1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to the protection of veterans who volunteer to participate in research. As outlined in this Standard Operating Procedure (SOP), the policy of the BVAMC HRPP is to assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the BVAMC Institutional Review Board (IRB).

Informed consent - an individual’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a research project - is a critical element of ethical research with human subjects. Informed consent is an ongoing process involving the interactions and communications between the subject and personnel conducting the study. There are multiple components to the informed consent process, including the presentation, reading, discussion about and signing of the Informed Consent Form (ICF), recruitment materials, verbal contacts prior to and after enrollment, and provision of new information that becomes available during the study.

The Belmont Report describes three basic ethical principles relevant to the ethics of research involving human subjects - respect for persons, beneficence, and justice. While the informed consent process helps ensure that all three of these ethical principles are upheld in the exercise of research at BVAMC, it is an especially important expression of respect for persons. By adherence to a policy of informed consent for research, BVAMC investigators and the HRPP demonstrate treatment of potential research participants as autonomous agents and ensure protection of those potential research participants with diminished autonomy. In its review of research proposals, the BVAMC HRPP, through the IRB, considers the entire informed consent process in relation to the required elements and has authority to observe the consent process (i.e., in person, periodic audits, etc.).

2. RESPONSIBILITIES

The BVAMC Medical Center Director has ultimate responsibility for the BVAMC R&D program.

BVAMC Research and Development (R&D) Committee must assure that provisions are made to obtain legally authorized informed consent prospectively from each research
participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the BVAMC IRB. The R&D Committee is also responsible for reviewing and evaluating all its subcommittees’ decisions, including IRB approval or exemption and waiver of informed consent.

**BVAMC Institutional Review Board** is responsible for protecting the rights and welfare of subjects. The BVAMC IRB will not approve a protocol unless its informed consent plan (form and process), or a waiver of informed consent, is in full compliance with relevant BVAMC and VHA policies.

Every investigator or VHA employee engaged in research must receive annual training in Human Subjects Protection and Good Clinical Practices, which includes specific training about the informed consent process. All individuals engaged in research at BVAMC must comply with this SOP and with relevant BVAMC and VHA policies regarding informed consent.

**Principal Investigators (PIs)** are responsible for developing and submitting a plan to the IRB and R&D Committee for obtaining legally authorized informed consent prospectively from each research participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the BVAMC IRB. If a waiver of informed consent is requested, the request must specify the specific criteria that justify consideration for such a waiver, as detailed below. PIs may delegate responsibility to conduct the informed consent process to appropriately credentialed and trained co-investigators, study coordinator(s) or research assistant(s). Though the PI is ultimately responsible for the informed consent process for each of his or her research projects, study personnel with delegated responsibility for informed consent are required to uphold the same standards in the conduct of the informed consent process as PIs. Research Personnel must understand the concept of a legally effective informed consent, must appropriately document the informed consent, and must understand the difference between the informed consent process and the documentation of informed consent, as described in this SOP.

### 3. DEFINITIONS

See HRPP SOP #24 HRPP DEFINITIONS

### 4. PROCEDURES

a. **Basic IRB Requirements**: No investigator may involve a human as a subject in research covered by these regulations, or conduct any procedures required by the protocol, unless:

1) A signed IRB-approved informed consent document of the subject or the subject's legally authorized representative has been obtained giving permission for the subject to be in the study, or
2) The investigator has obtained IRB-approved waiver of informed consent. A subject's legally authorized representative (for a subject determined to be incapable of making an autonomous decision) is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [38CFR16.102(c)]. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and any steps taken that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Translated consent forms are used for studies involving non-English-speaking subjects. Investigators should note if any waiting period exists between informing the prospective participant and obtaining informed consent. No Informed Consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive, or appear to waive, any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Informed Consent must be obtained prior to initiation of any clinical screening procedures that are performed solely for the purposes of determining eligibility for research unless the IRB has specifically approved access to prospective subject’s information or identifiable biospecimens for recruitment and screening purposes or a waiver of informed consent for recruitment purposes has been approved.

