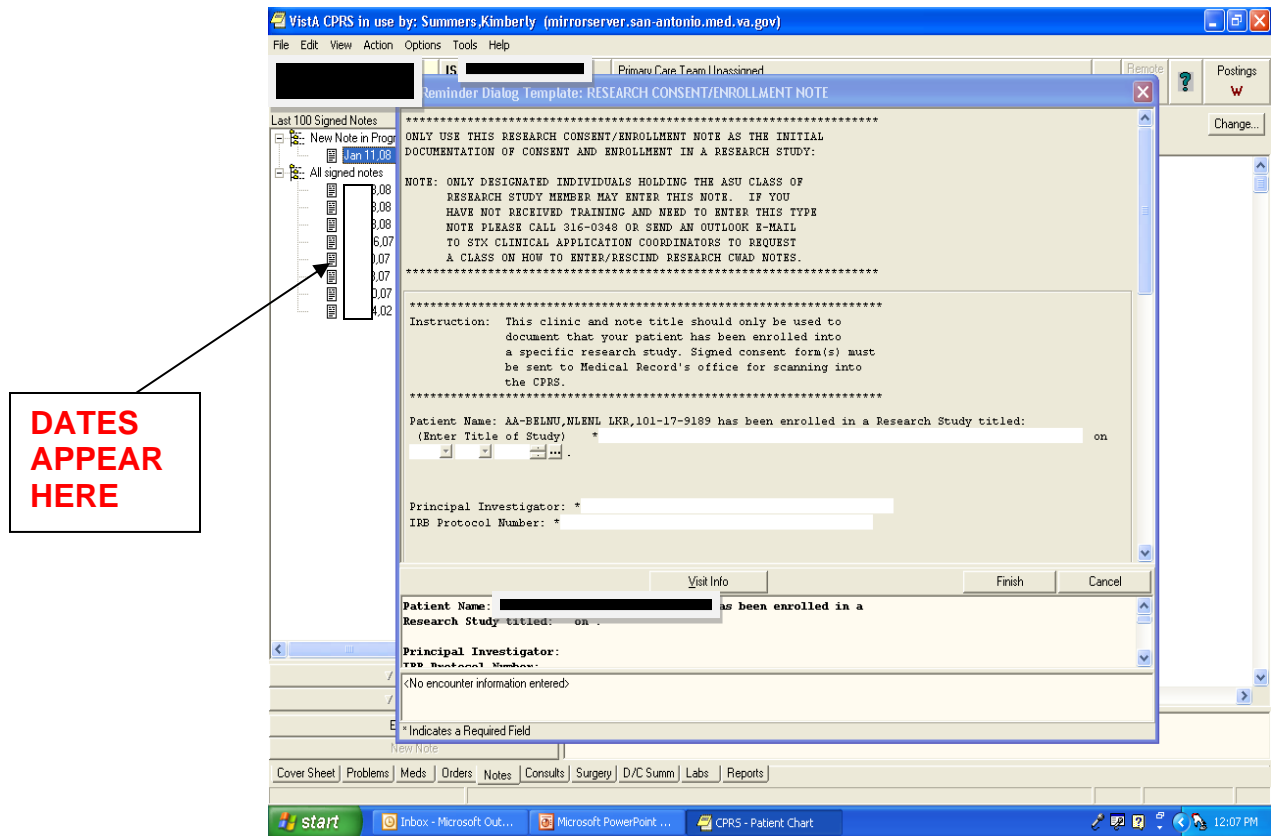


January 30, 2023

RESEARCH STANDARD OPERATING PROCEDURES
Documentation of Research Study Procedures in the Patients' Health Record

1. **PURPOSE:** To describe the policies and procedures for the documentation of human research activities conducted at South Texas Veterans Health Care System (STVHCS) in a patient's health record when a participant (research subject) is involved in a human research study.
2. **POLICY:** A research participant's health record includes the electronic medical record and any hard copy documentation located in Medical Records, combined, and is also known as the legal health record. Research files maintained by the Principal Investigators (PIs) and/or research staff are not part of the legal health record. A research record must be created or updated, and a progress note created, in the legal medical record when informed consent is obtained, a research visit has the potential to impact medical care (i.e. the research intervention may lead to physical or psychological adverse events), when the research requires use of any clinical resources (i.e. radiology, cardiology, pharmacy), or when a participant is disenrolled or terminated from a study.
3. **ACTION:**
 - a. **Documentation of the informed consent process**
 - (1) The PI or designated, trained study staff initiates the informed consent process with the use of the VA Form 10-1086 (IC document).
 - (a) The IC must include the patient's **full name, date of birth (DOB), and full social security number (SSN)** on the first page.
 - (b) The **patient's last name initial and last four of the SSN** must be included on the bottom of every page that follows.
 - (2) The IC document must be signed by
 - (a) The participant or the participant's legally authorized representative
 - (b) The person obtaining the informed consent
 - (3) The PI or designated, trained study staff must enter a "Research Consent/Enrollment Note" in the computerized patient record system (CPRS) after informed consent is obtained.
 - (a) When the note is entered in CPRS select the following template: Research <Research Consent/Enrollment Note> under Progress Note Title. The following template will be displayed:

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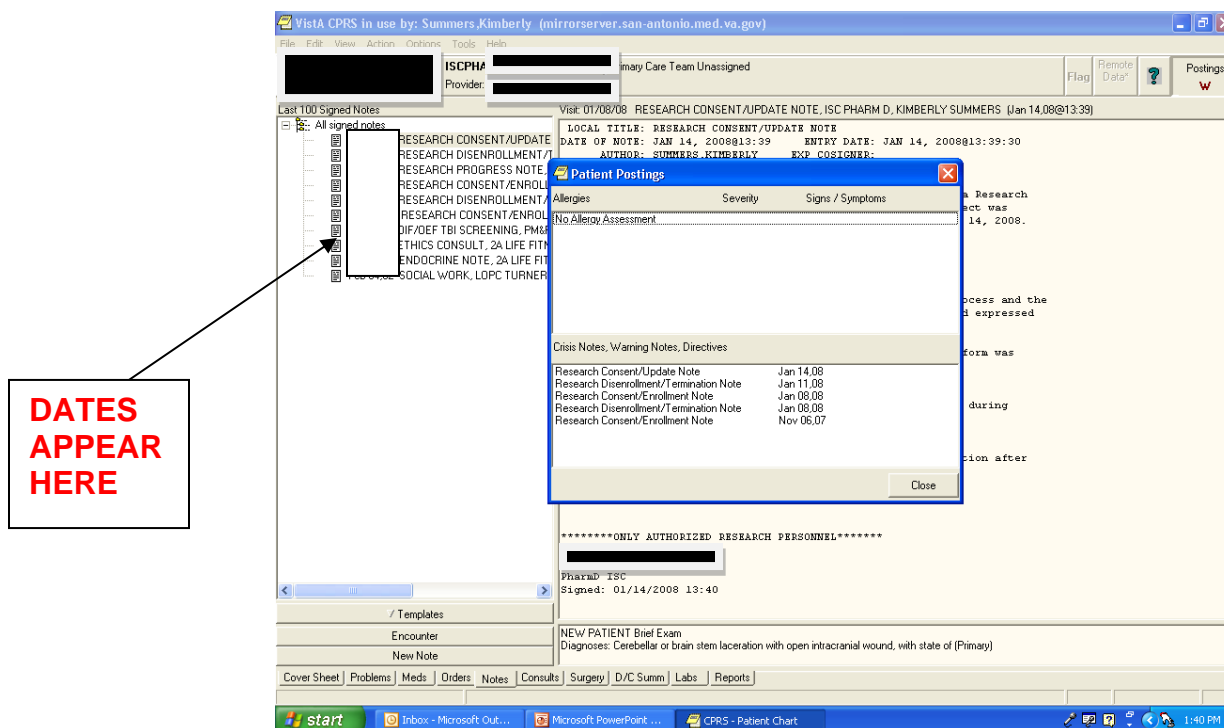


(b) The template contains fields to enter the required information for documentation of the consent process including:

1. Name of the study
2. Name of the PI
3. IRB protocol number
4. Name of the person obtaining the participant's consent
5. A statement that the participant, or the participant's legally-authorized representative, could understand the consent process
6. A statement that the study was explained to the participant
7. A statement that the participant was given the opportunity to ask questions
8. A statement that the participant was given a copy of the consent form
9. A statement to indicate if the study involves the use of any investigational drugs
10. Contact information for a member of the research team that is always available and from whom additional information concerning the study can be obtained.

(c) Use of this note template will ensure the participant's medical record is flagged to indicate the participant is enrolled in a research study. This can be viewed by selecting "Postings" in the CPRS chart.

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- (4) Use of this note template also documents compliance with VHA Handbook 1605.04 verifying and documenting that all non-vet subjects have received and signed the notice of Privacy Practice form.
- (5) The “Research Consent/Enrollment Note” may be entered by the person obtaining the signed IC or by a study staff member documenting the IC process. The R&D Office recommends the note be co-signed by the person who obtained the signed IC and/or the PI if documentation is by another person.
- (6) A copy of the signed and dated VA Form 10-1086 (IC document), HIPPA authorization, and signed notice of Privacy Practice form if applicable must be submitted to Medical Records for scanning and electronic attachment to the “Research Consent/Enrollment Note”.
 - (a) A copy of documents to be scanned should be emailed to VHASTX HIM Scanning: VHASTXHIMScanning@va.gov
 1. The document will be scanned within 72 hours.
 2. The PI or study staff must assure there are patient identifiers on all pages of the scanned documents.
 3. The “Research Consent/Enrollment Note” must be completed prior to the request for scanning.
- (7) If the IRB has determined that entering the informed consent document would increase participants’ risks or compromise the study results, documentation in the participants’ health records may be waived. You must contact the R&D office in this situation, prior to initiation of the protocol and enrolling any participants.

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b. If the study involves the use of an investigational agent

- (a) An Investigational Drug Information Record(s) (VA Form 10-9012) is required for an investigational agent.
- (b) All signed 10-9012 forms, which are submitted as part of the initial R&D application, are returned to the PI/study coordinators with their R&D approval letters in an electronic format.
- (c) A copy of the completed and signed VA Form 10-9012 must be submitted to the medical Records office for scanning and electronic attachment to the “Research Consent/Enrollment Note” for each study participant, if the study involves investigational agents.
- (d) Scanning of the 10-9012 forms will document in the participants’ health records any possible drug interactions and adverse effects of the investigational agents being administered.
- (e) If the research protocol involves the administration of investigational agents on INPATIENT wards the author of the consent enrollment note should assign the attending physician for the patient, the nurse manager, and assistant nurse manager for the unit as additional co-signers on the note.
- (f) Pharmacy will not dispense any study medication for a research participant until all 10-9012 forms have been scanned.
- (g) If scanning is required immediately, for the dispensing of medication on the same day as the signing of the IC document:
 - (a) Contact: Medical Records by email marked with high importance and subject “Needs Immediate Scan” to VHASTXHIMScanning@va.gov
 - (b) Scanning will be completed within 15 min.
 - (c) Please do not abuse this system; it is only for situation where dispensing of medications in less than 24 hours of initial consenting is required.
- (h) Medical Records is staffed from 7:00am-12:00am Monday – Friday. Between the hours of 12:00am-7:00am or on weekends, a copy of the IC document and 10-9012 forms can be faxed to Medical Records and documents will be scanned into CPRS the next business morning.
- (i) The Research Pharmacists is available from 8:00am-4:30pm Monday-Friday. If dispensing of investigational medications is anticipated outside normal business hours, the PI must contact the Research Pharmacist in advance of protocol initiation to make arrangements.

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c. Documentation of updates to the informed consent process

- (a) Any changes to the IC resulting in an addendum or updated IC document, must be entered into the participant's health record.
- (b) The PI or designated, trained study staff must enter a "Research Consent/Update Note" in CPRS after informed consent is obtained.

- (a) When the note is entered in CPRS select the following template: Research <Research Consent/Update Note> under Progress Note Title. The following template will be displayed:

The screenshot displays the CPRS software interface. The main window is titled "Reminder Dialog Template: RESEARCH CONSENT/UPDATE NOTE". It contains the following fields and options:

- Principal Investigator: *
- IRB Protocol Number: *
- Select one of the following:
 - (Enter name of person who obtained consent:) * provided an explanation of the study/consent process and the research subject was given an opportunity to ask questions and expressed an understanding of the study. Consent was obtained from the subject. A copy of the consent form was provided to the subject.
 - (Enter name of person who obtained consent:) * provided an explanation of the study/consent process and the research subject and/or the legally authorized representative (Enter name of representative, if applicable:) * was/were given an opportunity to ask questions and expressed an understanding of the study. Consent was obtained from the subject or legally authorized representative. A copy of the consent form was provided to the subject or legally authorized representative.
- Contact: * Phone: * Ext: for further information during business hours.
- Contact: * Phone: * Ext: for further information after business hours.
- Buttons: Visit Info, Finish, Cancel
- Bottom section: Patient Name [redacted] as enrolled in a Research Study titled: on .

A callout box on the left side of the screenshot points to the date column in the "Last 100 Signed Notes" list, containing the text "DATES APPEAR HERE".

- (b) The template contains all the required information for documentation of a change in the IC document including:

1. Name of the study
2. Name of the PI
3. IRB protocol number
4. Name of the person obtaining the participant's consent
5. A statement that the participant, or the participant's legally-authorized representative, could understand the consent process
6. A statement that the study was explained to the participant
7. A statement that the participant was given the opportunity to ask questions
8. A statement that the participant was given a copy of the consent form
9. Contact information for a member of the research team that is available at all times and from whom additional information concerning the study can be obtained.

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- (c) Use of this note template will ensure the participant's medical record is flagged to indicate the participant is enrolled in a research study which has updated information since initial enrollment.
- (c) The "Research Consent/Update Note" may be entered by the person obtaining the signed IC or by a study staff member documenting the IC process. The R&D Office recommends the note be co-signed by the person who obtained the signed IC and/or the PI if documentation is by another person.
- (d) A copy of the signed and dated new or updated IC document must be submitted to Medical Records for scanning and electronic attachment to the "Research Consent/Update Note".
 - (a) A copy of IC document should be scanned and emailed to VHASTX HIM Scanning: VHASTXHIMScanning@va.gov
 1. The document will be scanned within 72 hours.
 2. The PI or study staff must assure there are patient identifiers on all pages of the scanned documents.
 3. The "Research Consent/Update Note" must be completed prior to the request for scanning.

d. **Documentation of research procedures**

- (a) A "Research Progress Note" must be entered into the participant's health record (CPRS) when a research visit has the potential to impact medical care.
- (b) Situations which require documentation include, but are not limited to:
 - (a) Any research procedure or interventions that may impact a participant's clinical care, including the indications and potential risks of physical or psychological adverse events.
 - (b) Any results, including laboratory studies, from the research study that are relevant to the medical care of the research participant.
 - (c) Any information regarding possible drug interactions and/or toxicity of the investigational agents administered as part of the research protocol.
- (c) The PI or designated, trained study staff must enter a "Research Progress Note" in CPRS. Research clinic visits done solely for research must be documented using a specific research note title to differentiate these visits from any other clinic visits.
 - (a) When the note is entered in CPRS the following template may be used:
Research <Research Progress Note> under Progress Note Title.
- (d) Alternatively, investigators or study staff may use their own Progress Note template.
 - (a) All progress note titles are standardized to start with "Research".

