THE INFORMED CONSENT PROCESS

1. **OBJECTIVES:**

a) Outline policies and procedures regarding the Informed Consent Process

b) Describe the policies and procedures for the review and documentation of VA Consent Form Documents to ensure that research volunteers are consented properly

c) Comply with federal guidelines and the Atlanta VA policies and procedures regarding the consenting process

2. **DEFINITION:** The Informed Consent Process is the exchange of information that takes place between a subject and investigator (or designee) before, during, and sometimes after the study.

3. PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES:

a) Ensures that when obtaining written informed consent for research, the most current IRB approved VA Form 10-1086 Informed Consent Form (ICF) is used for all VA-approved research including, but not limited to studies in which VA investigators working on VA research, enroll subjects at the affiliate hospital or other sites outside VA.
(A template of VA Form 10-1086 is available on the AREF Website.)

For the appropriate use of Informed Consents, please refer to Appendix A "Use of Informed Consents for VA Funded Research" or Appendix B "Use of Informed Consents for Collaborative Research (non-VA Funded or Unfunded Research)." If your research project does not follow either Appendix A or Appendix B, please discuss with the Research Office and Research Compliance Office.

b) Includes all elements (as required) in the consent document and/or consent process (as appropriate)

c) Obtains proper informed consent from prospective research subjects and discusses all relevant aspects of the study (e.g., study procedures, risks, and benefits, etc.)

d) Obtains informed consent prior to initiating any study activity

e) If delegating the responsibility of obtaining consent, the Principal Investigator (PI) is responsible for doing so **prospectively and in writing** (either in the protocol or the IRB submission). It is suggested that the person(s) delegated be identified by position rather than name, in the event that study staff changes.

f) Ensures the person(s) obtaining consent is knowledgeable, trained & qualified to do so

g) Obtains written "VA HIPAA (Health Insurance Portability and Accountability Act) Authorization" (unless no VA HIPAA is required, see Section 9 on HIPAA) from each subject authorizing the use or disclosure of PHI (Protected Health Information) prior to starting study activities

4. **INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES:**

a) Oversees compliance regarding the Informed Consent Process according to institutional policies and Federal Regulations

b) Ensures that the consent process is appropriately documented

c) Has the authority to observe, or have a third party (VA Research Compliance Officer) observe the informed consent process

d) Requires the use of the most recent, approved consent form documents (VA Form 10-1086, VA Form 10-3203, VA HIPAA Authorization, etc.)

e) The IRB must review and approve all research studies prior to R&D Committee approval. If the R&D Committee requires additional changes upon review, the project must be resubmitted to IRB with the R&D Committee suggested changes. After final IRB approval of the resubmission, the project must be resubmitted and receive final R&D Committee approval.

f) Ensures that the consent has all required elements and is written in a language that the subject or Legally Authorized Representative (LAR) can understand

5. PROCEDURES FOR OBTAINING VA WRITTEN INFORMED CONSENT:

a) The subject must read, sign, date, and enter the time on the ICF prior to starting any study activities

b) Subjects must be allowed sufficient time to read the ICF and consider whether or not they wish to take part in the study

c) Study staff should discuss all elements of the consent and ensure that all questions are answered before the subject decides whether or not to participate in the study

d) If the subject's competency to provide consent is questionable, a clinical assessment is required. This must be documented in CPRS (Computerized Patient Record System) in a signed/dated progress note (see Section 6e below)

e) Study staff must ensure that the subject gives consent willingly, without coercion or undue influence

f) Study staff should assess the subject's ability to read and comprehend the consent document and it's risks (i.e., asking a few simple questions)

g) In addition to the research subject (#5a above), the following persons must also sign, date and enter the time on the VA ICF:

I. The person obtaining consent
II. **If** required by the IRB, a witness whose role is to witness the subject's signature

h) The study staff must keep an original signed and dated ICF with the investigator's VA study files unless a waiver of documentation has been approved by the IRB. If so, then the appropriate method of documenting consent must be followed.

i) Study staff must keep a Master List of all study subjects. This list and all ICFs must be kept secure, and in compliance with all VA confidentiality and information security requirements.