The IRB reviews the informed consent form and plan/process at the time of expedited, initial, modifications/amendments, and/or continuing review and evaluates whether the consent process is effective, provides sufficient opportunity for the prospective participant/surrogate/legally authorized representative to consider whether to participate, minimizes the possibility of coercion or undue influence, is in language understandable to the participant/surrogate/legally authorized representative, and is free of exculpatory language. The IRB must also determine if any participants involved have diminished decision making capacity and the additional safeguards that are provided to ensure appropriate consent. See section e. for guidelines on defining individuals with diminished decision making capacity. The IRB utilizes a checklist to document the review and whether the required elements are thoroughly and clearly described to the prospective participant and/or their surrogate/or legally authorized representative.

The IRB requires that:

1) The consent document does not overstate benefits and understate risks.

2) Federally required basic elements of informed consent (listed below) are stated.
3) Information is presented and understood in simple language at approximately the 6th grade level. Individual studies may deviate from the policy when appropriate for the populations being recruited for those studies (with IRB approval).

4) Unless the IRB grants a waiver of documentation of the consent process for research, the consent document for research must include a discussion of why photographs, or voice or video recordings are being taken for the research, who will have access to them, and what their disposition will be after the research is completed.

5) 2018 Requirements specify that:
   a. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and on opportunity to discuss that information.
   b. The informed consent must begin with a concise and focused presentation of key information about the research study.
   c. The informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR’s understanding of the reasons why one might or might not want to participate.
   d. No informed consent process, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive, any of the subject’s legal rights, or releases, or appears to release, the investigator, the sponsor, the institution or its agents from liability for negligence.

   b. Designating Responsibility for Obtaining Informed Consent: If the PI does not personally obtain informed consent, the investigator must formally and prospectively designate to another research team member, in writing the protocol or the application for IRB approval, the responsibility for obtaining informed consent:

      1) The PI does not have to designate the individual by name, but can designate the position(s) title in the protocol or the application for IRB approval.

      2) Any person designated to obtain informed consent must receive appropriate training and be knowledgeable enough about the protocol to answer the questions of prospective subjects.

   c. An approved VA Informed Consent Document must be used (unless waived, or Department of Defense (DOD) research) and it must contain all of the required elements as described below. The IRB review process focuses on the Informed
Consent document and validates inclusion of the basic and appropriate additional required elements set forth in VA and other Federal and state regulations.

The IRB can provide a template to guide the PI in the requirements of informed consent and VA-specific information. Obtaining signatures on the consent form is not, in itself, the goal of the informed consent process, but the form both documents the elements of a thorough informed consent discussion and prompts research staff, potential study participants, and authorized representatives to discuss each of these elements.

The required elements of informed consent are (also see Research Informed Consent Template):

1) Name of the study.

2) Name of the Principal Investigator, and/or research staff qualified/delegated to complete informed consent process. 2018 Requirements have eliminated the need to obtain the signature of the individual obtaining consent.

3) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

4) The approximate number of subjects involved in the study.

5) A description of any reasonably foreseeable risks or discomforts to the subject (including physical, psychological, social and/or economic).

6) A description of any benefits to the subjects or to others, which may reasonably be expected from the research.

7) A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.

8) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes (if applicable) the possibility that the VA, FDA or other Federal oversight agencies may inspect the records.

9) For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where additional information may be obtained about research subjects’ rights. 2018 Requirements have eliminated the need to incorporate any payments the subject may receive for participating in the study.
10) An explanation of whom to contact for answers to pertinent questions about the research, research subjects' rights, any concerns about the research, complaints about research, and who to contact in the event of a research-related injury to the subject (a qualified clinician). The IRB shall ensure that the Informed Consent has accurate information for subjects about the availability of compensation and/or treatment for injury occurring in the research study. However, this requirement does not apply to treatment for injuries due to non-compliance by the subject with study procedures. In the event of research related questions, concerns or complaints, the policy and procedures can be found in BVAMC SOP #14.