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- (b) If you require assistance with creating a Research Progress Note template, contact the CPRS helpdesk.

e. Documentation of research disenrollment or termination

- (a) Disenrollment or termination from a research protocol must be entered into the participant's health record. When access to the patient health record is no longer required for a study, the study has been completed, or when authorization is revoked the disenrollment/ termination note should be entered into CPRS.
- (b) The PI or designated, trained study staff must enter a "Research Disenrollment/Termination Note" in CPRS.
- (a) When the note is entered in CPRS select the following template: Research <Research Disenrollment/Termination Note> under Progress Note Title. The following template will be displayed:

Vista CPRS in use by: Summers, Kimberly (mirrorserver.san-antonio.med.va.gov)

File Edit View Action Options Tools Help

Primary Care Team Unassigned

Reminder Dialog Template: RESEARCH DISENROLLMENT/TERMINATION NOTE

ONLY USE THIS RESEARCH DISENROLLMENT/TERMINATION NOTE AS DOCUMENTATION OF DISENROLLMENT/TERMINATION IN A RESEARCH STUDY:
NOTE: ONLY DESIGNATED INDIVIDUALS HOLDING THE ASU CLASS OF RESEARCH STUDY MEMBER MAY ENTER THIS NOTE. IF YOU HAVE NOT RECEIVED TRAINING AND NEED TO ENTER THIS TYPE NOTE PLEASE CALL 316-0348 OR SEND AN OUTLOOK E-MAIL TO STX CLINICAL APPLICATION COORDINATORS TO REQUEST A CLASS ON HOW TO ENTER/RESCIND RESEARCH CWAD NOTES.

Patient Name: AA-BELNU, MLENL LKR, 101-17-9189 has been disenrolled/terminated from Research Study titled: (Enter Title of Study) * on

Contact: * Phone: * Ext: for further information.

*****ONLY AUTHORIZED RESEARCH PERSONNEL*****

Visit Info Finish Cancel

Patient Name: AA-BELNU, MLENL LKR, 101-17-9189 has been disenrolled/terminated from Research Study titled: on

Contact: Phone: Ext: for further information

<No encounter information entered>

* Indicates a Required Field

Cover Sheet Problems Meds Orders Notes Consults Surgery D/C Summ Labs Reports

start Inbox - Microsoft Out... CPRS - Patient Chart CPRS Templates Microsoft PowerPoint ... 11:40 AM

- (b) The template contains the following information:

1. Name of the study
2. Date of disenrollment or termination
3. Contact name and number

- (c) Use of this note template will ensure the participants' medical record is flagged to indicate the patient is no longer enrolled in a research study.

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f. **Flagging of the Medical Record Waived by IRB**

- (1) If the UTHSCSA IRB determines that flagging the medical record and scanning the informed consent document would increase the subject's risk or compromise the study results, flagging the record and documentation in the subject's health record will be waived.
- (2) The IRB protocol approval letter must state the flagging requirement has been waived to protect the subject or study integrity.
- (3) The investigator will be notified of the approval to waive the flagging requirement in the R&D protocol approval letter.

g. **VA Compliance Office**

- (a) The STVHCS Research Compliance Quality Assurance component of the Human Research Protection Program (HRPP) will conduct focused reviews and routine audits of research documentation.
- (b) Results of the Compliance audits will be submitted to the QA Subcommittee at least quarterly for review.

4. REFERENCES: VHA Directive 1605.1: Privacy and Release of Information; VHA Directive 1907.01: Health Information Management and Health Records; VHA Directive 1200.05

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RECESSIO: Research Service Policy Memorandum 21-42, dated June 8, 2021

7. RECERTIFICATION: January 2028

[Signed on File]

AMRITA KAMAT, PhD
ACOS for Research and Development