The master list:

I. Should not have a subject's name added to it until after informed consent has been obtained.
II. May be waived by the IRB if there is a waiver of documentation of consent (See Sections 7 and 8) and the IRB determines that the master list would pose a potential risk of breach of confidentiality.

j) Study staff must provide a copy of the signed, dated and timed VA consent forms (including the HIPAA Authorization and Notice of Privacy Practices (NOPP), if appropriate) to:

I. The study subject
II. The Research Pharmacist (if the study involves drugs)
III. The Medical Records Scanning department for scanning into CPRS (if appropriate within 72 hours of obtaining consent. To submit for scanning:

- Provide a good quality copy (not original) of the documents to be scanned.
- Write the subjects full name and social security number on the bottom of the first page ONLY and do this ONLY on the copy of the documents
- Complete the "Scanned Research Document Requisition" and attach it to the copy of the consent and HIPAA forms. Make of copy of this document and put it in your research study binder.
- Place the documents to be scanned and the "Research Document Scanning Request" form into a sealed envelope and place all of those in the lock box located in the Clinical Studies Center Main Office (Room 11C119)
- Medical Records Scanning staff picks up forms from the lock box once per day, Monday-Friday. Forms will be available for viewing within 48 hours after being picked up. All forms submitted for scanning will be shredded unless otherwise specified (reminder: DO NOT SEND ORIGINALS).

k) Study staff must document the consent process in CPRS (see the Policy & Procedure entitled "Documentation Requirements" on the AREF website) within 72 hours after it o ccurs

l) Study staff should reinforce the study information throughout the course of the study.

m) If the protocol is amended, the IRB may require that study participants sign a revised consent form containing these changes. If the VA ICF is amended, it must be reviewed and approved by the IRB each time. It also must be reviewed and approved before being used to consent any new subject(s). Some amended ICFs may require that a previous subject be re-consented. If so, this process must also be documented, as appropriate (see "k" above).

n) Each time a study subject signs a consent form, the process must be documented, as appropriate, unless waived by the Research and Development (R&D) Committee (see the Policy & Procedure on "CPRS Documentation Requirements")

o) An unbiased person (not a member of the study staff) must witness***** all oral

presentations when a short form consent is used. A summary of the short form consent may also be used. Signatures, dates and times must be entered on the form(s) as follows:

I. On the short form- by the witness and the subject or LAR
II. On the copy of the summary- by the witness and the person actually obtaining consent. *****NOTE: The IRB cannot waive the requirement for a witness or witness signature when the short form is used.

p) Signed and dated copies of the short form and summary forms should be provided to the subject or LAR and the original should be filed in the investigator's research file for that subject.

6. OBTAINING VA INFORMED CONSENT FROM A LEGALLY AUTHORIZED REPRESENTATIVE (LAR):

a) Under appropriate conditions, informed consent may be obtained from the subject's LAR if the prospective research participant is incompetent or has an impaired decision-making capacity.

b) The determination of competency must be documented and made according to the following requirements:

I. The practitioner, in consultation with the chief of service, may determine after a medical evaluation that the subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time
II. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity and is based on a diagnosis of mental illness

c) A Legally Authorized Representative (LAR) is an individual(s) authorized under applicable law to provide permission on behalf of a prospective subject for a subject's participation in the procedure(s) involved in a research study.

d) A Legally Authorized Representative can be (in this order):

I. Individuals with durable power of attorney for healthcare
II. Legal guardians
III. Spouse
IV. Adult children
V. Parents of adult children
VI. Siblings
VII. Grandparents
VIII. Grandchildren
IX. Close Friend

e) Study staff should contact the Regional Council regarding any legal questions about the LAR.

f) If possible, study staff should explain the proposed research to the prospective subject even when the LAR gives consent.

g) Under no circumstances may a subject be forced or coerced to participate in a research study.

h) The same consenting process and requirements followed for subjects, applies to the subject's LAR.

7. ALTERNATIVES TO VA WRITTEN INFORMED CONSENT:

a) The PI may request, and the IRB can determine, in which circumstances written informed consent may be obtained in an alternative manner.

b) Only the IRB may grant either (1) a waiver of the documentation of informed consent or (2) a waiver of informed consent (or elements of consent).

c) The PI can find the documentation of the IRB's determination regarding these types of waivers in the IRB minutes, the protocol file and/or the approval letter.

d) When a waiver of documentation of informed consent is granted, the IRB may require that the PI provide a written statement regarding the research to the study subjects.

e) If a standard written ICF cannot be obtained, the IRB may require that the PI submit a written summary or script that embodies the elements of the ICF for approval.

8. EXCEPTIONS FROM GENERAL REQUIREMENTS:

a) Obtaining consent shall be deemed feasible unless both the Investigator and another physician who is not otherwise participating in the clinical investigation certifies in writing all of the following:

I. The subject is confronted by a life-threatening situation needing the use of the test article

II. Consent cannot be obtained from the subject because of an inability to communicate with or obtain legally effective consent from the subject

III. Time is not sufficient to obtain consent from the subject's legal representative

IV. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject

9. **VA HIPAA AUTHORIZATION:**

a) VA HIPAA Authorization is required when individually-identifiable health information is used for research:

i. The VA HIPAA Authorization used for a research study may not be combined with any other authorization unless it is for use or disclosure of psychotherapy notes.

ii. The VA HIPAA Authorization must be a standalone document and cannot be attached to any other document (including the consent form).

