INVESTIGATOR RESPONSIBILITIES

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to ensuring that any research involving human participants undergo Institutional Review Board (IRB) review before it is initiated. The research must be conducted at all times in compliance with all applicable regulatory requirements or determinants by the IRB. The investigator may contact the IRB office for information about whether an activity must be reviewed by the IRB, whether the review may be performed by expedited procedures, and/or whether informed consent or its documentation may be waived.

It is the policy of the BVAMC to ensure the compliance with all VA policies as well as all federal, state, and local laws and regulations. As outlined in this Standard Operating Procedure (SOP), investigators are responsible for following all BVAMC HRPP SOPs, following ethical principles and standards pertaining to research, following Good Clinical Practice guidelines defined by the Food and Drug Administration, in protecting the rights and welfare of research participants as their primary concern.

2. INVESTIGATOR RESPONSIBILITIES

Investigators (Principal and Co-investigators) are responsible for conducting their research in accordance with all BVAMC HRPP policies and requirements (SOPs listed below). These responsibilities include, but are not limited to, the following requirement of all investigators:

- To maintain appropriate oversight of their research protocols (including multi-sites if the lead investigator) and research staff, including recruitment and selection of study participants, study conduct, and appropriately delegating responsibilities.

- Inform BVAMC IRB if conducting research at external sites, include contact information from each site, and IRB (and R&D if appropriate) approval letters from each site. If external sites rely on another organization’s IRB for approval this must be communicated to the BVAMC IRB.

- To adhere to ethical principles as named in the Belmont Report (HRPP SOP#1).

- Employ sound study design in accordance with the standards of the discipline.
- Take actions that minimize the risk of harm to research participants and provide the IRB with an evaluation of less risky alternatives, if any, and with plans for detecting harm
promptly and mitigating potential injuries, as described in the protocol requirements (HRPP SOP#3).

- Document in the protocol the resources that will be utilized to conduct the research and to protect human participants (HRPP SOP#3).

- Seek and obtain IRB and R&D Committee approval along with the ACOS/R&D acknowledgement letter prior to initiating any research activities (HRPP SOP#3).

- Seek and obtain IRB approval prior to the expiration date through the continuing review process (HRPP SOP#6).

- Read all IRB correspondence, follow IRB Conditions for Approval, take appropriate actions and follow IRB instructions, and maintain an organized file of IRB correspondence, IRB documents, and all essential study documents.

- Do not make changes in the research protocol without prior IRB approval (HRPP SOP#4).

- Consider conflicts of interest that might affect the relationship with the participant or the outcomes of the research, and with the organization and submit a conflict of interest disclosure form at the time of initial review (HRPP SOP#9A).

- Obtain, document, and file the written informed consent, for each human subject or his/her Legally Authorized Representative or next-of-kin, unless specifically waived by the IRB (HRPP SOP#7) using the IRB stamped approved consent form, prior to allowing the participant to participate in research activities.

- Understand the difference between the informed consent process and the documentation of informed consent (HRPP SOP#7).

- Recruit research subjects in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the risks to them (HRPP SOP#8).

- Obtain IRB approval of all recruitment materials and advertisements prior to use (HRPP SOP#8).

- Design and carry out research studies with adequate data and safety monitoring during the research and adequate data security to protect the privacy of human subjects. The Privacy and Information Security Checklist must be completed for initial review. If changes are applicable to the privacy of the subject and confidentiality of the data, these changes are to be reported to the IRB. (HRPP SOP#3 and HRPP SOP#10).

- Adhere to all IRB reporting requirements for adverse events, serious adverse events, unanticipated events/problems, and protocol violations/deviations (HRPP SOP#11).
Remember that the unfounded classification of a serious adverse event as “anticipated” constitutes serious non-compliance.

- Complete the mandatory annual training, as a means to understand when activities are subject to HRPP IRB approval, when to seek guidance, and gain knowledge of applicable federal, state, and local regulations and Good Clinical Practices, Protection of Human Subjects, Data Security, Ethics, and Privacy (HRPP SOP#12 and MCM 151-04)

- Complete Research Compliance Training 101 with Research Compliance Officer (RCO) prior to initiating any research studies, and obtaining a copy of the most recent BVAMC HRPP SOP’s and all other materials related to the HRPP.

