

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

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PBM DRUG SAFETY ALERTS

OBJECTIVES:

- To allow for a timely assessment of risks to research subjects and, when indicated, modifications in research protocols, informed consent, and prompt notification of research participants to ensure the highest level of protections for these research subjects.
- To alert investigators to the need for the reporting, monitoring, and surveillance of adverse drug events (ADEs), whether they were observed Adverse Drug Reactions (ADR) or historical ADRs from FDA approved investigational drugs.
- To ensure timely inclusion of patient or research subject information to the national VA Adverse Drug Event Reporting System (VA ADERS), the newly formed VA ADERS Advisory Committee (VA ADERS AC), and the FDA MedWatch System.

SCOPE & POLICY:

PBM notifications are generated by the Veterans Health Administration (VHA) Pharmacy Benefits Management (PBM) Service. These alerts include safety issues and adverse events related to Food and Drug Administration (FDA) approved medications and biologics used in human research projects conducted by VA. There are two types of PBM alerts: a “National PBM Bulletin” and a “National PBM Communication” (see below for definitions).

PBM notifications of safety issues and adverse events related to pharmaceuticals have long been available to VHA clinicians. However, there has been no formal mechanism to ensure direct dissemination of such information to the VA research community including, when appropriate, research participants.

On October 30, 2008 the VHA issued Directive 2008-072, “Research Personnel Notification of Pharmacy Benefits Management Drug Safety Alerts and Adverse Drug Events Related to Interventional Human Subjects”.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

This VHA Directive requires facilities to establish policy and procedures that will ensure that the investigators, Associate Chiefs of Staff for Research and Development (ACOS for R&D), Administrative Officers for Research and Development (AO for R&D), and Institutional Review Boards (IRBs) receive rapid notification of relevant Department of Veterans Affairs (VA) Pharmacy Benefits Management (PBM) Services alerts.

Within the VAMHCS community, PBMs are accessed through the daily “VAMHCS eNEWS”. Additionally, the ACOS/R&D and Chief, Pharmacy Services, receive PBM notifications through VHA Pharmacy Benefits Management Services.

It is VAMHCS Research Service policy to ensure appropriate notification of research subjects involved, and appropriate modifications to the research protocol and informed consent to ensure the highest level of protections for the research subjects.

DEFINITIONS

Adverse Drug Event (ADE). An ADE is an injury from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug including dose reductions and discontinuation of drug therapy. An ADE is a response to a drug which is noxious and unintended and which occurs at doses normally used in people for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. It can be a causal or suspected link between a drug or adverse drug reaction. However, causality or association of the drug to the adverse drug reaction does not have to be established in order to report an adverse drug reaction or adverse drug event. [VHA Directive 2007-072 Par 2.b(1)]

Adverse Drug Reaction (ADR). A response to a drug which is noxious and unintended and which occurs at doses normally used in people for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. [VHA Directive 2007-072 Par 2.b(2)]

Observed ADR. Defined in the Computerized Patient Record System (CPRS) as a reaction that is “directly observed or occurring while the patient was on the suspected causative agent.” Observed refers to a newly noted adverse outcome, typically within the past 3 months. Although the term implies that the provider of record made the diagnosis, the fact that a provider may not have visually observed an ADR does not preclude reporting as observed. [VHA Directive 2007-072 Par 2.b(2)(a)]

Historical ADR. An event that occurred greater than 3 months prior to or that reportedly occurred in the past at another healthcare setting. It is defined in the system as “reported by the patient as occurring in the past: no longer requires intervention.” [VHA Directive 2007-072 Par 2.b(2)(b)]

Allergy. An adverse drug reaction mediated by an immune response (e.g. rash, hives). [VHA Directive 2007-072 Par 2.b(2)(c)]

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

Side Effect. A side effect is an expected and known effect of a drug that is not the intended therapeutic outcome. The term side effect tends to nominalize the concept of injury from the drug. It is recommended that the term should generally be avoided in favor of ADR. [VHA Directive 2007-072 Par 2.b(2)(d)]