iii. Both the VA HIPAA Authorization and VA HIPAA Revocation forms should be submitted on the proper VA template (see AREF website).

b) VA HIPAA Authorization is valid when signed by:

i. The research study subject

ii. A court appointed legal guardian

iii. Legal guardian authorized to act on behalf of the study subject (i.e., power of attorney)

iv. If deceased, then the executor of the estate, next-of-kin, or other person authorized to act on behalf of study subject

*Note: The definition of LAR (who can sign a consent form for a subject) and a

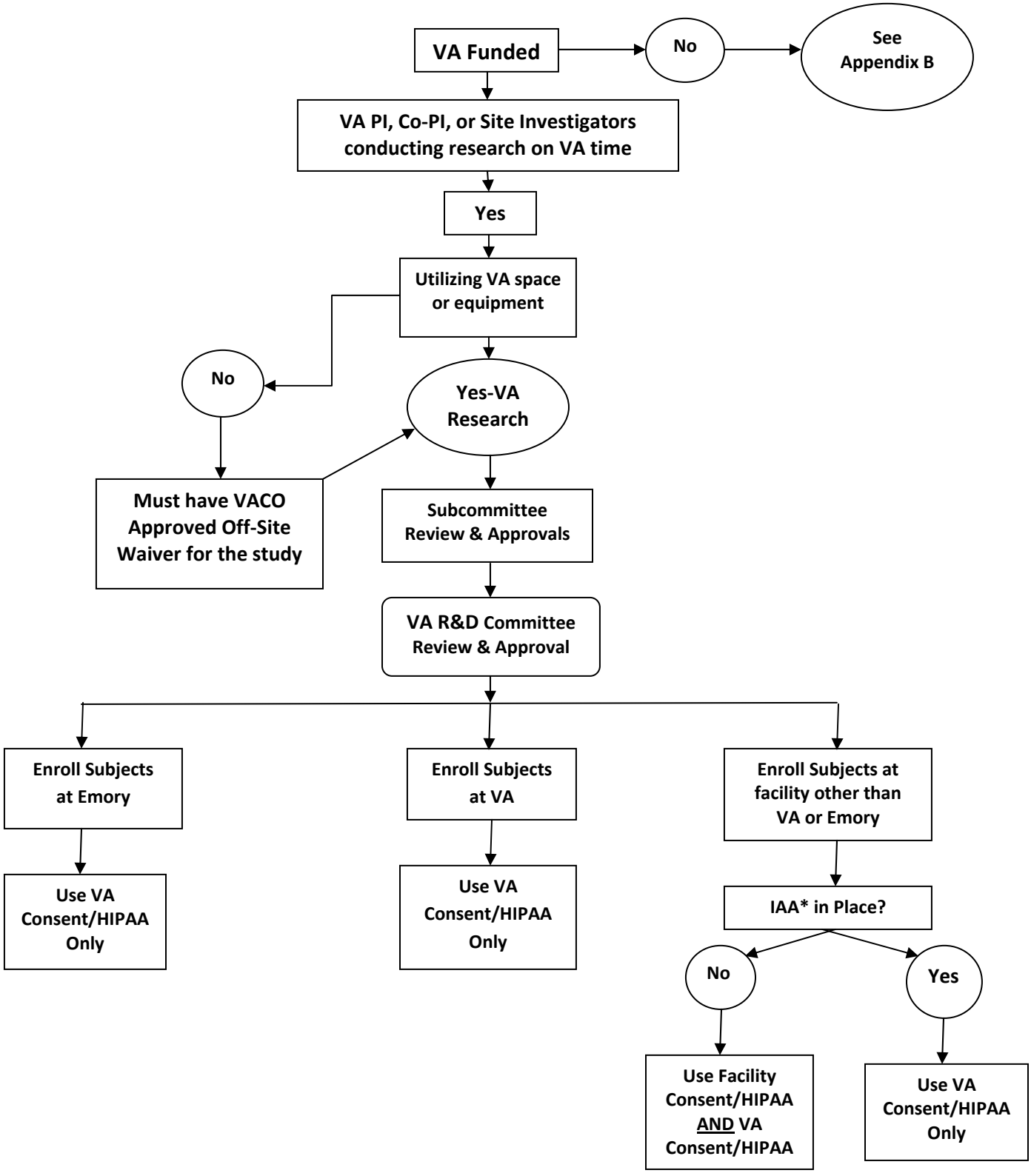
patient representative (see “ii”, “iii” and “iv” who can sign a VA HIPAA form) are different. Please contact the appropriate VA support staff if you have any questions.

c) Copies of the signed VA HIPAA Authorization and a VA HIPAA Revocation form must be provided to the study subject.

d) Waiver of VA HIPAA Authorization- A request from a PI for the IRB to waive VA HIPAA Authorization must have sufficient information with it to make a determination. The IRB must document its findings.

