

SOP: HRP 07.08 / PM 039

| | | | |
|-----------|--|---|-------------|
| Version | 1.0 | Origin | Version N/A |
| Author | Jessica Mendoza | | |
| Changes | Replaces HRP 07.01 | New Version # | N/A |
| Approved | <hr/> Christopher T. Bever, ACOS/R&D Date: | NOTE: This SOP applies to work since July 6, 2015 when written documentation of the change in process was communicated to the research field. Prior to that date, the CPRS consent note requirement stated in HRP 07.01 had been required in order to continue with scanning of informed consent documents for the purpose of Office of Research Compliance ICD audits. | |
| File Name | \\Progress Notes for Research Participants (HRP 07.08)2015v1.0 | | |

PROGRESS NOTES FOR RESEARCH PARTICIPANTS

OBJECTIVE:

- To clarify the circumstances under which research progress notes must be documented.

POLICY:

1. The VA Computerized Patient Record System (CPRS) is a patient health record that is not to be used as a research record repository except in particular circumstances.
2. Research consent notes and informed consent documents (informed consent forms and HIPAA authorizations) must not be placed into CPRS.
3. Research enrollment notes must be entered into CPRS *only when research procedures or interventions are used that may impact the medical care of the research subject*. This applies to participants who are VAMHCS inpatients (whether or not the admission was for research purpose), VAMHCS outpatients or others (if the research intervention or procedure occurs at VAMHCS medical facilities, VAMHCS Annex, etc.). Even if a CPRS chart exists for the participant, there is no requirement to enter enrollment notes unless the research intervention may impact the medical care of the research subject.
4. Additional research progress/procedure notes must be entered into CPRS if the research intervention may impact the medical care of the research subject or if the principal investigator, medical advisor, or clinical research team

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

members determine that a CPRS note is advisable with regard to the medical care of the participant.

5. Persons enrolled in a VAMHCS research study (Veterans or Non-Veterans) must have a CPRS medical record **only if** their involvement in the research involves admission to VA facilities as in-patients, treatment as outpatients at VA medical facilities, or when research procedures or interventions are used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or nursing homes).
6. A “Research Subject Clinical Warning” (RSCW) must be placed in the participant’s CPRS chart **if** the study involves the use of an investigational drug or investigational device. Investigators may choose to use an RSCW for other reasons if it will contribute to the safety of research participants or will assist in the conduct of the study. The IRB may choose to require an RSCW for participant safety or other issues.

DEFINITIONS:

- **Certificate of Confidentiality.** A certificate of confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), Title 42 United States Code (U.S.C.) 241(d), to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. Some types of research projects that are eligible for a Certificate of Confidentiality include: Research on HIV, Acquired Immune Deficiency Syndrome, and other sexually transmitted diseases; Studies that collect information on sexual attitudes, preferences, or practices; Studies on the use of alcohol, drugs, or other addictive products; Studies that collect information on illegal conduct; Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community; Research involving information that might lead to social stigmatization or discrimination if it were disclosed; Research on participants' psychological well-being or mental health; Genetic studies, including those that collect and store biological samples for future use; and Research on behavioral interventions and epidemiologic studies.
- **Consent Note.** Describes the informed consent process, including discussion with participant, the participant’s understanding of the research, voluntariness, the right to withdraw, etc. (See Attachments B and C).
- **Progress Note:** a note (generally in the medical record) that document actions, activities, assessments, interventions, etc. that have impact on the medical care of a patient
- **Research Subject Clinical Warning (RSCW).** Provides study and contact information to VAMHCS clinical staff to assist in assuring the safety and welfare of

the study participant when they are receiving an investigational drug or device. (See Attachments D and E).

RESPONSIBILITIES:

The Principal Investigator is responsible for:

- Maintaining accurate and complete research records in the investigator's research study files;
- Entering CPRS progress notes when research procedures or interventions may impact the medical care of the patient;
- Ensuring that a Research Subject Clinical Warning is placed into the medical record when required.

