

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

SOP: HRP 07.01
Approval Date: 4/08

ENROLLMENT NOTES FOR RESEARCH PARTICIPANTS

This SOP, originally approved on 1/10/08, underwent changes on 4/16/08 summarized below:

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Author	Jessica Mendoza		
Reviewed/ Revised by	Jessica Mendoza	Dates Reviewed / Revised	4/18/08
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Approved	Leslie Katzel, R&D Chair 5/8/08	Approved R&D / Dennis Smith	5/8/08
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This amended version (2.1) was approved by the Chair, R&D Committee / by the R&D Committee on 5/8/08.

Leslie Katzel, MD, PhD
Chair, R&D Committee

Date

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SOP: HRP 07.01

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ENROLLMENT NOTES FOR RESEARCH PARTICIPANTSOBJECTIVE:

- To assist research staff and scanning personnel by establishing a consistent format for research progress notes and clinical warnings.
- To establish a means of notifying medical personnel of a patient's participation in a research study (and its consequent medical implications) through an enrollment progress note, clinical warnings and termination notes.
- To outline the procedures to create a template for research progress note and clinical warnings.
- To outline the procedures to enter research progress notes in research participant's electronic medical record (CPRS).
- To outline procedure for deactivation of a research subject clinical warning.

POLICY:

All persons enrolled in a VAMHCS research study must have a medical record (CPRS) that "flags" the person as a study participant unless:

1. The study involves only one encounter,
2. The study involves only the use of a questionnaire,
3. The study involves only the use of previously collected biological specimens,
OR
4. If the identification of the patient as a participant in a particular study (if the study is not greater than minimal risk) would place the patient at greater than minimal risk (for example, the study has a certificate of confidentiality).

This flag protects the participant's safety by notifying hospital staff that the person is a participant in a research study, and by identifying the source of more information about the study. At the VAMHCS this flag is known as the "Research Subject Clinical Warning" (RSCW).

In addition, all informed consent forms, signed when persons enroll in a VAMHCS research study, must be scanned into CPRS to become part of the participant's medical record unless 1-4 above apply.

DEFINITIONS:

- **Research Subject Clinical Warning (RSCW)** –provides study and contact information to the VAMHCS clinical staff to assist in assuring the safety and welfare of the study participant when they are receiving a study agent/device

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- **Enrollment Progress Note** – describes the informed consent process, including discussion with participant and provides the link for scanning of the informed consent document.
- **Termination note** – provides information to staff regarding termination of study participation by a research patient.

RESPONSIBILITIES:

- The Principal Investigator is responsible for ensuring that a progress note(s) documenting the informed consent process and subject enrollment is completed and placed in the participant's medical records.
- The Principal Investigator is responsible for ensuring that a Research Subject Clinical Warning is placed into the medical record when required.
- The Principal Investigator is responsible for delivering copies of signed informed consent forms and HIPAA authorizations to the Research Service to be scanned into CPRS.

COMPONENTS OF THIS SOP:

1. Templates
2. Enrollment Notes
3. Scanned Consents
4. Research Subject Clinical Warnings

PROCEDURES:

1. When a patient is screened for or enrolled in a study, the following notes are required to be entered into the subject's electronic medical record (CPRS):
 - a progress note / consent note,
 - a progress/enrollment note (if not already documented in the consent note),
 - a Research Subject Clinical Warning,
 - the signed informed consent form subsequently scanned into CPRS by Research Service staff and tagged to the consent note.
- 1.1. Consent notes and enrollment notes can be combined when both occur at the same visit.
- 1.2. Notes are not required if:
 - The study involves only one encounter,
 - The study involves only the use of a questionnaire,
 - The study involves only the use of previously collected biological specimens, OR
 - If the identification of the patient as a participant in a particular study (if the study is not greater than minimal risk) would place the patient at greater

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than minimal risk (for example, the study has a certificate of confidentiality).