11) A statement that 1) participation is voluntary, 2) refusal to participate will involve no penalty or loss of benefits or eligibility for continuing care to which the subject is otherwise entitled, and 3) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

12) A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.

13) When appropriate a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

14) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

15) Any additional costs to the subject that may result from participation in the research (if applicable and consistent with Federal laws concerning veterans’ eligibility for medical care and treatment).

16) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (if applicable).

17) Information concerning compensation to the subjects for participation in the study, including amounts and schedule of payments. 2018 Requirements have eliminated the need to incorporate any payments the subject may receive for participating in the study.

18) Provisions for confidentiality and the protection of a subject's privacy must include 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.
19) Informed consent forms used after July 10, 2006 must include information about where and how a veteran could verify the validity of a study by contacting the IRB administrator in the Research Office who will direct them to the appropriate site.

20) A statement must be included in accordance with Title 38 that some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply for medical care and services provided by VA that are not part of this study (See Informed Consent template).

21) If a Department of Defense (DOD) study, the IRB determines that the disclosure includes the provisions for research-related injury follow the requirements of the DOD research.

22) If the Investigator believes that human biologic specimens obtained could be a part of or lead to the development of a commercially valuable product, or if the specimens are to be retained after the end of the study, current VA policy and VHA regulations must be followed and noted in the IRB approved informed consent document, unless documentation of informed consent is waived.

23) A statement if data or specimens will be retained after the study for future use, where the specimens or data will be retained or stored, who will have access, and how long they will be retained. Organizations, VA and other Federal requirements must be met for use and storage of data.

24) A statement of how subjects will be re-contacted for future studies if applicable.

25) A statement if the subject will receive a report of the aggregate results or any results specific to the subject.

26) Informed Consents for clinical trials, approved after March, 2012, must contain the following wording: “A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

27) Informed Consents for studies collecting DNA must contain the following sub-heading and wording:

**Genetic Research**
A new Federal law, the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this research.
- Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

1) Review SOP # 15 DNA Research and Tissue Banking for additional wording requirements.

2) If the production and use of verbal or written statements, photographs, digital images, and/or video or audio recordings will be used for research purposes all elements of VA Form 10-3203 must be included in the informed consent document, but it is not required that VA Form 10-3203 be used.

3) For studies subject to the 2018 Requirements, a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

4) For studies subject to the 2018 Requirements, a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

5) For studies subject to the 2018 Requirements and involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

If compensation is to be provided:

Pre-2018 Requirements: For participation in a BVAMC research study, a statement about any compensation the subject is to receive for participation, the required conditions for compensation, and the compensation schedule should be included in the VA Research Consent Form for that study (this should include how
compensation will be made, monetary, gift certificate etc). There should be a description of how compensation will be prorated and calculated for subjects who withdraw early (completion of the research may not be made a condition of compensation).

2018 Requirements have eliminated the need to incorporate any payments the subject may receive for participating in the study.

d. Broad Consent: For studies subject to the 2018 Requirements, the IRB may approve the use of a broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent can only be used in VA research when identifiable data or biospecimens are collected solely for research purposes. The form used to document broad consent may be standalone or combined with the informed consent. If a combined informed consent document is used, the information provided to subjects for broad consent must be clearly discernable from the informed consent for obtaining or collecting the identifiable private information or identifiable biospecimens. The BVAMC IRB will not waive documentation of informed consent for broad consent. The following information must be provided to each prospective subject or LAR:

1) A description of any reasonably foreseeable risks or discomforts to the subject;

2) A description of any benefits to the subject or to others that may reasonably be expected from the research;

3) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

4) A statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

5) A statement that VA will provide treatment for research related injury in accordance with applicable Federal regulations;

6) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

7) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
8) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which could be indefinite);

9) Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

10) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject;

11) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm;

12) If appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research;