Mild ADE Severity. An event that requires minimal therapeutic intervention such as discontinuation of drugs. [VHA Directive 2007-072 Par 2.b(2)(e)]

Moderate ADE Severity. An event that requires active treatment of adverse reaction or further testing or evaluation to assess extent of non-serious outcome. [VHA Directive 2007-072 Par 2.b(2)(f)]

Serious ADE Severity. An event is serious when the patient outcome is: death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, other serious or important medical events. It may result in an organ threatening situation, significant or permanent disability, requiring interventions to prevent permanent impairment or damage, or prolonged hospitalization or death. [VHA Directive 2007-072 Par 2.b(2)(g)]

Adverse Drug Event Reporting System (ADERS). The VHA intranet spontaneous ADE reporting system known as the VA Adverse Drug Event Reporting System (VA ADERS) standardizes reporting at the facility level, centralizes ADE data analysis, and improves efficiency of ADE report coding used to categorize and classify symptoms associated with the event. [VHA Directive 2007-059 Par 2]

Comparator Drug. A comparator drug is an agent that the investigational drug is being compared to in a clinical trial. A comparator drug may be the current standard of care for the disease state being studied. [VHA Directive 2007-072 Par 2.b(3)]

Corrective Action Plan (CAP). A written plan designed by investigators, the IRB, Research Service, R&D Committee, and/or other individuals or entities, to address improvements necessary to resolve adverse events, prevent future adverse events or otherwise improve the safety and rights of research participants or the scientific integrity of the research project.

Investigational Drug. An investigational drug is a chemical or biological drug that is used in a clinical investigation. An investigational drug can be a new chemical compound which has not been released by the FDA for general use, or an approved drug that is being studied for an approved or unapproved use, dose, dosage form, or administration schedule, under an Investigational New Drug (IND) application, in a controlled, randomized, or blinded clinical trial. [VHA Directive 2007-072 Par 2.b(4)]

National PBM Bulletin. A National PBM Bulletin is a Drug Safety Alert that includes standard sections: Issue, Background, Recommendations, and References. It is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Bulletin include

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

provider notification as well as actions to be carried out by the provider. When warranted, recommended actions include patient notifications by phone call, in person or by letter. Confirmation that actions have been completed will be required. [VHA Directive 2007-072 Par 2.b(5)]

National PBM Communication. A National PBM Communication is a Drug Safety Alert that does not include standard sections, but is warranted to further clarify and/or emphasize what is noted in the drug-related safety information. It is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Communication include provider notification and when warranted, patient notifications by phone call, in person or by letter. Confirmation that actions have been completed will be required. [VHA Directive 2007-072 Par 2.b(6)]

Reportable New Information (RNI). Certain information that must be reported to the IRB in a prompt manner, within FIVE (5) business days of the investigator becoming aware of the information. See the UMB HRPO document, "[REPORTABLE NEW INFORMATION](#)", for a list of information that is requires prompt reporting. All other events can be reported to the IRB in an aggregate fashion at the time of continuing review.

Study-related Drugs. Any specific molecular entity that is related to a study outcome and is specifically mentioned in the research informed consent documents. [VHA Directive 2007-072 Par 2.b(7)]

RESPONSIBILITIES:

1. The Medical Center Director is responsible for:
 - Disseminating all Drug Safety Alert documents within the facility;
 - Confirming document dissemination and follow-up action to the VISN Director when required;
 - Ensuring that the VA Investigator or clinician documents in CPRS any observed ADEs that occurred or were recognized in association with any FDA-approved drug or biologic used in a research study;
 - Ensuring that all VA investigators or clinicians involved in direct patient care receive employee health care orientation training on entering ADEs into CPRS and VA ADERS of any FDA approved drug or biologic;
 - Ensuring participation of research staff with appropriate VAMHCS departments or groups involved in the ADE process for the coordination of ADE reporting and risk assessments.
2. The Chief of Staff (COS) is responsible for:
 - Disseminating all Drug Safety Alerts and related materials to the Associate Chief of Staff (ACOS) for Research and Development (R&D);
 - Verifying that all required actions have been completed including mailing of patient or subject letters, and the appropriate documentation of all actions has been completed;

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- Reporting to the facility Director that all research subjects have been notified when notification is required.
3. The Chief, Pharmacy Service is responsible for:
- Through the Investigational Drug Pharmacist (IDP), maintaining current records of all pharmaceutical products that are being used as either investigational drugs or comparator drugs;
 - Designating a research pharmacist to serve as liaison to the facilities research program in areas such as; the use of a study related drugs, evaluation of the impact of the research on the Pharmacy Service, and review of the research protocol;
 - Serving as a subject matter expert for the IRB when necessary.
4. ACOS/R&D and AO/R&D are responsible for:
- Ensuring that a current list of all investigational drugs, comparator drugs, or study-related drugs being used in the facility's VA approved human subjects research is maintained. The list **must be computerized, and must contain the name of the investigator and the study name. It must be provided electronically to the Pharmacy Service;**
 - Reviewing all National PBM Bulletins or National PBM Communications as soon as they are received;
 - Determining whether or not the specific pharmaceuticals addressed in the PBM Alerts are on the current list of pharmaceuticals (investigational drug, comparator drug, study-related drug) being used in any of the facility's human research protocols.
 - If the pharmaceutical is being used in a protocol, directing corrective actions and notifications, and documentation:
 - Contacting the investigator (verbally and in writing) as soon as possible and always within 5 working days,
 - Forwarding a copy of the National PBM Bulletin or National PBM Communication to the IRB with the name of the study involved.
 - Ensuring that records are maintained of all notifications and the resulting actions and communications.
 - Determining in conjunction with the investigator, the Pharmacy Service, or other qualified individual, if the report contains information that may indicate an increased risk or potential risk to research subjects, or require changes to any part of the research protocol and informed consent.
 - Notifying the COS that all research subjects have been notified if notification was required, and that the notification of the research subjects was appropriately documented, OR, if all research subjects were not notified, informing the COS in writing that they have not and why they were not notified;
 - If the VAMHCS Deputy ACOS/R&D or AO/R&D is the designee to carry out this procedure, ensuring that the COS or designee is consulted regarding any determinations that are made regarding the VA-PBM safety alerts.
5. The Principal Investigator is responsible for:
- Determining in consultation with the ACOS/R&D, the IDP, or other qualified individuals, whether the information in the PBM represents apparent immediate harm or potential increased risk to research subjects;
 - If it is determined that there is increased risk or possible harm to research subject, compiling a list of research subjects who may be at risk, and

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- Determining if there is “apparent immediate harm to the subjects” or “possible increased risk to research subjects” (see section 3.1 below).
 - Developing a corrective action plan (CAP) as necessary.
 - Initiating all modifications approved or required by the IRB in a timeframe required by the IRB and documenting the implementation in the research record and, as appropriate, medical record. (See Procedure 4.1 below).
 - Responding to FDA withdrawal of marketed drugs.
 - Documenting all ADEs in research subjects into CPRS and VA ADERS as required by VHA Directive 2008-072. All other requirements in that directive must also be followed.
6. VA R&D Committee is responsible for:
- Reviewing the findings of the IRB and making any other appropriate recommendations;
 - Communicating these recommendations to the investigator and the IRB.
 - Ensuring that the R&D Committee minutes appropriately documents all discussions and actions taken.
 - Ensuring that the facility’s research compliance officer or other designated individual, audits all aspects of the requirements of this directive to ensure compliance in the appropriate timeframe.
 - Documenting all recommendations and communications with the investigator and the IRB.
7. The IRB is responsible for review and approval of actions and corrective action plans in accordance with VHA Directive 2008-072 and IRB Policies and Procedures. (see Procedure 5 below).

PROCEDURE:

1. Tracking of Study Drugs
 - 1.1. At the time that studies are submitted to the R&D Committee for review, investigators whose studies involve the use of study drugs must meet with the VAMHCS Investigational Drug Pharmacist (IDP). The IDP must approve the study as a pre-requisite for R&DC approval. The ensuing VAMHCS Pharmacy Services (IDS) Memorandum to the investigator contains a statement of the investigator’s requirement to report ADEs.
 - 1.2. The IDP maintains a database of study drugs for R&DC-approved studies.
 - 1.3. As delegated by the ACOS/R&D, the R&DC Coordinator maintains an electronic database for all VAMHCS studies, including the name of the investigator and the study name. For studies involving drugs, this database also includes a list of the drugs (investigational or not) that are used for each study. This list is electronically updated with the IDP on a monthly basis, following the convened R&D Committee (RDC) meeting.
2. Dissemination of PBM Alerts
 - 2.1. PBM Alerts are accessible by all VAMHCS employees through the daily VAMHCS electronic newsletter, “VAMHCS eNEWS”.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- 2.2. The RDC coordinator checks the PBM alerts (if any), searches the updated research study database¹ for an indication that the alert references a study drug in use in a VAMHCS research study and, if so, notifies the Investigational Drug Pharmacist (IDP). The IDP may also check the “VAMHCS eNEWS”. In addition, the ACOS/R&D receives PBM notifications from VA Central Pharmacy.
 - 2.3. If a PBM alert involves a VAMHCS research study drug, the IDP (or RDC Coordinator) notifies the ACOS/R&D, Deputy ACOS/R&D, and AO/R&D.
 - 2.4. The ACOS/R&D, Deputy ACOS/R&D, and/or AO/R&D review the PBM alert and:
 - 2.4.1. Contacts the investigator (verbally and in writing) as soon as possible and always within 5 working days,
 - 2.4.2. Forwards a copy of the National PBM Bulletin or National PBM Communication to the IRB with the name of the study involved, and
 - 2.4.3. Determines, in conjunction with the investigator, the Pharmacy Service, or other qualified individual:
 - 2.4.3.1. whether the report contains information that may indicate an increased risk or potential risk to research subjects, or require changes to any part of the research protocol and informed consent.
 - 2.4.3.2. Whether there may be a apparent immediate harm to subjects (see 3.1 below),
 - 2.4.3.3. Or whether there may be possible increased risk to the subject (see 3.2 below).
 - 2.4.4. If the VAMHCS Deputy ACOS/R&D or AO are the designees for the alert (non-physicians), they must consult with the COS or designee regarding any determinations that are made regarding the VA-PBM safety alerts.
 - 2.4.5. *If a notification recommends discontinuing an investigational drug, a comparator drug, or a drug that is named in the research informed consent, the Office of Research and Development (ORD) must approve any such recommendation. ORD’s decision must be conveyed to the IRB and the investigator.*
 - 2.5. Actions proceed according to items 3-7 below.
3. Actions: ACOS/R&D, Deputy ACOS/R&D, AO/R&D, Investigator
 - 3.1. If it is determined that immediate action is needed (“**apparent immediate harm**”):
 - 3.1.1. A list of research subjects who may be at risk must be compiled by the investigator;
 - 3.1.2. The Investigator must notify the IRB Chair as soon as possible but within 3 working days of the investigator becoming aware of the apparent immediate harm. This is done through the CICERO RNI mechanism.
 - 3.1.3. The Investigator must immediately modify the protocol and informed consent document as appropriate.
 - 3.1.3.1. Modifications in the amendment may be instituted prior to IRB approval to eliminate apparent immediate harm to the research subjects or to reduce the magnitude of the harm.
 - 3.1.3.1.1. If they are instituted, the IRB Chair must be notified of the actions taken and the amended protocol and consent must be submitted to the IRB as required by VHA policy. *Any actions*

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

taken by the investigator must be reported to the IRB within 3 working days through the CICERO RNI mechanism.

- 3.1.4. The Investigator must send the *PBM notification letter to [the study's] Data Monitoring Committee (DMC). The DMC will convene within 5 days if practicable, and will submit a summary of their findings to the IRB within 24 hours of the meeting.*
- 3.2. **If it is determined that immediate action is not needed (“possible increased risk to subjects”):**
 - 3.2.1. A list of research subjects who may be at risk must be compiled by the investigator;
 - 3.2.2. The Investigator must notify the IRB Chair within 5 working days of the investigator becoming aware of the risk. This is done through the CICERO RNI mechanism.
 - 3.2.2.1. The notification is made through the “Reportable New Information” mechanism in CICERO and must include the new information, the risk to the subjects, and a proposed action plan.
 - 3.2.2.2. The proposed plan may include amendments to the protocol and the informed consent.
 - 3.2.2.3. **NOTE:** *If the PBM alert includes a notification letter for all patients and subjects, the letter must be submitted to the IRB for approval prior to sending it to the subjects unless there is apparent immediate harm to the research subject.*
4. **Additional Actions :Investigator**
 - 4.1. The Investigator must initiate all modifications approved or required by the IRB in a timeframe required by the IRB (see Action 5 below).
 - 4.1.1. The implementation of these modifications must be documented in the research record and as appropriate, in the subject’s medical record.
 - 4.1.2. The modifications or changes may include, but are not be limited to, notification of the subjects by letter or phone call, amendments to the informed consent that must be signed by the subjects, additional laboratory testing or safety monitoring, or unscheduled subject visits.
 - 4.1.3. *It may be necessary to develop a timeline for implementation depending on the number, the complexity, and the urgency of the modifications. In addition, the documentation may need to include such issues as: when attempts at contact were made, and the content of the material provided to the subject; notation of the date and content of subject’s response; dates of all successful or unsuccessful attempts to contact the subject; date when subject signed the amendment to the informed consent; and, the date and content of any oral discussion of the issue with the subject (in person or by phone)*
 - 4.2. The Investigator must respond to FDA withdrawal of marketed drugs.
 - 4.2.1. Notify the IRB through the RNI mechanism in CICERO.
 - 4.2.2. If a research investigational drug, comparator drug, or other drug named in the research informed consent is withdrawn from the market by FDA no new study subjects may be entered into the study. Those subjects already entered into the study will be notified to stop taking the drug, noting how the drug should be stopped, and if any additional follow-up is required.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- 4.3. All ADEs in research subjects must be entered into CPRS and VA ADERS as required in VAMHCS Policy Memo 512-119-014. All other requirements in that directive must also be followed.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE5. Actions: IRB

- 5.1. **Apparent immediate harm.** Upon receiving information on a National PBM Bulletin or Communication from the investigator, ACOS for R&D, or the facility's COS, that a notification may represent apparent immediate harm to subjects, the IRB Chair (or designee, as appropriate):
- 5.1.1. Must determine and document what steps are required to protect the human subjects from harm;
 - 5.1.2. If the investigator has already initiated some modifications to eliminate or reduce the risk of harm, the IRB must review;
 - 5.1.3. If the IRB Chair (or designee, as appropriate) determines that specific immediate actions have not been but must be implemented, the IRB Chair (or designee as appropriate) must communicate these determinations to the investigator in a timeframe consistent with the potential for apparent immediate harm to the subject. This must also be communicated to the full IRB as required by the facility's SOPs. **NOTE:** *If the research subjects and/or the investigators are blinded and do not know if individual research subjects are on the medication addressed in the National PBM Bulletin or National PBM Communication because it may be either the investigational drug or comparator drug, the required notifications, re-consenting or other steps should be sent to all subjects as determined by the IRB.*
 - 5.1.4. Upon making its determinations, the IRB Chair (or designee as appropriate) must also notify the investigator, the R&D Committee Chair, the ACOS for R&D, the COS, and the Facility Director what steps will be taken based on the apparent immediate harm to the subjects.
 - 5.1.5. The investigator must be directed to initiate the required steps and the timeframe in which they must be implemented
- 5.2. **Possible Increased Risk to Subjects.** The IRB must review and take action on the information submitted by the investigator as required by the IRB SOPs. The information may include an amendment to the protocol or the informed. During its review the IRB must determine:
- 5.2.1. If the new information provided in the notification represents increased risk to the research subjects;
 - 5.2.2. What, if any, communication must be sent to the research subjects (current and/or former research subjects) and in what time frame;
 - 5.2.3. What, if any, information must be discussed with the research subjects (current and/or former research subjects) in person and in what time frame;
 - 5.2.4. What, if any, changes must be made to the informed consent document and the protocol;
 - 5.2.5. What research protocol amendments must be made to address the risk or amend the safety plan for the study;
 - 5.2.6. If the amended protocol and informed consent submitted by the investigator contain all required actions or if the IRB must identify additional changes;
 - 5.2.7. The IRB's determinations must be conveyed in writing to the investigator in a time frame that is appropriate to the possible increased risk posed by the pharmaceutical. The notification must include a timeframe for all

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- actions. Copies of the written communication must be filed in the IRB's records;
- 5.2.8. All IRB deliberations and requirements must be recorded in the IRB records.
6. Documentation of Actions and Resolutions
- 6.1. The IRB's determinations and actions are maintained in the CICERO protocol management system.
- 6.2. The investigator must document the implementation of modifications or other actions in the research record and as appropriate, in the subject's medical record.
- 6.2.1. *The documentation may need to include such issues as: when attempts at contact were made, and the content of the material provided to the subject; notation of the date and content of subject's response; dates of all successful or unsuccessful attempts to contact the subject; date when subject signed the amendment to the informed consent; and, the date and content of any oral discussion of the issue with the subject (in person or by phone).*
- 6.3. PBM alerts involving a VAMHCS research study are reported to the RDC at its next scheduled meeting.
- 6.3.1. The report must include the nature of the alert, the corrective actions taken by the investigator, additional actions required by the IRB, whether written notifications to participants was necessary, the effectiveness of the written notifications, and other relevant details.
- 6.3.2. The RDC reviews the findings of the IRB and making any other appropriate recommendations.
- 6.3.3. Communicates these recommendations to the investigator and the IRB.
NOTE: *If the recommendations require an amendment to the protocol or the informed consent, these amendments must be approved by the IRB.*
- 6.3.4. Documents all recommendations and communications with the investigator and the IRB.
- 6.3.5. RDC minutes reflect this documentation.
- 6.4. If a PBM alert involves a VAMHCS research study (and therefore activating the actions above), the ACOS/R&D (or designee) reports the nature of the alert, the corrective actions taken by the investigator, additional actions required by the IRB, whether written notifications to participants was necessary, the effectiveness of the written notifications, and other relevant details at his/her next scheduled COS meeting.
- 6.4.1. The COS verifies that all required actions have been completed including mailing of patient or subject letters, and the appropriate documentation of all actions has been completed.
- 6.4.2. The COS makes a final report to the MCD, with particular attention to the notifications to research participants (when notifications have been required).

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

COMPLIANCE

The VAMHCS Research Compliance Officer (RCO) or other designated individual, audits all aspects of the requirements of this directive to ensure compliance in the appropriate timeframe

REFERENCES:

VHA Directive 2008-072, October 30, 2008	Research Personnel Notification of Pharmacy Benefits Management Drug Safety Alerts and Adverse Drug Events Related to Interventional Human Subjects
VHA Directive 2008-059, September 29, 2008	Adverse Drug Event Reporting and Monitoring
VAMHCS Policy Memo 512-119-014	Adverse Drug Event Reporting Program

ⁱ See Action 1c above.