- For questions regarding the IRB forms or procedures, investigators are encouraged to contact the IRB administrator. For research questions, suggestions, problems or concerns investigators may contact the RCO, the ACOS, R&D or the AO. If the question/suggestion/concern involves data security or privacy the investigator is encouraged to contact the Information Officer, or the Privacy Officer. Contact information for questions concerns etc., is communicated to the investigators during each training session. Training on various research topics (including any new regulation or information provided from Central Office or the Office of Research Oversight) is conducted monthly and handouts are given to new investigators and coordinators that include phone numbers and email addresses of staff involved with research.

- Respond appropriately to participants’ complaints or requests for information, in a timely manner (HRPP SOP#14).

- Follow all policies and procedures pertaining to Research Pharmacy Service (HRPP SOP #21, BVAMC MCM 119-20, MCM 119-21).

- Follow all FDA policies and procedures for obtaining and documenting either an IND, or an IDE, including if the Investigator sponsors the research and is obtaining the IND or IDE (HRPP SOP’s 21 and 22).

- Know the HRPP definitions utilized in SOPs (HRPP SOP# 24)

- Prior to submissions, contact the IRB office to confirm the current versions of SOPs and forms and any other regulatory information pertaining to human participant’s protection is in use.

- Track and submit disclosure forms (at Continuing Review) with a listing of sponsors or individuals in which information has been disclosed outside of the VA system.

- Utilize a VA e-mail account to communicate with the Research Office as outlined in VHA Handbook 1200.15 Eligibility for VA Research Support.
As with all persons involved in the HRPP, Investigators may bring forward to the ACOS/R&D, R&D AO, RCO, IRB Chair, IRB Administrator or R&D Committee Chair any concern, suggestion, or question regarding the HRPP.

Investigators are reminded that they are personally responsible for the careful, thoughtful execution of studies involving human subjects. This includes asking questions about relevant procedures, policies etc that are provided to all involved with research. Conscientious disregard of subject’s rights or failure to comply with all safeguards listed in the protocol will be met with severe sanctions. Non-compliance with HRPP requirements could result in suspension of approval for a specific project. Serious or continuing noncompliance may result in suspension of the investigator’s privilege to conduct research at the BVAMC (HRPP SOP#18).

3. PROCEDURES:
Submission documents can be located on the Birmingham VAMC Intranet page (http://www.visn7.med.va.gov/intranet/facilities/11603/), click the “Service Lines and Departments” link, click on “Research.”

a. Initial Review

1) Utilize documents/process outlined in SOP #3 IRB Initial Review

2) Initial Submission will be reviewed by IRB. Results of this review will be communicated to Investigator.

3) Once the protocol receives IRB approval, the study will be forwarded to the R&D Committee for review.

   a) R&D Committee meets once a month (First Wednesday of each month)

4) The Investigator will be notified of the R&D Committee action. Upon all committee approvals, the study will be reviewed by the ACOS/R&D.

   a) The Investigator must receive the ACOS/R&D letter before initiating research.

b. Continuing Review

1) The timeframe for Continuing Review is determined by the IRB.

2) If the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. (If the IRB reviews the study more than 30 days prior to the study’s expiration date, the Continuing Review timeframe will be re-set to an earlier date.)

3) Submitting for Continuing Review
   a) Follow the directions on the Continuing Review Submission Checklist
i. Submit each item addressed on this checklist in the order it appears

b) Sign and submit the Continuing Review Submission Form (received along with the IRB Approval Letter)

c) Complete and submit the Progress Report Document

d) Provide the IRB Administrator one original and 12 copies of the Continuing Review Submission Packet

c. Amendment to Studies: All amendments to the protocol or changes in the informed consent form must be reviewed, and approved in writing by the IRB prior to the investigator's initiating the changes, except when necessary to eliminate immediate hazard(s) to the subject(s).

1) The amendment, a justification for the amendment, and when relevant, a copy of the protocol with the amendment incorporated, a copy of the amended informed consent form, and documentation of HIPAA authorization or waiver of HIPAA authorization must be submitted to the IRB. When submitting any amended document provide the currently approved document, the document with the amendment highlighted and a clean copy for your study file.

2) Amendments may be reviewed and approved by expedited procedures if the amendment represents a minor change in previously-approved research during the period (of 1 year or less) for which approval is authorized.

3) When amendments include substantive modifications or clarifications directly relevant to the determinations required by the IRB and do not fall within the list of categories of research that may be entitled to expedited review according to 38 CFR 16.110(b), the amendment must be reviewed by the convened IRB. (See SOP #24, HRPP Definitions).

4) Because the protocol and the informed consent form must be consistent with each other, if there is an amendment or modification to the protocol that affects the informed consent form, there must be an analogous amendment or modification to the informed consent form.

5) Similarly, if there is an amendment of modification of the informed consent form that affects the protocol, there must be an analogous amendment or modification to the protocol.

6) Both the protocol and informed consent form must be consistent with the HIPAA authorization. If an amendment to the protocol or the informed consent form is not relevant to uses or disclosures of PHI, the HIPAA authorization does not have to be modified.
d. Adding/Removing Personnel

1) Use the Miscellaneous Submission Form and submit electronically to the IRB Administrator.

2) When adding personnel - identify the role the new member will assume, particularly if the new member will be consenting research participants.

3) Electronically submit all required training, current CV, resume or biosketch, and a scope of practice for the new study personnel. **If the new member has participated in research before, contact the IRB Administrator to verify current required documentation is on file for the individual.**

4) When removing personnel - for personnel members who have access to a secure study folder, provide the link to the study folder for IT to use to remove the study personnel’s access from the folder.

e. Expiration of Study Approval

1) There is no provision for any grace period to extend the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

2) If approval expires:
   a) The local research office will promptly notify the investigator.

   b) The investigator must:

      i. Stop all research activities including, but not limited to, enrollment of new subjects (consenting and/or data extraction); continuation of research interventions or interactions with currently participating subjects; and data analysis.

      ii. Immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping study procedures.

      iii. IRB re-review and re-approval must occur before the study can resume. The IRB cannot retrospectively grant approval to cover a period of lapsed IRB approval. This re-review must be completed within 90 days of the expiration date.

         1. If re-review/approval does not take place within 90 days, the Investigator must submit an Initial Application to the IRB for review.
2. The IRB may ask for an explanation why study expired, solution to prevent an expiration in the future, etc.

3. If the Investigator does not submit Continuing Review documents to the IRB, the study will be administratively closed 90 days after expiration and noted in the IRB minutes. The Investigator’s Service Chief will be notified of the closure.

f. Study Closure

1) Use the Continuing Review Submission Form & Progress Report

2) Complete the study closure process the same as a continuing review, however you will not have to submit clean copies of the Informed Consent Document, HIPAA Documents or training documents.

3) Bring all paper research records to the Research Office for permanent storage.

4) Provide the IRB Administrator a link to the secure research file where the electronic research documents are stored so that IT can close access to the secure file.

g. Publications:

1) Acknowledgement of VA Research Support. All publications and presentations of VA research results must contain the following (or equivalent) acknowledgment:

   a) “This work was supported (or supported in part) by (type of award, e.g., Merit Review, Career Development Award, Pilot Project) award # (award/project number, e.g., 101 RX000123) from the United States (U.S.) Department of Veterans Affairs (as applicable, Biomedical Laboratory Research and Development, Clinical Sciences Research and Development including the Cooperative Studies Program, Rehabilitation Research and Development Service, or Health Services Research and Development) Program.” The type of award and the electronic award/project number (e.g., 101 BX123456) must be included in the acknowledgment as indicated above unless prohibited by journal policy.

   b) If VA provided no direct research funding, but the research involved the use of other VA resources (e.g., facilities or patients), the publications or presentations must contain a similar acknowledgment. For example, “This material is the result of work supported with resources and the use of facilities at the (name and location of VA medical facility).”

   c) Failure to acknowledge VA support or employment may result in discontinuation of current VA R&D funding or eligibility to apply for funding. In extreme circumstances, it may result in the revocation of the privilege to conduct research in VA.
NOTE: Some journals do not have an acknowledgment section in their published articles so this requirement would not apply.

2) Disclaimer Requirement. Publications or presentations must include a disclaimer stating that the contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.

3) Acknowledgement of VA Employment. Authors of research manuscripts, abstracts, books, book chapters, and presentations that use VA resources must acknowledge their employment using the following format: “VA title, name of VA medical facility, city, and state.”

   a) When the author also holds a faculty appointment, the academic title and school also may be acknowledged.

   b) When the work was solely funded by VA, authors must list their VA affiliation first.

4) VA Acknowledgement in Media Reports. News media and other individuals outside VA may not understand the contributions and roles of VA in intellectual advances, or VA’s collaborative relationships with universities and other affiliated institutions.

   Accordingly, investigators with VA salaries or funding support must make, when presenting or discussing with the news media their VA research results, a serious and good-faith effort to obtain appropriate recognition for VA. A serious and good-faith effort requires:

   a) Securing a written agreement, or an oral agreement when a written agreement is not possible, that VA will be cited in news reports before participating in a media interview; or

   b) Providing news media, prior to interviews, with a document on VA letterhead that:

      (1) Contains the investigator’s name, VA title, and VA medical facility;

      (2) Explains the importance to VA of citing the investigator’s VA employment in any resulting feature; and

      (3) Expresses a preference that the investigator’s VA title be used when media time or space limitations permit the use of only one professional title.

5) VA Acknowledgment During Other Professional Activities. VA support and employment, as appropriate, must be acknowledged during professional activities in which VA research results are being discussed or recognized. Acknowledgment may be oral or written, in accordance with the nature of the professional activity.
6) **Publications by Contractors.** Publications of research results by firms providing contracted services to VA are governed by the terms of the contract. The contract terms must be consistent with the provisions of VHA Handbook 1200.19, *Presentation of Research Results* with respect to review and acknowledgement of VA support.

7) **U.S. Copyright Act.** Title 17 United States Code (U.S.C.) Section 105, the U.S. Copyright Act provides that copyright protection is not available for any “work of the United States Government” defined under the Copyright Act as a work prepared by an U.S. Government employee as part of that person’s official duties (17 U.S.C. 101). Consequently, VA employees cannot copyright material prepared in the course of their employment and must decline to sign any copyright assignment. However, they may authorize a publication to publish a submitted article in accordance with their standard editorial policies.

**h. Public Access to Peer-reviewed articles:**

1) Investigators must make available to the public all peer-reviewed publications reporting the results of ORD-funded research without restrictions in accordance with VHA Handbook 1200.19 *Presentation of Research Results*.

2) Investigators are responsible for depositing manuscripts in PubMed Central operated by the National Library of Medicine (NLM) upon acceptance for publication. Manuscripts are made available to the public no later than 12 months after publication in PubMed Central. Specific procedures for depositing manuscripts are detailed at: [http://www.research.va.gov/resources/policies/default.cfm](http://www.research.va.gov/resources/policies/default.cfm)

   a) Investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this policy.

   b) The final peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.

**NOTE:** VA investigators receiving research funds from entities external to VA (e.g., the National Institutes of Health, Department of Defense) may be subject to public access requirements specific to those funders.

3. **REFERENCES**

List of HRPP Standard Operating Procedures and Medical Center Memorandums

- HRPP SOP#1: *Human Research Protection Program (HRPP)*
- HRPP SOP#2: *Organizational Structure of the Institutional Review Board*
- HRPP SOP#3: *IRB Initial Review*
- HRPP SOP#4: *Expedited Review Process*
- HRPP SOP#5: *Exempt Research*
- HRPP SOP#6: *IRB Continuing Review*
- HRPP SOP#7: *Research Informed Consent*
• HRPP SOP#8: Participant Selection, Recruitment, and Vulnerable Subjects
• HRPP SOP#9A: Investigator Conflict Of Interest
• HRPP SOP#9B: Institutional Conflict Of Interest
• HRPP SOP#10: Research Data Security And Privacy
• HRPP SOP#11: Reporting Requirements
• HRPP SOP#12: Annual Research Training Requirements
• HRPP SOP#13: Investigator Responsibilities
• HRPP SOP#14: Participant Outreach
• HRPP SOP#15: DNA Research
• HRPP SOP#16: Sponsored Research
• HRPP SOP#17: Compliance and Quality Improvement
• HRPP SOP#17B: Auditing and Compliance
• HRPP SOP#18: Allegations of Non-Compliance
• HRPP SOP#19: HRPP Resources and Annual Reporting Requirements
• HRPP SOP#20: IRB Modification Review
• HRPP SOP#21: Investigational Drugs
• HRPP SOP#22: Investigational Devices
• HRPP SOP#23: Emergency Use of a Test Article/Humanitarian Use Device (HUD)
• HRPP SOP#24: HRPP Definitions
• VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research
• VHA Handbook 1200.15 Eligibility for VA Research Support
• VHA Handbook 1200.19 Presentation of Research Results
• Medical Center Memorandum 151-01 Research and Development Committee
• Medical Center Memorandum 151-03 Subcommittee on Human Subjects (IRB)
• Medical Center Memorandum 151-04 Data and IT Security in Research
• Medical Center Memorandum 119-20 Medication Management Policy
• Medical Center Memorandum 119-21 Investigational Drugs
• Medical Center Memorandum 001-10 Privacy Policy
4. **ATTACHMENTS**

None.

5. **RESCISSIONS**


6. **REVIEW DATE**

February 1, 2021

[Signature]

`Louis Dell'Italia, MD`

ACOS, Research and Development