13) If appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; and

14) If appropriate for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Note: Broad consent can only be obtained for the use of information or biospecimens that are collected initially for research purposes. Subjects consented using a broad consent may withdraw their broad consent at any time. Broad consent cannot be approved by an IRB for studies subject to the pre-2018 Requirements.

e. The Informed Consent Process: It is important that informed consent be viewed as a process rather than an event. Though the signing of the informed consent document (ICD) is the most visible feature of this process, the process of informed consent begins with recruitment and continues throughout the course of the study. During recruitment and before the ICD is signed, this process includes:

1) Informed consent may not be administered when a patient does not have the opportunity to adequately think about voluntary enrollment in the study (except in situations where informed consent can be waived as described elsewhere in this
document). Examples of occasions where administration of informed consent is not appropriate are during a procedure where a patient may feel stressed or while a patient is under the influence of a drug that may interfere with cognitive function (e.g., medications used for sedation). The IRB may also require that Investigators include a “waiting period” within the consent process or use devices such as audio-visual aids or tests of comprehension.

2) After answering the patient’s questions, the individual administering the informed consent completes the informed consent process by having the subject review each page and sign the last page. The person conducting the informed consent process must also sign, documenting the process. The VA no longer requires a witness to the subject signature on the informed consent form.

Any person that is knowledgeable about the study including; study personnel, Fellows, Graduate Students, Assistants, and Co-Investigators can conduct the informed consent if listed on the IRB-approved Informed Consent document and authorized in writing by the Principal Investigator. Participants’ questions regarding medical illnesses, procedures, treatments, or investigational drugs must be directed to an investigator or delegated clinician with relevant clinical training and competency. If someone other than the investigator conducts the informed consent, the protocol must define the formal delegation of this responsibility and the training or credentials of the person delegated to perform this activity. Using the IRB-approved stamped consent form, investigators must obtain consent (signature and date) prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB. In addition, informed consent must be obtained prior to initiating any screening tests or procedures that are performed solely for the purposes of determining eligibility for research.

f. Protection of Vulnerable Patients and Patient Populations: An essential part of ensuring that the three basic ethical principles relevant to the ethics of research involving human subjects - respect for persons, beneficence, and justice – are respected in the exercise of clinical research at BVAMC is ensuring that potentially vulnerable patients and patient populations are given special consideration and protection. Potential research participants may be vulnerable in the informed consent process for a variety of reasons that may affect their abilities to understand, evaluate, and consider information presented or the “voluntariness” of their consent. The BVAMC HRPP assesses potential vulnerability in terms of the potential for limitations on autonomy in considerations of whether research projects contain sufficient safeguards to protect the rights and welfare of these subjects.

Examples of “potentially” vulnerable patients and patient populations relevant to research performed at BVAMC include:

- Patients with serious mental illness that might interfere with decision-making capacity or who are otherwise cognitively impaired (capacity-related cognitive vulnerability);
- Veterans, military personnel, employees, and students
• Seriously or chronically ill patients who may view research treatments with unrealistic hope for cure or recovery (medical vulnerability);
• Economically disadvantaged persons who might enroll in a research study due to a financial incentive when they would otherwise not do so;

Since research at BVAMC focuses on veterans, and veterans are accustomed to obeying orders and making sacrifices, particular attention is paid to potential vulnerabilities related to veteran status in the review of proposed research at BVAMC.

Other potentially vulnerable patients and patient populations include pregnant women, young children, prisoners, and research involving human fetal tissue, but research with these patient populations is not conducted at BVAMC.

As part of the IRB initial review and continuing review application process, investigators are required to identify any potentially vulnerable populations and to describe precautions taken to protect autonomy and prevent coercion. The IRB may require special precautions or safeguards to be taken by the investigator to protect the rights and welfare of potentially vulnerable populations (e.g., the IRB may require a patient advocate or authorized person to witness consent, a waiting period between initial contact and enrollment, or oversight of the informed consent process).

