# 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 informed Consent Form (ICF) is used for all VA approved research. This includes, but is not limited to, studies in which VA investigators working on VA research enroll subjects at the affiliate hospital or other sites outside VA

A VA ICF template is available on the AVAMC research website

For the appropriate use of Informed Consents, please refer to:

- Appendix A titled "Use of Informed Consents for VA Funded Research"
- Appendix B titled "Use of Informed Consents for Collaborative Research"

If your research project does not follow either Appendix A or Appendix B, please discuss with the Research Office

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

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 in writing

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 and/ or disclosure of PHI (Protected Health Information) prior to initiating any study activities

**4. INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES:**

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

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

c) Requires the use of the most recent, approved consent form documents as appropriate (VA ICF, HIPAA Authorization – VA Form 10-0493, VA Revocation Letter, etc.)

d) The IRB date of approval must be on each page of the informed consent form

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 the 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 and Associate Chief of Staff for Research (ACOS/R) approval

f) Ensures that the consent has all required elements as well as additional elements, as needed

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

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

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

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

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

h) 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)

i) Study staff must document the consent process in CPRS within 72 hours after it occurs (see the Policy & Procedure entitled "Documentation Requirements" on the Atlanta VAMC research website at www.atlanta.va.gov/services/research/investigators.asp
If the research project has obtained a *Certificate of Confidentiality,* refer to section 9 below.

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

k) 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 and before being used to consent any new subject(s). R&D Committee approval will also be required when the modification includes an increase in the risk/benefit ratio, a change in the PI, and/or creation of a data or tissue repository. Some amended ICFs may require that a previous subject be re-consented. If so, this process must also be documented, as appropriate (see "i" above).

l) Each time a study subject signs a new consent form, the process must be documented

m) An unbiased person (not a member of the study staff) must witness***** all oral presentations when a short form consent is used. An IRB approved summary of the short form consent must 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.

n) 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) When planning to enroll subject's with impaired decision-making capacity, investigators must address in the protocol how they will determine when surrogate consent (i.e. LAR) will be required.

c) Research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision making capacity

d) 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.

e) 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

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

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

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

i) 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.

f) The IRB may waive the requirement that the person obtaining consent sign and date the ICF where there is no physical contact with the subject (e.g. where the only contact with the subject is by telephone or mail.) See the Policy and Procedure entitled "Waiver of Person Obtaining Consent Signature" on the Atlanta VAMC research website.

**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. CERTIFICATES of CONFIDENTIALITY (CoC):**

a) A certificate of confidentiality is a document issued by Health and Human Services agencies to protect research subjects. Generally any research project that collects personally identifiable sensitive information is eligible for a CoC. Sensitive information for purposes of a CoC include information relating to sexual attitudes, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

When a study is protected by a CoC, the following documentation guidelines apply

I. For studies that do not involve a medical intervention (e.g., observational studies, including interview and questionnaire studies), no annotation may be made in the health record CPRS)

II. For studies that involve a medical intervention, a progress note entry should indicate that an individual has been enrolled in a research study, any details that would affect the subject's clinical care, and the name and contact information for the investigator conducting the study. Subjects' ICFs and HIPAA documents are not to be included in the health record (CPRS)

**10. VA HIPAA AUTHORIZATION:**

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

i. The VA HIPAA Authorization must be a standalone document and cannot be attached to any other document (including the consent form).
ii. Both the VA HIPAA Authorization and VA HIPAA Revocation forms should be submitted on the proper VA template (see Atlanta VA research 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