- 1.3. In rare cases where visit documentation will not be done in CPRS (see 2.1 and 2.2 below), the research staff must be scrupulous in their documentation in the research study charts. In this case, study charts MUST contain:
 - Signed informed consent form,
 - Signed HIPAA authorization (if applicable)
 - Enrollment notes,
 - Visit notes,
 - Termination notes.
2. When a participant has finished participation in the study, withdraws, is excluded at screening, is terminated from the study, etc., a closure note must be written and the RSCW removed from CPRS (if applicable). See Item 10 below for details.
3. Both veterans and non-veterans must be registered into CPRS in order to establish a patient record (for notes and RSCWs) as well as to be able to receive services, process clinical laboratory tests, etc.
 - 3.1. If a non-veteran objects to being registered into CPRS, it may still be possible for the non-veteran to enroll in the research, particularly if it is a minimum risk study. This will be handled on a case-by-case basis through the Research Compliance Office.
 - 3.2. If a Certificate of Confidentiality has been obtained for the study, it is possible that there could be CPRS issues related to study participation. The PI should meet with the Research Compliance Officer prior to study initiation to develop a plan for documentation of consent and study visits as well as subject safety (for example, obtaining medical interventions if necessary).
 - 3.3. Registration into CPRS requires a VA Form 10-10EZ to be completed and processed through MAS.
4. The VHA requires the following information in consent/enrollment 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, and
 - A statement that the participant was given opportunity to ask questions.
 - 4.1. The VAMHCS requires the following additional elements:
 - Name of the Principal Investigator
 - IRB # and validation dates
 - Date and time the consent form was signed
 - Any special circumstances of consent, for example the use of a short form consent process and reasons why, physical limitations to prevent a

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participant's signature, impaired decision making capacity and the need for a legally authorized representative (LAR), etc.

4.2. Research staff is advised to create enrollment note templates, visit note templates, and RSCW templates to save time and to ensure that all required elements are included. Instructions follow in 4-7 below; examples are in the Appendices.

5. Creating a Template:

5.1 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.

5.1.1 Use the blank progress note forms in Appendix B (Enrollment Note Form) and D (Clinical Warning Form) as models.

5.1.2 Compose the template in Microsoft Word to be later pasted into CPRS "My Templates" or compose it directly in "My templates".

5.2 Open CPRS.

5.3 Select a research subject's medical chart.

5.4 Select the Notes tab.

5.5 Select <Options> from the tan bar at the top of the screen.

5.6 Select <Create New Template> from the dialogue box.

5.7 Rename the template as appropriate (Suggested template names could be "[study name] Enrollment", "[study name] Clinical Warning", etc.).

5.8 Place the cursor in the Template Boilerplate box and enter the new template:

5.1.1 By typing content directly into the box,

5.1.2 By pasting in content from a personal file (such as a document already composed in Word format on your PC),

5.1.3 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.

5.1.4 Edit and format the content as necessary.

5.1.5 Select <OK> to save the template.

5.9 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.

6. Editing a Research Progress Note Template:

6.1. Open CPRS and select a participant's medical record.

6.2. Select the Notes tab.

6.3. Select <Options> from the tan bar at the top of the screen.

6.4. Select <Edit Templates> from the dialogue box.

6.5. Choose the template to be edited from the "Shared Templates" list or your "My Templates" list.

6.6. The text will appear in the Template Boilerplate box.

6.7. Edit as necessary.

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- 6.8. 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.*
 - 6.9. Select <OK> to save note.
 - 6.10. 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.
7. Creating the Enrollment Note / Using a Template
- 7.1 Open CPRS and select a participant’s medical record.
 - 7.2 Select the Notes tab.
 - 7.3 Click <New Note>.
 - 7.4 Choose the clinic for the research study.
 - 7.5 Choose “Research Note” from the menu in the “Title” box.
 - 7.6 Enter the visit date/time as the date/time of the enrollment visit.
 - 7.1.1 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.
 - 7.7 Click <OK>.
 - 7.8 Select <Templates>.
 - 7.9 Click <My Templates>.
 - 7.10 Double Click on the template of your choice. This will paste the template into the progress note box.
 - 7.11 Complete the form, make any comments as necessary. The Comments should include study-specific information. For example:
 - 7.12 Sign the note.
 - 7.13 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.
 - 7.14 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.
 - 7.15 Print the note and place in the participant’s research chart. See Appendix C for a completed Enrollment Note.
 - 7.16 Repeat for each participant.
 - 7.17 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.
8. Entering a Research Subject Clinical Warning as a Posting
- 8.1. Open CPRS and select a participant’s medical record (or select “New Note” and skip to step --- if already in the subjects record).