Certain types of studies may raise issues of vulnerability due to study design (as opposed to population) and the potential for limitations on autonomy will receive special consideration during IRB review. Examples of such types of studies include:

1) Studies involving the withdrawal of therapy, whether or not the withdrawn therapy is replaced by experimental treatment, when there is significant risk of morbidity or mortality;

2) Significant risk of serious impairment; and

3) Risks when there is no potential clinical benefit to the subject (e.g. Phase I studies).

g. Informed Consent for Potential Research Participants Who Lack Decision-Making Capacity or who are Incompetent: Before an incompetent person or persons with impaired decision-making capacity may be considered for participation in any VA research, the investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision making capacity as participants. Incompetent persons or persons with impaired decision making capacity may not be proposed as participants simply because they are readily available. Additionally, the research cannot impose a risk of injury, unless that research was intended to benefit the participant and the probability of benefit is greater than the probability of harm. The IRB must then evaluate whether the proposed plan for the assessment of the capacity to consent was adequate and when assent of the participants was a requirement and if so, whether the plan for assent was adequate. Investigators must determine the decision-making capacity of all potential research participants.
approached for informed consent and document this process in a progress note in the subjects' electronic medical record (note entitled “Research” or “Progress Note”). Determination of capacity to make a decision is made on an individual basis following VA requirements. As documented in the consent note, decision-making capacity can be assessed by one or more of the following individuals:

1) A legal determination, or

2) The practitioner, in consultation with the ACOS/R&D, after appropriate medical evaluation that the prospective participant lacked decision making capacity and was unlikely to regain it within a reasonable amount of time, or

3) The Chief of Staff may make this determination after appropriate medical evaluation, or

4) If based on mental illness consultation with a psychiatrist or licensed psychologist, with appropriate testing and evaluations.

If the potential research participant does not have the capacity to make a decision or if the research project involves cognitively impaired individuals, surrogate informed consent is required by the IRB. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study. LAR’s or Surrogate Informed Consent are necessary for potential research participants who lack decision making capacity or who are incompetent to participate in research. The IRB reviews informed consent processes for this population to assure the investigator is devising procedures to ensure that participants’ legally authority representatives are well informed regarding their roles and obligations to protect incompetent individuals or persons who lack decision making capacity, and that the legally authorized representatives were told their obligation was to determine what the prospective participant would do if competent, or if the prospective participants’ wishes could not be determined, what they thought was in the incompetent persons’ best interest.

1) Incompetent persons or persons with impaired decision making capacity may not be proposed as participants simply because they are readily available.

2) Additionally, the research cannot impose a risk of injury, unless that research was intended to benefit the participant and the probability of benefit is greater than the probability of harm.

The IRB must then evaluate whether the proposed plan for the assessment of the capacity to consent was adequate and when assent of the participants was a requirement and if so, whether the plan for assent was adequate. The IRB must then determine and document in the minutes or the IRB records points 1 and 2 listed above.
h. Surrogate Informed Consent: Some BVAMC research studies focus on populations with impaired decision-making capacity (e.g., patients with dementia). For such studies, surrogate informed consent is required as a matter of course and protocols submitted to the IRB for consideration must demonstrate:

- A compelling reason to focus the study on populations with impaired decision-making capacity, and, specifically, why populations with intact decision-making capacity are not suitable for the proposed research;
- A favorable risk/benefit ratio;
- Provision and plan to obtain surrogate informed consent from the subject’s authorized representative.

VHA Directive 1200.05 describes the conditions under which consent from authorized representatives (i.e. surrogate consent) can be obtained in lieu of consent from the patient. The BVAMC HRPP recognizes the following, in descending order of priority, as authorized representatives for research informed consent when potential research participants lack decision-making capacity:

1) Persons appointed as health care agents under a Durable Powers of Attorney for Health Care or a similar document (Legally Authorized Representative for Surrogate Consent);

2) Court-appointed guardian (Legally Authorized Representative for Surrogate Consent);

3) Next-of-kin willing to participate in surrogate informed consent, in the following order of priority (unless otherwise specified in the BVAMC medical record for designated next of kin): spouse, adult child (age 19 or older), parent, adult sibling (age 19 or older), grandparent, or adult grandchild (age 19 or older) or close friend.