COMPONENTS OF THIS SOP: This SOP/process module covers the following topics:

1. Consent Notes
2. Progress Notes
3. Enrollment Notes
4. Research Subject Clinical Warnings
5. Participant Closure Notes
6. Implications of Certificates of Confidentiality
7. Other Types of Documentation
8. CPRS Charts
9. Appendixes (summary chart, templates, instructions)

PROCEDURES:

1. Consent Notes are used to document the informed consent process, both at the time of initial signing of consent documents, and on an ongoing basis. Research informed consent is a research-specific activity and documentation of the informed consent process is required by Good Clinical Practices (GCP) regulations.
 - 1.1. Research consent notes are placed **into the PI's research records** (e.g., participant files, informed consent files).
 - 1.2. Research consent notes are **not** placed into CPRS.
 - 1.3. Use the template in Attachment B to assist in meeting the GCP requirements for documentation of the consent activity.
2. Progress Notes are notes (generally in the medical record) that document actions, activities, assessments, interventions, etc. that have impact on the medical care of a patient.
 - 2.1. *For studies that involve a medical intervention*, a progress note entry in CPRS should indicate that an individual has been enrolled in the research study, any details that would affect the participant's clinical care, and the name and contact information for the investigator conducting the study.
 - 2.2. Additional research progress notes, procedure notes, etc. are entered as appropriate, i.e. they document an intervention or information that may impact the medical care of the participant.
 - 2.3. It is recommended that Investigators and their study teams create study-specific guidelines for creating research progress notes in CPRS based on the types of

study interventions (invasiveness, pharmaceutical, investigational device, etc.) or if expected possible risks could affect the health or care of the participant. The decision about the medical necessity of entering a note in CPRS is left up to the judgement of the investigator or the study's medical advisor.

3. Enrollment Notes are a specific type of progress note used to document that the participant has met eligibility criteria and has enrolled in a study. Enrollment is a research-specific activity. Therefore enrollment progress notes should be placed into CPRS *only in particular circumstances*.
 - 3.1. GCP regulations require that enrollment notes or some other mechanism of documenting a participant's enrollment into a study *must be placed in the PI's research records* (e.g., participant files, informed consent files).
 - 3.2. *Only for studies that involve a medical intervention or that may impact the medical care of the research subject at a VA medical facility*, should an enrollment note or some other progress note be entered into CPRS. See item 2 above.
 - 3.3. Studies that *do not involve* a medical intervention or that *will not impact* the medical care of the research subject at a VA medical facility **should not have** enrollment progress notes entered into CPRS.

4. Research Subject Clinical Warnings (RSCW) are "flags" in CPRS that alert clinicians that a patient is participating in a research study.
 - 4.1. A "Research Subject Clinical Warning" (RSCW) must be placed in the participant's CPRS chart **if** the study involves the use of an investigational drug or investigational device.
 - 4.2. Investigators may choose to use an RSCW if it will contribute to the safety of research participants or will assist in the conduct of the study.
Examples of this:
 - 4.2.1. If it is important for the research team to be notified of clinical changes in the participant's care, hospitalization, etc.;
 - 4.2.2. If it is important for clinical staff to be aware of the individual's participation in a study;
 - 4.2.3. Provision of contact information for questions to the study team; etc.
 - 4.3. If an RSCW has been created, a closure note must be entered into CPRS at the time of the participant's completion of study activities, and the RSCW must be removed from CPRS. See Appendix E for details.