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- 8.2. Select the Notes tab
 - 8.3. Click <New Note>.
 - 8.4. Choose the clinic for the research study.
 - 8.5. 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.
 - 8.6. Click <OK>.
 - 8.7. Title of the note is “Research Subject – Clinical Warning”.
 - 8.8. 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)
 - 8.9. Select <OK>.
 - 8.10. Select <Templates>.
 - 8.11. Click <My Templates> to choose a clinical warning template, or the Research Service template
 - 8.12. Double Click on the selected template. This will paste the template into the progress note.
 - 8.13. The form should be complete. Verify the information. Sign the note.
 - 8.14. Print the Clinical Warning and place in the participant’s research chart. See Appendix G for a sample of a completed Clinical Warning.
 - 8.15. Repeat for each participant.
 - 8.16. 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.
9. Scanning Informed Consent Forms into VISTA Imaging:
- 9.1. Each signed Informed Consent form for a protocol is scanned into VISTA Imaging by VAMHCS Research Staff. The image will be attached to the Enrollment Note as an addendum and an icon will appear in the list of progress notes in CPRS. Therefore, it is essential that the date of the progress note entitled Enrollment Note correspond to the date the Informed Consent was signed by that particular participant.
 - 9.2. Research staff must deliver each signed Informed Consent form to the Research Service, 3A-125, in a timely fashion.
 - 9.3. A cover letter (see Appendix E) should be submitted with each consent form or group of consent forms.
 - 9.4. An incomplete cover letter, CPRS chart, or consent form will delay the scanning process. The study contact person is contacted if any discrepancies are found. Study personnel are responsible for making the necessary corrections in adherence to GCP Guidelines and documenting the corrections as completed on the Request for Corrections form. Return completed corrections to the Research Service.
 - 9.5. See Appendix D for a completed Enrollment Note with the Scanned Consent addendum.

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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:

10.1. Make an Addendum

10.1.1. Click on <Notes> tab

10.1.2. Find date in left hand column that corresponds to the date when the Research Subject- Clinical Warning was initially entered

10.1.3. Hit <Enter>

10.1.4. Click <Action> on tool bar

10.1.5. Choose < Make addendum>

10.1.6. Enter the following text on the blank form: The participant's involvement in this protocol ended (enter date).

10.1.7. Click <Action>

10.1.8. Choose <Sign Note Now>

10.1.9. Enter electronic signature

10.2. 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.

10.3. 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.

APPENDICES:

- A. Enrollment Note Algorithm
- B. Enrollment Note Form
- C. Clinical Warning Algorithm
- D. Clinical Warning Form
- E. Sample of an Enrollment Note
- F. Sample of an Enrollment Note with Scanned Consent Addendum
- G. Cover Letter – Scanned Consent Process
- H. Request for Corrections – Scanned Consent Process
- I. Sample Clinical Warning