If needed, the PI may consult with the BVAMC Privacy Officer, IRB, Research Compliance Officer, or VA Regional Counsel if there are uncertainties about who should serve as a surrogate for an individual patient. When needed, the PI, Privacy Officer, IRB, or other staff on behalf of the BVAMC HRPP can consult with VA Regional Council for assistance in applying laws involving authorized representative surrogate consent.

Surrogate consent is allowed when a subject is deemed to lack decision-making capacity and the surrogate is provided the same information that would be given the potential subject if competent. Whenever possible, surrogates should make decisions based on “substituted judgment”, using views the individual expressed while fully capable; if the values of the subject are not known, “best interest” standards may be used. The surrogate signs the informed consent on the appropriate signature line and the process of the surrogate consent is documented in the individual patient’s medical record.
Under all circumstances, the subject’s autonomy should be respected; their assent to participate should be obtained whenever possible, and their decision to withdraw at any time (whether expressed verbally or by resistance to participation) must be honored. Under no circumstances may a subject be forced or coerced to participate in a research study. Incompetent people or persons with impaired decision making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.

i. **Telephone Surrogate Consent; Consent of Illiterate Persons; Consent of Non-English Speaking Participant:** On a case by case basis the IRB may consider allowing the consent process to be obtained via the telephone. If approved, the process for obtaining telephone consent is to send the informed consent document to the authorized representative/surrogate and conduct the consent interview by telephone when the surrogate can read the consent as it is discussed. A witness to the consent process needs to also be on the telephone during the call. If the surrogate agrees, he/she can sign the consent and return the signed document to the PI by facsimile or mail. Illiterate persons who understand English may have the consent read to them and “make their mark” with a witness to the entire consent process. Informed Consent should be obtained in language that is understandable to the subject (or the subject’s authorized representative). When the prospective subject does not understand the language of the person who is obtaining consent, a reliable translator is required. If recruitment of non-English speaking subjects is anticipated, an IRB approved Consent Form written in the language understandable to the subject must be made available (and approved by the IRB). Translation of the document is not generally necessary for the BVAMC study population however, if translation is required, translation services will be necessary and will be arranged by the PI. If ever planned, the recruitment of non-English speaking persons should be stated in the protocol.

j. **Re-consent of Participant Subjects:** If the IRB determines re-consent of participant subjects is necessary, an amendment must be added to the original CPRS research consent note and state why the IRB made such a determination. A copy of the new consent must be provided to the: 1) Patient; 2) HIMS Scanning Unit; 3) RCO; and, if applicable, 4) Research Pharmacist

k. **Written Consent Document (Short Form):** A shortened version of the written consent document that states the elements of informed consent (previously listed) have been presented orally to the subject and/or the subject’s legally authorized representative, including all additional elements as appropriate. When this method is used, there must be a witness to the oral presentation. If the participant does not speak English the witness must be bilingual and speak the language of the informed consent and the language of the prospective participant. This process must include the following:

- An IRB approved written summary of what is to be said to the subject or legally authorized representative.
• Only the short form is to be signed by the subject or the subject’s representative.
• The witness must obtain and sign both the summary and the short informed consent document, and the person actually obtaining the consent must sign the short form. Both the short form and the summary must be filed with the study in the IRB office.
• A copy of the summary must be given to the subject or the subject’s legally authorized representative, in addition to a copy of the signed short informed consent document.
• The participant or the participant’s legally authorized representative would obtain and sign the (short) informed consent document.
• If FDA regulated the participant and/or the legally authorized representative would obtain, sign and date the short informed consent document, and receive copies of it afterwards.


