SUBJECT: VA Ann Arbor Healthcare System (VAAAHS) Instructions for Scanning Consents into CPRS

1. **PURPOSE:**

   The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. This guidance outlines the local requirements and instruction for scanning consent forms into the medical records.

2. **SCOPE**: Determinations are made locally by the IRB committee regarding the requirement to scan consent forms into the local medical record. CIRB studies will not be rigorously reviewed for this determination by our local IRB so a basic set of criteria will be established for the study team to make this determination.

3. **DEFINITIONS:**

   Research: Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalized knowledge.

   VA Research: VA research is research conducted by VA investigators while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

   VA Investigator: A VA investigator is an individual who conducts research approved by the VA Research & Development committee (RDC) while acting under a VA appointment, including full and part-time (VA Paid) employees. VA investigators must uphold professional and ethical standards and practices and must comply with all applicable VA and VHA and federal regulations and policies.

   Principal Investigator (PI): The PI is an investigator in charge of a research project or program. The PI must hold a current paid VA appointment with a set tour of duty (i.e., not an intermittent VA employee, WOC employee, fee-basis physician, or contracted employee). Trainees can serve as a co-investigator but must have a VA PI sufficiently experienced in the area of the trainee's research interest to serve as PI. The PI oversees scientific and technical aspects of a grant or protocol and the day-to-day management of the research. For an investigation conducted by a team of individuals, the PI is the responsible leader of that team. Research projects must have a single PI as point of contact. Studies funded by the VA Office of Research and Development (VA-ORD) in which a "Multiple PI" form was filed and accepted by VA-ORD may name both PIs. Exceptions to the guidelines listed here for PI roles may be granted by the ACOS on an individual basis except in cases where approval would constitute deviation from published VHA Handbooks or Directives.

   Study Team Member: Any person associated or listed on a Study Team Roster either in the Project or in the Protocol.

4. DETERMINATIONS REGARDING REQUIREMENTS FOR SCANNING CONSENT FORMS:

During the process for local IRB-approval of a protocol, the IRB committee will make a determination whether consent forms obtained for the protocol should be scanned into the local medical record. Upon approval of the protocol, the PI will be notified by the IRB coordinator if the protocol meets this requirement.

Protocols meeting any of the following criteria, should scan all obtained consents into the medical record by creating a Research Enrollment Note:

- Protocol involving pharmaceuticals,
- Protocols involving interventions that interfere with standard clinical care,
- Protocols with any reasonable need to inform the participants Primary Care Provider.

If a study team is uncertain if a protocol meets this requirement, they should consult their local compliance officer and/or IRB coordinators.

5. REQUIRED ACCESS PERMISSIONS TO SCAN CONSENT AND SIGN CPRS NOTES:

Approved study team members must obtain permission in order to utilize the scanner, currently located in the Research Office in Building 22 of the main hospital. Requirements to scan include:

- Login credentials for CPRS to create Research Enrollment Notes,
- Signature Code for CPRS to sign Research Enrollment Notes,
- VISTA Menu Option: MAG CAP TIU.

6. PROCUDURE FOR GAINING PERMISSIONS TO USE CPRS:

Permissions to use CPRS are granted per request during the onboarding or WOC (for non-VA employees) process. If a study team member was not granted CPRS/VISTA credentials during the onboarding or WOC process, they can be requested through their supervisor or ADPAC.

7. PROCEDURE FOR CREATING A SIGNATURE CODE IN CPRS:

In order to sign a note in CPRS, study team members must create a signature code. A signature code can be created by logging into VISTA and entering the following commands:

- Type "U" and press enter,
- Type "Electronic Signature Code Edit" and press enter
- Verify information is correct by hitting enter through the next several commands until reaching the option to create a signature code.
- Enter a signature code of choice and press enter.

The signature code is now ready to be utilized in CPRS for signing clinic notes.

8. PROCEDURE FOR OBTAINING A VISTA MENU:

If a study team member is not already assigned the appropriate VISTA menu, they must request this menu from their ADPAC. The research service ADPAC can also enter a request for this menu. The menu the study team member needs to request is "MAG CAP TIU". The request can take a day or more to be completed.

9. PROCEDURE FOR CREATING A RESEARCH ENROLLMENT NOTE IN CPRS:

Scanned research consents should be attached to the Research Enrollment Note in CPRS. Follow these instructions to enter a Research Enrollment Note:

1. **Log into CPRS (will need IRM approval for access)**
2. Select patient by searching for them in the search field and selecting their name from the list
3. Select [New Note]
4. Select [New Visit] Tab
5. IMPORTANT: Check Box for [Historical Visit]
6. Select New Visit Location = "AA CONSENT FORM – RESEARCH"
7. In the Date select box (default = "Now") click and select the date of consent
8. Click [Okay]
9. Select Progress Note Title from the scrolling list: "<RESEARCH STUDY ENROLLMENT>"
10. Use the automatic template for required information to be typed into the new Note
    (Click Mouse or use Tab Key to move through Note)
Name of VA Principal Investigator:	Phone Number & Pager Number:
Name of Study Coordinator:	Phone Number & Pager Number:
Title of Research Study:	Date of Subject Enrollment:
Comments:	Date Participation Expected to be Completed:
11. Click [ACTION] on the horizontal Toolbar
12. Click [Sign Note Now]
13. Enter Electronic Signature code (The new note will be listed in [Postings WAD])
    a. If you do note have an electronic signature, you may create one using VISTA as described above.
    b. To save & sign the note later: [ACTION] -> [Save Unsigned Note]
        i. You will not be able to attach the consent to an unsigned note.

10. PROCEDURE FOR SCANNING CONSENT FORMS INTO CPRS & ATTACHING TO RESEARCH ENROLLMENT NOTE

1. **Log into VISTA IMAGING CAPTURE (aka Tele19n or Mag Image Capture) (will need RMS approval for access)**
2. Select [Research Consent] on the top left
3. Click [Select Patient]
4. Click [Select Progress Note]
    a. Select the CPRS Enrollment Note you created in steps 1-13 – "Research Enrollment Note"
5. In the drop-down boxes, select the following:
    a. Document type: Consent
    b. Specialty: Research

6. Make sure the box for "MultiPg Doc" is selected (may be automatically selected)
7. Select [Capture]
8. After document has scanned in (place upside down and backwards), use preview the image in the window to verify proper scanning
9. Select [Image Okay]
10. Select [Okay] (last chance to make edits)
11. The image has been permanently attached to the enrollment note in CPRS (Contact HIMS office for edits)

11. **PROCEDURE FOR VIEWING EXISITING RESEARCH CONSENT FORM IN CPRS**

1. In CPRS, from the tabs, select [Tools] -> VISTA Imaging Display
2. Log into VISTA Imaging (will need additional RMS approval for access)
3. Select patient (Can practice using patient AAVAMC, TL1)
4. Click [NOTES] Tab, notes with the image icon contain scanned documents
5. Select the note with a scanned image
6. In the thumbnail preview window, select an image to transfer to viewing window

12. **PROCEDURE FOR ESTABLISHING CPRS RECORD FOR NON-VA PATIENT**

1. Contact the Patient Admitting Office

13. **CONTACTS:**

Compliance Office   Scott Sample, Compliance Officer at 734 845-3766

IRB Coordinators: Cathy Kaczmarek at 734-845-3439
                                             Sheena Hatcher at 734-845-5901

Research Service ADPAC: Christopher Robinson at 734-845-5600

14. **FOLLOW-UP RESPONSIBILITY:** IRB Committee Coordinators