5. Participant Closure Note is used when study activities have ended for a participant, such as: the participant has not met eligibility criteria and therefore is never enrolled into the study, a participant has completed the study activities, withdraws from the study, is withdrawn from the study, etc.
 - 5.1. A participant closure note or other mechanism of documentation must be placed into the Investigator's research files at the time of completion of study activities.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- 5.2. If an enrollment note/research progress note has previously been entered into CPRS, a participant closure note should be entered at the time of completion of study activities.
6. Impact of a Certificate of Confidentiality. When VA conducts a study that is protected by a Certificate of Confidentiality (see Definition above), the following health record documentation provisions apply:
- 6.1. 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.
- 6.2. For studies that involve a medical intervention, a progress note entries must be limited to the least information possible. Progress note(s) should indicate that an individual has been enrolled in a research study (no title), any details that would affect the subject's clinical care, and the name and contact information for the investigator conducting the study. Subjects' informed consent forms and HIPAA authorization documents are not to be included in the health record.
7. Other Types of Research Documentation
- 7.1. No research documentation may be entered into CPRS unless it is a medical activity (including VAMHCS clinical laboratory results, VAMHCS imaging reports, etc.) or it affects the medical care of the participant (including reasonably expected side effects of an intervention, etc.).
- 7.2. Except as specified in the items above, the investigator's research records must not be stored in CPRS. Research records include: IRB and R&D Committee records, records of all observations, other data pertinent to the investigation, progress notes (except as applicable above), research study forms, surveys, questionnaires or other documentation regarding the study.
- 7.3. See R&D Service Guidances HRP07.02G *Guidelines for Setting up a Study Binder and Regulatory Documents Binder* and HRP0703G *Guidance on Source Documents* for information on additional types of study documentation. A study's source documents or data collection forms may often suffice in place of research notes.
8. Requirement for the Need for a CPRS Chart
- 8.1. VA research participants (Veterans or Non-Veterans) must have a CPRS medical record ***if*** their involvement in the research involves admission to VA facilities as in-patients, treatment as outpatients at VA medical facilities, or when research procedures or interventions are used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or nursing homes).
- 8.2. Registration into CPRS requires a VA Form 10-10EZ to be completed and processed through Medical Administration Service.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

ATTACHMENTS:

- A. Summary Chart of Circumstances for Research Records v. CPRS Progress Notes
- B. Sample Consent Note Template
- C. Creating And Editing Progress Notes And Templates In CPRS
- D. Template For Research Subject Clinical Warning
- E. Creating And Editing Research Subject Clinical Warnings And Templates In CPRS

ATTACHMENT A

Summary Chart of Circumstances for Research Records v. CPRS Progress Notes

| Type of Note | Location of Note | | |
|--|------------------|-----------------|--|
| | Research File | CPRS | Comments |
| Consent Note | Yes | No | The consent note is documentation of the consent. This is a research-specific activity. |
| Enrollment Note | Yes | Possible* | *If, medical interventions are required for the research, or in the PI's/clinicians' opinion, enrollment in the study has significance for the <i>medical care</i> of the participant. Not to be used for documentation of research activities that do not reasonably have impact on the medical care of the participant. |
| Progress Notes | Yes | Possible* | " |
| Research Subject Clinical Warning (RSCW) | No | Yes | Must be placed in CPRS if a study involves an investigational drug or device |
| Certificate of Confidentiality | Yes | No ⁺ | ⁺ (1) 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. (2) 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' informed consent forms and HIPAA authorization documents are not to be included in the health record. |
| Participant Closure Note | Yes | No ^o | ^o Only if an enrollment note/research progress note was entered into CPRS at the time of entry into the study. |

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

ATTACHMENT BSAMPLE CONSENT NOTE TEMPLATE¹

Protocol Title:

Principal Investigator:

IRB #:

IRB Validation Dates:

Date the Informed Consent form was signed:

Time the Informed Consent form was signed:

Person Obtaining Consent:

Participant was enrolled in above-mentioned protocol. Participant/legal guardian has been fully informed about the study including procedures, risks and benefits. Participant/legal guardian has read the consent form or had it read to them and was given the opportunity to have questions answered prior to signing the informed consent document. Participant/legally authorized representative (LAR)² was [*description of participant's/LAR's mental capacity and the type(s) of assessments used*]. Participant/LAR agreed to comply with all follow-up procedures including the length of participation. The participant/LAR was given a copy of the informed consent document and study contact information.

STUDY-SPECIFIC COMMENTS (If applicable):

- Specific aspects of the study's consent process
- Combine with an "entry note" if applicable.
- Special circumstances of the informed consent process such as reason for LAR

¹ Requirement for content of consent notes:

- The name of the study,
- The person obtaining the participant's consent,
- A statement that the subject or the subject's legally authorized representative was capable of understanding the consent process,
- A statement that the study was explained to the participant,
- A statement that the participant was given opportunity to ask questions, and
- Any special circumstances of consent, for example the use of a short form consent process and reasons why, physical limitations to prevent a participant's signature, impaired decision making capacity and the need for a legally authorized representative (LAR), etc.