m. HIPAA Authorization Form and Waiver of HIPAA: Regardless of expedited or convened procedures, at the time of initial review, the investigator submits a Health Insurance Portability and Accountability Act (HIPAA) Authorization Form (VA 10-0493), HIPAA Revocation Form, or Request for Waiver of HIPAA, following or using the templates found on the Research website. Unless waiver is approved by the IRB, the HIPAA Authorization Form is signed at the time of the informed consent by the participant or surrogate and filed with all copies of the informed consent. The HIPAA is a standalone document reviewed by the Privacy Officer. Documentation of this review will be placed in the IRB minutes and the IRB notification letter to the PI. If the investigator is requesting a Waiver of HIPAA Authorization, she/he must submit a memo with the explanation of how it meets the below criteria, a brief description of the Protected Health Information (PHI) for which the investigator plans to use in the research. Waiver of HIPAA Authorization is based on the IRB review (expedited or convened) and approval, provided that the request meets the following:

1) The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on at least, the presence of the following elements:

   a) An adequate plan to protect the identifiers from improper use and disclosure
   b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
   c) Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the
use or disclosure of the requested information would be permitted by the Privacy Rule.

2) The research could not be practicably conducted without the waiver or alteration.

3) The research could not practicably be conducted without access to and use of the requested information.

All of the above must be clearly and specifically documented in the IRB minutes and the approval letter to the investigator if a Waiver has been granted.

n. IRB Approval Stamp: After all contingencies are satisfied and IRB-approval has been obtained, the approved informed consent document is stamped on each page with an IRB approval stamp using the date of the most recent IRB approval date. If the consent form is amended during the protocol approval period, the form must bear the approval date of the revised consent rather than the date of the approved study. The most recently IRB approved and stamped consent form must be used thereafter. The IRB and/or IRB Chair may deem it necessary for participants who are currently active in a study, to sign a new consent form at their next study visit if substantial or significant changes to the consent form have been made.

o. IRB Procedures for Evaluation and Observation of the Informed Consent Process: The IRB has authority to designate a member of the IRB or the HRPP to observe or have a third party observe the investigators or research assistants conducting an informed consent process. Role-play or situations with actual patients can be used to demonstrate the informed consent process. Some situations where observation may be used include: to reduce the possibility of coercion and undue influence, if the study poses significant risk to the participant, if subjects may have trouble understanding the information, and when IRB has identified problems associated with an investigator or research project.

p. Waiver or alteration of the Requirement to Obtain Informed Consent for Participation in a BVAMC Research Project: The criteria for waiver or alternation of the requirement to obtain informed consent for participation in a BVAMC Research Project such as a determination are in the checklist “IRB Checklist Determining Waiver of Informed Consent.” When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB must receive and review a written description of the information that would be provided to participants.

q. Subject withdrawal from a study: When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains a part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed. The investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional part of the study. Under this circumstance, the discussion with the subject distinguishes between
study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject’s information. The investigator must obtain the subject’s consent for this limited participation in the study (assuming such a situation is not already described in the original consent document). The IRB must approve the consent document. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposed related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

For studies subject to the 2018 Common Rule, clinical trials conducted or supported by a Federal department or agency, must post an IRB-approved informed consent form used to enroll subjects on a publicly available Federal Web site after the study is closed to recruitment and no later than 60 days after the last study visit by any subjects, as required by the protocol.

5. REFERENCES

- VHA Directive, 1200.05—Requirements for the Protection of Human Subjects in Research
- VHA Handbook, 1200.05 – Requirements for the Protection of Human Subjects in Research
- VHA Handbook, 1907.01 – Health Information Management and Health Records
- BVAMC Center Memorandum No. 151-01, Research and Development Committee
- BVAMC Medical Center Memorandum 151-03 Medical Center Human Research Protection Program
- Title 21 CFR 50.23 (a-c) and CFR 50.24 (a-e)

6. ATTACHMENTS

- VA Informed Consent Document Template
- Checklist Determining Waiver of Informed Consent or Alterations of Informed Consent
- IRB Informed Consent Checklist

7. REVISION HISTORY

8. **REVIEW DATE**

January 1, 2019

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Louis Dell’Italia, MD
ACOS, Research and Development