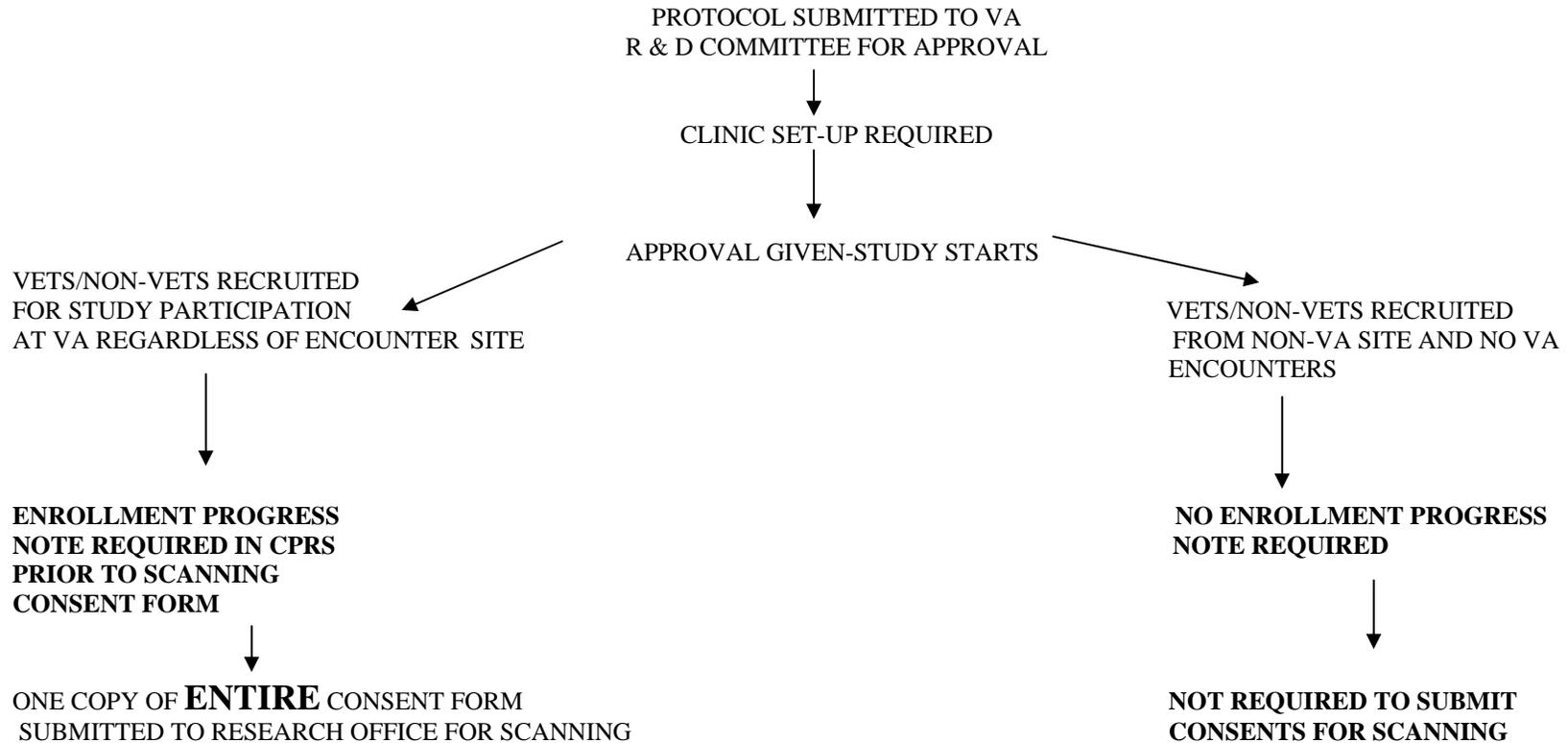
APPROVAL

This SOP entitled "Establishing a Patient in CPRS" has been re-approved by the Medical Center Director, effective 4/10/08.

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APPENDIX A

ENROLLMENT PROGRESS NOTE ALGORITHM



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ENROLLMENT NOTE FORM

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/legal guardian was [*description of participant's/guardian's mental capacity and the type(s) of assessments used*]. Participant/legal guardian agreed to comply with all follow-up procedures including the length of participation. The participant/legal guardian was given a copy of the informed consent document and study contact information.

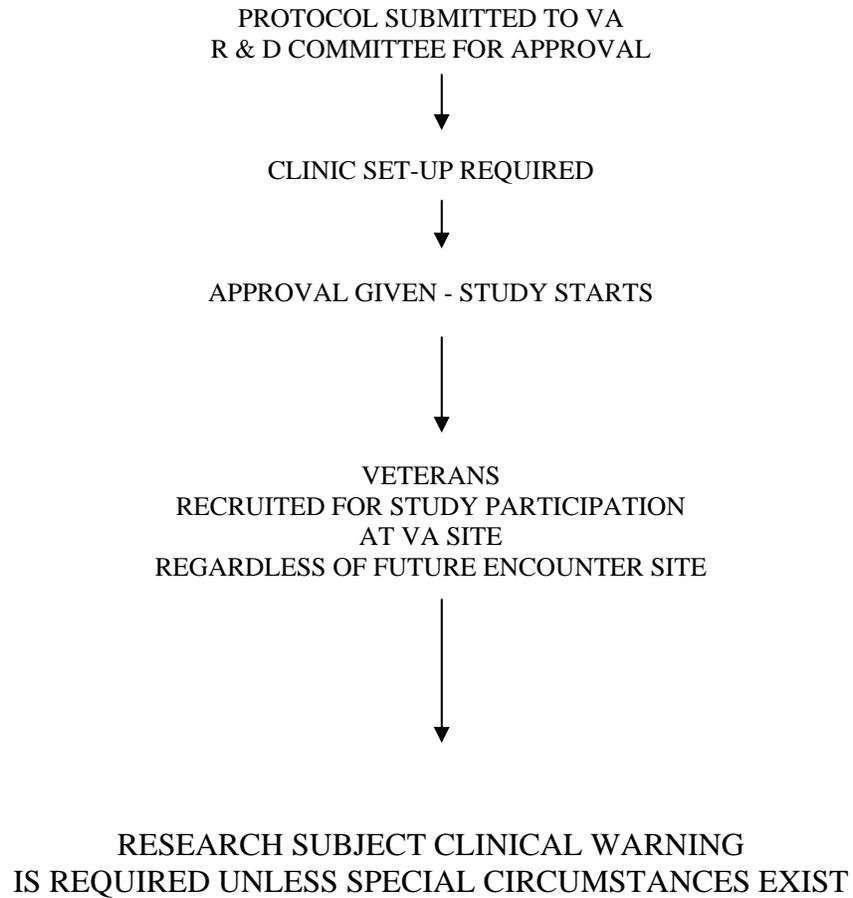
STUDY-SPECIFIC COMMENTS (If applicable):

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

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APPENDIX C

CLINICAL WARNING ALGORITHM



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APPENDIX D

CLINICAL WARNING FORM

CLINICAL WARNING

REQUIRED (Complete all of the following):

Protocol Title:

Principal Investigator:

Phone Number:

Pager:

E-Mail:

Co-Investigators:

Study Coordinator:

Phone Number:

Pager:

E-Mail:

Important Information (including any FDA-approved medications and/or medical devices)

OPTIONAL (Complete the following as determined by the PI):

Persons Responsible For Prescribing Drugs For This Study:

1) All Designations For Drug #1

Generic Name:

Trade Name:

Dosage Forms and Strengths:

Source of Drug:

Expected Therapeutic Effects:

Usual Therapeutic Dose and Range for Study:

Route and Rate Of Administration:

Possible Adverse Effects, Known Side Effects and Toxicities:

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Storage:

Special Handling Precautions For Pharmacists and Nurses (describe in detail):

- 2) All Designations For Drug #2
Generic Name:
Trade Name:

Dosage Forms and Strengths:

Source of Drug:

Expected Therapeutic Effects:

Usual Therapeutic Dose and Range for Study:

Route and Rate Of Administration:

Possible Adverse Effects, Known Side Effects and Toxicities:

Storage:

Special Handling Precautions For Pharmacists and Nurses (describe in detail):

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STANDARD OPERATING PROCEDURE**APPENDIX E****SAMPLE OF AN ENROLLMENT NOTE**

Principal Investigator: John Doe, MD
Protocol Title: The Effect of a Caffeine Pill vs. a Multi-vitamin on Work Performance
IRB #: 1001567a1
IRB Validation Dates: 10/01/01-9/30/02
Date the Informed Consent form was signed: 10/10/01
Time the Informed Consent form was signed: 1400
Person Obtaining Consent: Julie Doherty

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/legal guardian was alert and oriented x3 and was able to restate to the Coordinator the major aspects of the study. Participant/legal guardian agreed to comply with all follow-up procedures including the length of participation. The participant/legal guardian was given a copy of the informed consent document and study contact information.

STUDY-SPECIFIC COMMENTS (If applicable):

Participant has dementia and required a legal guardian's signature to enroll in the Caffeine Study. Jessica Smith, mother, signed as the legal guardian.

After the legal guardian signed the Informed Consent, the participant was screened for inclusion/exclusion criteria.

Signed by: /es/ Julie Doherty
Research Coordinator 10/10/01 16:01

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STANDARD OPERATING PROCEDURE**APPENDIX F****SAMPLE OF AN ENROLLMENT NOTE
WITH SCANNED CONSENT ADDENDUM**

Principal Investigator: John Doe, MD
Protocol Title: The Effect of a Caffeine Pill vs. a Multi-vitamin on Work
Performance
IRB #: 1001567a1
IRB Validation Dates: 10/01/01-9/30/02
Date the Informed Consent form was signed: 10/10/01
Time the Informed Consent form was signed: 1400
Person Obtaining Consent: Julie Doherty

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/legal guardian was alert and oriented x3 and was able to restate to the Coordinator the major aspects of the study. Participant/legal guardian agreed to comply with all follow-up procedures including the length of participation. The participant/legal guardian was given a copy of the informed consent document and study contact information.

STUDY-SPECIFIC COMMENTS (If applicable):

Participant has dementia and required a legal guardian's signature to enroll in the Caffeine Study. Jessica Smith, mother, signed as the legal guardian.

After the legal guardian signed the Informed Consent, the participant was screened for inclusion/exclusion criteria.

Signed by: /es/ Julie Doherty
Research Coordinator 10/10/01 16:01

ADDENDUM:

THIS SCANNED RESEARCH CONSENT FORM
CAN BE VIEWED IN VISTA IMAGING

Date of Scanning: 10/15/01
Scanned by: Research Staff

Signed by: /es/ Judith Murray
Research Coordinator 10/19/01 16:01

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APPENDIX G

COVER LETTER – SCANNED CONSENT PROCESS

Date: _____

Protocol Title:

Principal Investigator:

IRB #: _____

Clinic Name: _____ N/A _____

IRB Validation Dates: _____

VA R&D Approval Date: _____

Contact Person: _____ Phone #:

Number of Consents Enclosed: _____

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APPENDIX H

REQUEST FOR CORRECTIONS – SCANNED CONSENT PROCESS

Date: _____

Protocol Title: _____

Principal Investigator: _____

Prepared By: _____

Dear PI or Authorized Representative,

The enclosed Informed Consent forms are being returned to you for the following correction(s).

Please complete the form, re-submit consent forms (as necessary) and return to the Research Service, 3A-125.

Incomplete Face Sheet

_____ Missing Protocol Title

_____ Missing PI

_____ Missing Clinic Name

_____ Missing IRB Validation Date or VA R&D Approval Date

Incomplete Electronic Chart Contents

_____ Clinic not found

_____ Participant not found in CPRS

_____ Enrollment Progress Note not found

Incomplete Consent Form

_____ Poor Print Quality of the Informed Consent Form

_____ Missing Page(s) of the Informed Consent Form. Page(s) #: _____

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- _____ IRB Validation Stamp or Protocol # is Not the Same on All Pages of the Consent Form
- _____ Invalid or Missing IRB Validation Stamp
- _____ Participant Signature is Not Legible – Identify and List below
- _____ Missing/Incorrect Participant's Social Security Number
- _____ Missing Participant's Signature/Date *
- _____ Missing Legal Guardian's Signature/Date*
- _____ Missing PI or Authorized Representative's Signature/Date*
- _____ Missing PI's Signature/Date of Awareness of Participation*
- _____ PI's Signature of Awareness Dated Prior to Participant's Signature*
- _____ Conflicting Dates of Consent Process (CPRS vs consent document)*
- _____ PI Signing the Consent Form is Not Listed on the Informed Consent Form*
- _____ Other: _____

Comments: _____

* Requires memo to file by PI/study staff. See FAQ section after CPRS algorithm.

Corrections completed by (sign): _____

(Print): _____

(Date): _____

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SAMPLE CLINICAL WARNING

REQUIRED (Complete all of the following):

Protocol Title: The Effect of a Caffeine Pill vs a Multi-vitamin on Work Performance

Principal Investigator: John Doe, MD
Phone Number: 410-555-7000
Pager: 410-555-5555
E-Mail: johndoe@va.gov

Co-Investigators: Bill Smith, MD

Study Coordinator: Jane Doe, RN
Phone Number: 410-555-9999
Pager: 410-555-0000
E-Mail: janedoe@va.gov

Important Information (including FDA-approved medications and/or medical devices):

Please contact study coordinator if participant complains of any of the side effects listed below for either medication.

OPTIONAL (Complete the following as determined by the PI):

Persons Responsible For Prescribing Drugs For This Study:
John Doe, MD Bill Smith, MD

- 1) All Designations For Drug #1:
 Generic Name: Generix
 Trade Name: StudyMed

Dosage Forms and Strengths: Tablet, 100 mg

Source of Drug: Drug Company

Expected Therapeutic Effects: Improve work productivity

Usual Therapeutic Dose and Range for Study: 100 mg

Route and Rate Of Administration: 1 tablet, qd

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Possible Adverse Effects, Known Side Effects and Toxicities:
hyperactivity, sleepiness, mental disorders

Storage: room temperature

Special Handling Precautions For Pharmacists and Nurses (describe in detail): None

- 2) All Designations For Drug #2:
Generic Name: Generix2
Trade Name: StudyMed2

Dosage Forms and Strengths: Tablet, 100 mg

Source of Drug: Drug Company

Expected Therapeutic Effects: Improve work productivity

Usual Therapeutic Dose and Range for Study: 100 mg

Route and Rate Of Administration: 1 tablet, qd

Possible Adverse Effects, Known Side Effects and Toxicities: sleepiness,
mental disorders

Storage: room temperature

Special Handling Precautions For Pharmacists and Nurses (describe in detail): None

Signed by: /es/ Julie Doherty
Research Coordinator 10/10/01 16:01