² LAR = Legally authorized representative

ATTACHMENT C

CREATING AND EDITING PROGRESS NOTES AND TEMPLATES IN CPRS

Creating a Template in CPRS (for routine research progress notes):

1. Templates can be stored in the “My Templates” file in CPRS Notes or stored on study desktops to be pasted into CPRS Notes when needed.
 - 1.1.1. Compose the template in Microsoft Word to be later pasted into CPRS “My Templates” or compose it directly in “My templates”.
2. Open CPRS.
3. Select a research subject’s medical chart.
4. Select the Notes tab.
5. Select <Options> from the tan bar at the top of the screen.
6. Select <Create New Template> from the dialogue box.
7. Rename the template as appropriate (Suggested template names could be “[study name] Enrollment”, “[study name] Clinical Warning”, etc.).
8. Place the cursor in the Template Boilerplate box and enter the new template:
 - 8.1. By typing content directly into the box,
 - 8.2. By pasting in content from a personal file (such as a document already composed in Word format on your PC),
 - 8.3. By choosing another template from the available boilerplates in “Shared Templates” (including the Research Service templates) or from the research study’s “Personal Templates” that can then be edited and renamed.
9. Edit and format the content as necessary.
10. Select <OK> to save the template.
11. Further details can be found in “Research Service Hot Topics” (Vol.1, No.4, 9/18/07) available in the archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp.

Editing a Research Progress Note Template:

1. Open CPRS and select a participant’s medical record.
2. Select the Notes tab.
3. Select <Options> from the tan bar at the top of the screen.
4. Select <Edit Templates> from the dialogue box.
5. Choose the template to be edited from the “Shared Templates” list or your “My Templates” list.
6. The text will appear in the Template Boilerplate box.
7. Edit as necessary.
8. If applicable, rename the template in the white “Name” box seen in the “Personal Template Properties” section. If you do not change the name of a personal template, then the newly edited template will be saved and the original template will be irretrievable.
9. Select <OK> to save note.

10. Further details can be found in “Research Service Hot Topics” (Vol.1, No.4, 9/18/07) available in the archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp.

Creating the Enrollment Note / Using a Template:

1. Open CPRS and select a participant’s medical record.
2. Select the Notes tab.
3. Click <New Note>.
4. Choose the clinic for the research study.
5. Choose “Research Note” from the menu in the “Title” box.
6. Enter the visit date/time as the date/time of the enrollment visit.
 - 6.1. The note should be entered on the same date as the Informed Consent form was actually signed by the participant. If the note is a late entry, the date/time of note should correspond to the day of enrollment. It is essential that the date of the visit, the date of the progress note, and the date the Informed Consent form was signed by the participant are the same in order to facilitate the retrieval of this documentation by non-study individuals.
7. Click <OK>.
8. Select <Templates>.
9. Click <My Templates>.
10. Double Click on the template of your choice. This will paste the template into the progress note box.
11. Complete the form, make any comments as necessary. The Comments should include study-specific information.
12. Sign the note.
13. If a legal guardian is required, the comment section should include why a legal guardian is required, state the legal guardian’s name and relation to the participant.
14. If the progress note is not entered on the same day of enrollment, a comment should be made that states the note is a late entry.
15. Print the note and place in the participant’s research chart. See Appendix C for a completed Enrollment Note.
16. Repeat for each participant.
17. Further details can be found in “Research Service Hot Topics” (Vol.1, No.4, 9/18/07) available in the archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp.

ATTACHMENT D

TEMPLATE FOR RESEARCH SUBJECT CLINICAL WARNING

ITEMS WITH ASTERISKS ARE REQUIRED FOR EACH INVESTIGATIONAL DRUG OR INVESTIGATIONAL DEVICE

*Protocol Title:

*Principal Investigator:

*Phone Number:

*Pager:

E-Mail:

Co-Investigators:

Study Coordinator:

Phone Number:

Pager:

E-Mail:

*Names for Authorized Prescribers:

- A.
- B.
- C.
- D.