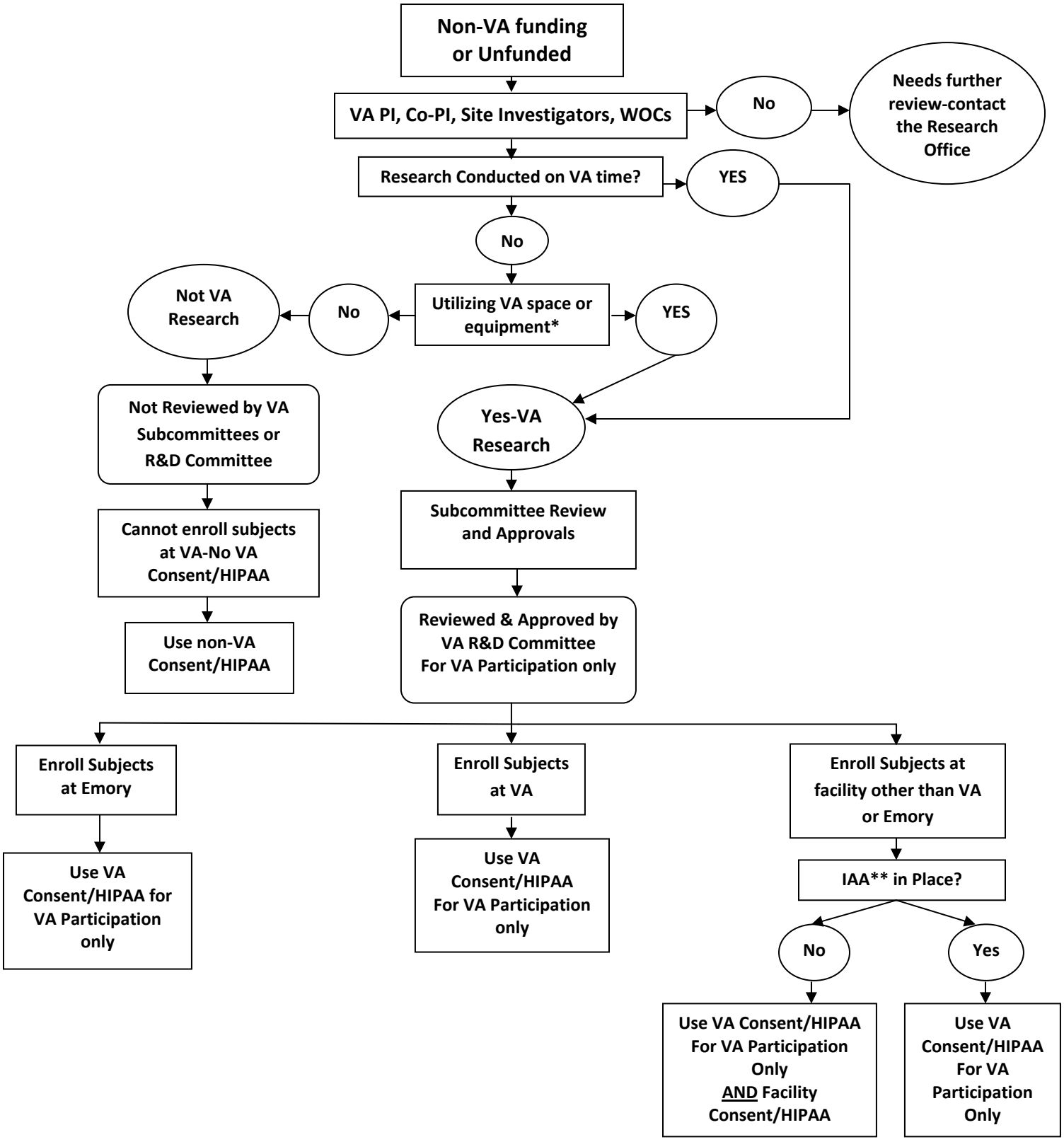
Note: The documentation of the IRB’s findings regarding HIPAA must be in the IRB minutes and/or the IRB protocol file to be considered valid.

Appendix A
Use of Informed Consents for VA Funded Research



***IAA is an IRB Authorization Agreement.**
Note: If your research project does not follow either the VA-Funded or Collaborative Research flow charts, please discuss with Research Office and RCO to determine appropriate course of action.
VHA Handbook 1200.05: Section 3 page 14; Section 33 page 60. **9/26/11**

Appendix B
Use of Informed consents for Collaborative Research (Non-VA Funded or Unfunded)



*For only recruiting at the VA. Must be discussed with the Research Office and RCO to determine the appropriate course of action. If your research project does not follow either the Appendix A or Appendix B, please discuss with Research Office and RCO.
**IAA is an IRB Authorization Agreement.
VHA Handbook 1200.05: Section 3 page 14; Section 33 page 60. 9/26/11