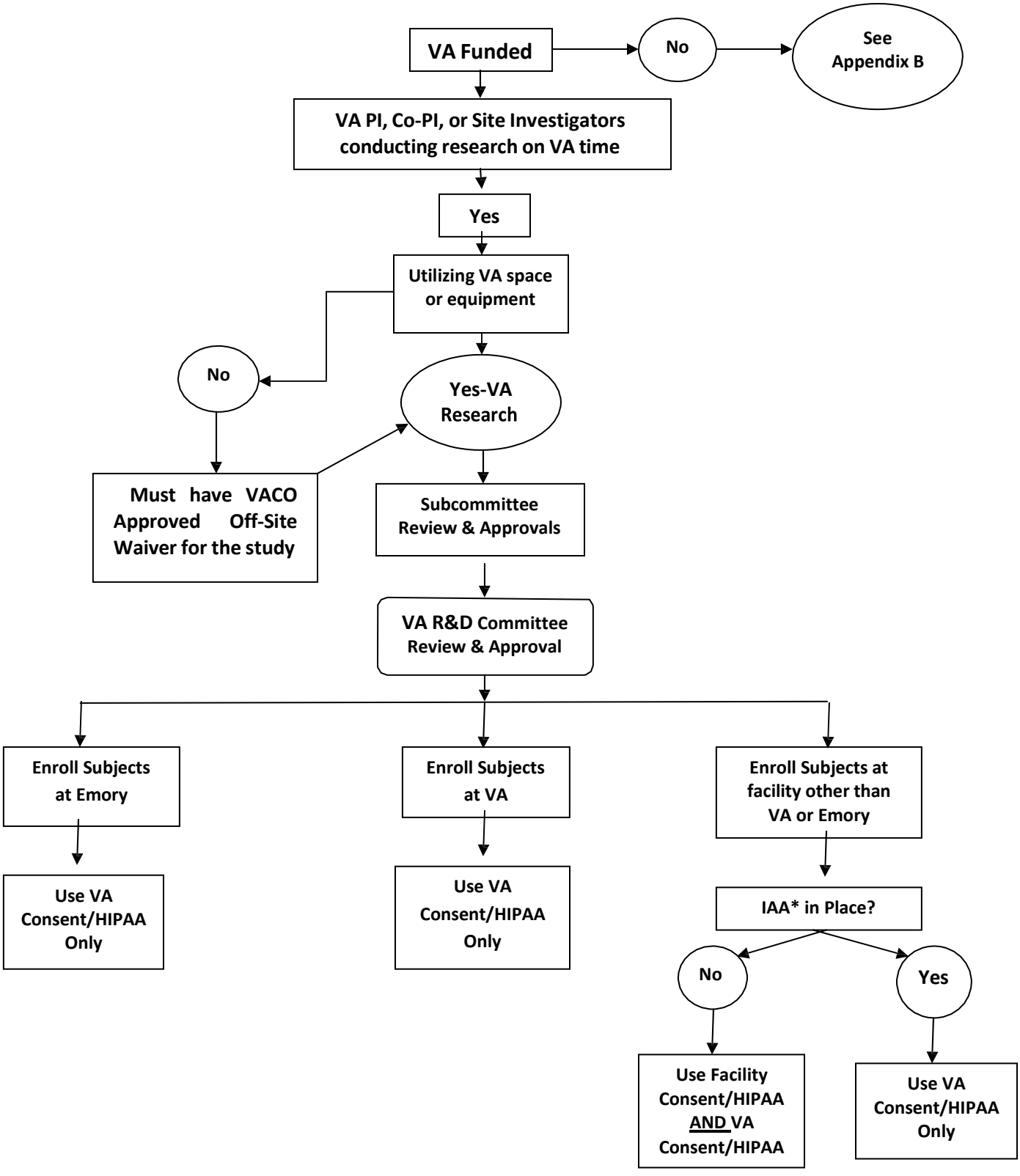
patient representative (see “ii”, “iii” and “iv” who can sign a VA HIPAA form) are different. Please contact the appropriate VA support staff if you have any questions.

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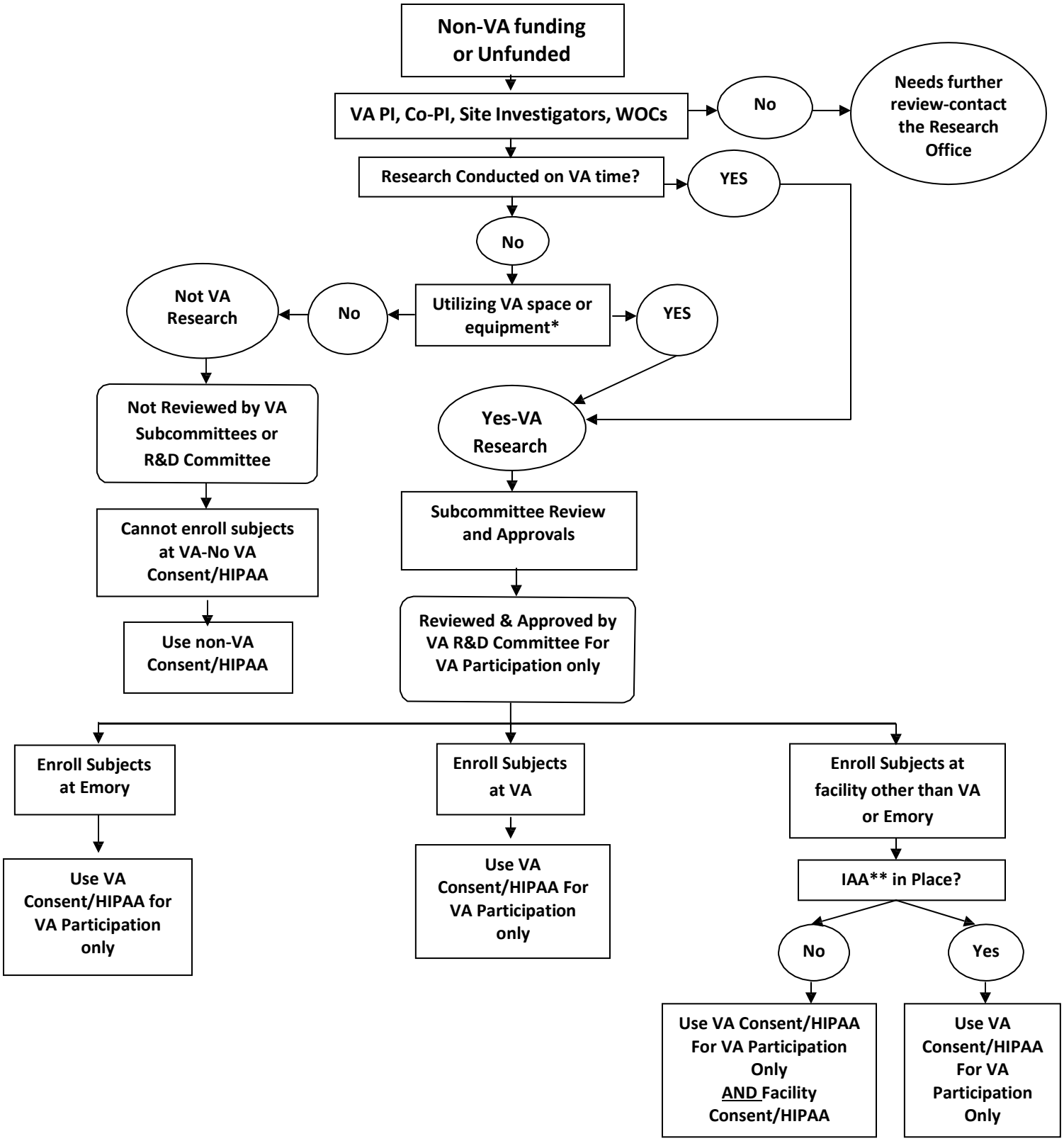
**Appendix B**
**Use of Informed consents for Collaborative Research (Non-VA Funded or Unfunded)**




*For only recruiting at the VA. Must be discussed with the Research 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.

**IAA is an IRB Authorization Agreement.

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