Drug/Device #1

*All Designations For Drug/Device #1

Generic Name:

Chemical:

Code:

Trade Name:

Other designations:

*Manufacturer or other sponsor:

*Source of Drug/Device (if other than manufacturer or sponsor):

*Is this an invasive device? (If Yes, explain):

*Therapeutic Classification and Expected Therapeutic Effects of the Drug/Device:

*Is this drug a controlled substance? (If Yes, give classification):

*Dosage Forms and Strengths:

*Prior to mixing, storage should be (list conditions for temperature, protection from light, etc.):

*After mixing, drug remains stable in refrigerator for (give time frame in minutes, hours, days, etc.):

* Drug Administration Procedures:

*Route and Rate of Administration

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- *Administration Directions:
- *Reconstitution Directions:
- *Usual Dosage Range:
- *Double Blind? (If YES, name and contact info for person who has code designation):
- *Special Precautions (*drug interactions (synergisms, antagonisms), contraindications, etc.*):
- *Antidote:
- *Status (Investigational, Phase I, Phase II, Phase III, Phase IV, Commercially available, Other):
- *Known side effects and toxicities:

Drug/Device #2

*All Designations For Drug/Device #1

- Generic Name:
- Chemical:
- Code:
- Trade Name:
- Other designations:
- *Manufacturer or other sponsor:
- *Source of Drug/Device (if other than manufacturer or sponsor):
- *Is this an invasive device? (If Yes, explain):
- *Therapeutic Classification and Expected Therapeutic Effects of the Drug/Device:
- *Is this drug a controlled substance? (If Yes, give classification):
- *Dosage Forms and Strengths:
- *Prior to mixing, storage should be (list conditions for temperature, protection from light, etc.):
- *After mixing, drug remains stable in refrigerator for (give time frame in minutes, hours, days, etc.):
- * Drug Administration Procedures:
 - *Route and Rate of Administration
 - *Administration Directions:
 - *Reconstitution Directions:
 - *Usual Dosage Range:
 - *Double Blind? (If YES, name and contact info for person who has code designation):
 - *Special Precautions (*drug interactions (synergisms, antagonisms), contraindications, etc.*):
 - *Antidote:
 - *Status (Investigational, Phase I, Phase II, Phase III, Phase IV, Commercially available, Other):
 - *Known side effects and toxicities:

ATTACHMENT E

CREATING AND EDITING RESEARCH SUBJECT CLINICAL WARNINGS AND TEMPLATES IN CPRS

Entering a Research Subject Clinical Warning as a Posting:

1. Open CPRS and select a participant's medical record (or select "New Note" and skip to step 8.4 if already in the subjects record).
2. Select the Notes tab.
3. Click <New Note>.
4. Choose the clinic for the research study.
5. Enter the clinic and the visit date/time, if prompted. The appointment date/time should correspond to the enrollment visit date/time. This appointment should already be in the system because the Enrollment Note should have been created.
6. Click <OK>.
7. Title of the note is "Research Subject – Clinical Warning".
8. Date/time of the progress note should be same date as date of randomization to study agent/device (date may be different than informed consent date).
9. Select <OK>.
10. Select <Templates>.
11. Click <My Templates> to choose a clinical warning template, or the Research Service template.
12. Double Click on the selected template. This will paste the template into the progress note.
13. The form should be complete. Verify the information. Sign the note.
14. Print the Clinical Warning and place in the participant's research chart. See Appendix G for a sample of a completed Clinical Warning.
15. Repeat for each participant.
16. Further details can be found in "Research Service Hot Topics" (Vol.1, No.3, 9/5/07) available in the archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp.

Removing a Clinical Warning:

Once a participant's involvement in the study has ended, the Research Subject Clinical Warning needs to be de-activated in CPRS. To do this:

1. Make an Addendum.
2. Find date in left hand column that corresponds to the date when the Research Subject- Clinical Warning was initially entered.
3. Hit <Enter>.
4. Click <Action> on tool bar.
5. Choose < Make addendum>.
6. Enter the following text on the blank form: The participant's involvement in this protocol ended (enter date).

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

7. Click <Action>.
8. Choose <Sign Note Now>.
9. Enter electronic signature.
10. Send an e-mail containing the participant's name, last four, date of birth and date of the addendum note to: the Clinical Informatics staff via email in exchange at VAMHCSCIS2@med.va.gov or using the g.CIS mail group in VistA/DHCP. The staff there will deactivate clinical warning.
11. Further details can be found in "Research Service Hot Topics" (Vol.1, No.5, 10/9/07) available in the archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp.