants.

8. Adequate provisions are in place to protect the privacy of subjects (may include securing a private area for conducting sensitive tests) and to maintain the confidentiality of the person and their data. See HRPP SOP #10 Research Data Security and Privacy.

9. Appropriate safeguards have been included to protect the rights and welfare of vulnerable subject populations, which may include mentally challenged or incompetent, institutionalized, inpatients receiving care for long-term chronic
illness (including Spinal Cord and Nursing Home), terminally ill (including cancer, HIV, genetic studies), employees, and students. The BVAMC does not conduct research on prisoners, children, pregnant women (as focus of research), fetuses, or neonates. See HRPP SOP #8 and SOP #7.

10. Certain studies may require special attention including:
   a) Withdrawal of therapy, whether or not it is replaced by experimental treatment, when there is significant risk of morbidity or mortality.
   b) Any invasive surgical procedure (including arterial catherization), even if the experimental procedure replaces a standard surgical procedure that is thought to involve higher risk.
   c) Significant risk of serious impairment.
   d) Risks when there is no potential clinical benefit to the subject. (e.g. Phase I studies).

NOTE: Risks

The risks should be thoroughly explained in the protocol and also in the consent form. Specific examples and explanation of these risks are described below.

Minimal Risk. In terms of research the meaning is that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performances of routine physical or psychological examinations or tests.

Physical Risks. Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical research usually result in no more than minor discomfort (e.g., temporary dizziness, the pain associated with venipuncture). Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and on occasion, can cause serious or disabling injuries.

Psychological Risks. Participation in research may result in undesired changes in thought processes and emotion (e.g., episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but some research has the potential for causing serious psychological harm. Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence. These feelings may be aroused when the subject is being interviewed or filling out a questionnaire. Stress may also be induced when the researchers manipulate the subjects' environment - as when "emergencies" or fake "assaults" are staged to observe how passersby
respond. Psychological harm may also result from behavioral research that involves an element of deception, particularly if the deception includes false feedback to the subjects about their own performance. Invasion of privacy is a risk of a somewhat different character. In the research context, it usually involves either covert observation or "participant" observation of behavior that the subjects consider private. Breach of confidentiality is sometimes confused with invasion of privacy, but it is really a different problem. Invasion of privacy concerns access to a person's body or behavior without consent; confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. A breach of confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, and so forth) or in social harm.

**Social and Economic Risks.** Some invasions of privacy and breaches of confidentiality may result in embarrassment within the subject's business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Some social and behavioral research may yield information about individuals that could "label" or "stigmatize" the subjects (e.g., as actual or potential delinquents or schizophrenics). Confidentiality safeguards must be strong in these instances. The fact that a person has participated in HIV-related drug trials or has been hospitalized for treatment of mental illness could adversely affect present or future employment, eligibility for insurance, political campaigns, and standing in the community. Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process. The IRB must seek information about risks to subjects and note when no risk exists. Even if a research study involves no risk, the IRB must consider this during risk/benefit analysis.

**Mitigation of risks and provisions for safety monitoring** should be explained in the protocol. Risks to subjects can be minimized: 1) by using procedures that are consistent with sound research design that do not unnecessarily expose subjects to risk, and 2) by using procedures being performed for diagnosis and/or treatment. The study design can increase or decrease the risk of the study (overall) by exposing varying numbers of subjects to the risks of the study (determined by the study design and required sample size). While the particular risks to an individual subject may not be affected by the statistical design, exposing subjects to unnecessary risks can be. A fundamental consideration in all clinical trials is the safety of those who would be at potential risk from their participation in the trial. All clinical trials require safety monitoring, but not all trials require monitoring by a formal committee. For FDA regulated studies, Data Monitoring Committees (DMC) have generally been established for large, randomized multi-site studies with mortality or major morbidity as a primary or secondary endpoint. NIH requires data and safety monitoring, generally, in the form of Data and Safety Monitoring Boards (DSMB) for Phase 3 clinical trials. For earlier trials (Phases 1, 2), a DSMB may be appropriate if the study has multiple clinical sites, if it is blinded (masked), or if it employs particularly high-risk interventions or vulnerable populations.

Department of Defense (DOD) requires that for studies involving greater than minimal risk, the IRB consider the appointment of a research monitor. This monitor can be required for a portion of the research study or studies involving no more than minimal risk if appropriate. This independent research monitor is appointed by name and has the authority to: stop a
research study in progress, remove individuals from a study and may take any steps to protect the safety and well being of subjects until the IRB can assess the situation.

g. **Investigator Assurance and Conditions of IRB Approval:** The Investigator Assurance includes the following conditions of IRB approval and the penalties for Noncompliance:

**Conditions of IRB Approval:**
1. Adhere to ethical principles:
   a) Respect for persons - consent, privacy, confidentiality,
   b) Beneficence - maximizes possible benefits to the subject and minimize possible harms, and
   c) Justice - equitable selection.
2. Obtain informed, written consent by the investigator for each human subject or his/her legally authorized representative (LAR), legally qualified guardian or next-of-kin, unless specifically waived by the IRB. If the patient lacks decision-making capacity or has been declared incompetent, surrogate consent is required.
3. Document the Informed Consent Form and informed consent procedure in the medical record. A copy of the informed consent form may be scanned into the electronic medical record or a hard copy may be delivered to the Medical Records Department for scanning. In addition, the original signed Informed Consent Form is filed in the subject's case history binder, a copy of the signed Informed Consent Form is given to the subject or the subject's legal representative, the RCO, and for those studies involving study medication, a copy of the signed Informed Consent Form is sent to the Research Pharmacist.
4. Report any serious adverse event (SAE) or unexpected/unanticipated adverse event or problem (UAE/UAP) or outcomes of this study in writing by the investigator to the IRB, within 5 days whether or not these are attributed to the research project itself or to unrelated factors (both events at the BVAMC and sponsor reports of events at other sites). The FDA defines Serious Adverse Events (21CRF312.32) (SAEs) as:
   a) death,
   b) life-threatening,
   c) hospitalization-initial or prolonged,
   d) persistent or significant disability or incapacity,
   e) congenital anomaly and/or birth defects, or
   f) an important medical event (based upon appropriate medical judgment) that may jeopardize the subject and may require medical or surgical intervention to prevent permanent one of the outcomes listed in this definition.
   In addition, serious or unexpected adverse reactions to drugs must be reported to the Committee on Pharmacy and Therapeutics.
5. Promptly report all deviations (including error and accidents) from the approved protocol and do not initiate any unapproved changes (amendments, consent form modifications, advertisements) without IRB review and approval, except where necessary to eliminate apparent immediate hazard to human subjects (Note these must be reported to the IRB within 5 days if determined to place subjects at risk).
6. Investigators are reminded that they are personally responsible for the careful, thoughtful execution of studies involving human subjects. Conscious disregard of
subject's rights as outlined in the Consent Form or failure to comply with all safeguards listed in the protocol will be met with severe sanctions.

7. If applicable, provide a copy of the Investigational Drug Information Record (VA Form 10-9012) to the Research Pharmacist prior to study initiation and request to receive, store, and dispense study medications. (The Pharmacy Department is responsible for the storage and dispensing of drugs).

8. Submit Continuing Review information to the IRB by the date specified and inform the IRB when your study is completed (federal law requires that every protocol must be reviewed a minimum of once per year). File a final report upon completion or termination of a study.

9. Submit all research manuscripts pertaining to this approved study to the R&D Committee for review and approval.

h. Suspension or Termination of IRB Approval of Research: The IRB votes to suspend or terminate approval of research not being conducted in accordance with IRB or regulatory requirements or that has been associated with unexpected/unanticipated problems or serious harm to subjects. A suspension of approval occurs when the IRB orders the research to stop pending an action (such as an investigation into the causes of adverse outcomes). Termination of approval occurs when the IRB determines that the research study must cease. The IRB shall notify the PI in writing of such suspensions or terminations and shall include a statement of reasons for the IRB’s actions. The terms and conditions of the suspension must be explicit. The investigator shall be provided with an opportunity to respond in person or in writing. The Investigator must provide a list of enrolled subjects for studies with lapsed approved for the IRB Chair to determine if any action is necessary to ensure the rights and welfare of those subjects. The IRB in consultation with the Chief of Staff, (after careful review of the safety and risks associated with the suspension of subjects previously enrolled) may require an immediate temporary suspension of enrollment of new subjects or of continued participation of previously enrolled subjects, pending review of the situation by the convened IRB. See HRPP SOP #18 Allegations of Noncompliance for more details.

i. Study Closure: The Continuing Review format will also be used for final study reporting when submitting for study closure.

5. REFERENCES
VA Handbook 1200.05 Requirements for the Protection of Human Subjects

6. ATTACHMENTS
Attachment A - Initial Submission Checklist

7. RESCISSIONS
HRPP SOP #3 Initial Review December 2010; August 4, 2011; January 9, 2013; June 27, 2013, January 2015
8. **REVIEW DATE**
   September 1, 2020

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Louis Dell’Italia, MD
ACOS, Research and Development