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**Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420**

**VHA HANDBOOK 1004.08
Transmittal Sheet
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DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. REASONS FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides procedures to ensure consistent practice in disclosing to patients (or to the patient's personal representative) the occurrence of adverse events related to the patient's clinical care.

2. SUMMARY OF MAJOR CHANGES. This is a new Handbook that:

a. Clarifies the relationship between clinical, institutional, and large-scale disclosure to emphasize that disclosing an adverse event is a process that may require any or all types of disclosure.

b. Defines the process that must be initiated when an adverse event has occurred that might warrant a large-scale disclosure. Appendix B, "Process for Assessment of Adverse Events that Might Require Large-Scale Disclosure," is a flow chart clarifying the roles and responsibilities of the facility, the Veterans Integrated Service Network (VISN), and Department of Veterans Affairs (VA) Central Office leadership for managing such adverse events.

c. Clarifies the trigger for initiating the process for assessment of adverse events that might require large-scale disclosure and therefore require referral to VA Central Office for review and consultation. That trigger is the discovery that a harmful or potentially harmful adverse event is not an isolated case but rather a systems issue affecting multiple patients.

d. Changes the name of the Clinical Risk Assessment Advisory Board (CRAAB) to the Clinical Review Board (CRB), whose Chairperson is appointed by the Principal Deputy Under Secretary for Health.

e. Establishes a mechanism for convening Subject Matter Experts (SME) to conduct fact finding and clinical determination of risk pertaining to adverse events that may require large-scale disclosure and to make recommendations to the Principal Deputy Under Secretary for Health concerning the level of risk.

f. Establishes specific responsibilities for the Principal Deputy Under Secretary for Health and the Deputy Under Secretary for Health for Operations and Management; Chief Officer, Office of Public Health; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; and VISN and Facility Directors concerning adverse events that potentially warrant large-scale disclosure.

g. Clarifies that clinical disclosure of events that cause minor harm may be performed by any member of the clinical team involved in the patient's care.

h. Clarifies the requirements for disclosing harmful or potentially harmful adverse events that are discovered during the associated episode of care versus those discovered sometime after the associated episode of care.

- i. Removes “potential legal liability” as a rationale for an institutional disclosure.
- j. Establishes that clinical disclosures may no longer be documented using the note template for institutional disclosure.
- k. Establishes requirements regarding the use of a new graphical user interface (GUI) Text Template for documenting institutional disclosure of adverse events to patients (see App. A).
- l. Establishes a requirement for Facilities’ Risk Managers to establish a process for collection, tracking, and analysis of relevant information related to institutional disclosures conducted at the facility for submission to the VISN Director in a quarterly report, and as requested.
- m. Establishes a requirement for VA medical facility Directors to provide a quarterly report, (and as requested) to the VISN Director, regarding the number and types of institutional disclosures that have been provided by the facility.
- n. Establishes a requirement for VISN Directors to submit facility-specific quarterly reporting of institutional disclosures to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value.

3. RELATED ISSUES. VHA Directive 1004.01, VHA Directive 1200.5, VHA Handbook 1058.01, and VHA Handbook 1605.1

4. RESPONSIBLE OFFICES. The Principle Deputy Under Secretary for Health is responsible for this Handbook and is supported by the National Center for Ethics in Health Care, the Office of Public Health; the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; and the Deputy Under Secretary for Health for Operations and Management (see paragraphs 13, 15, 16, and 17 for further details). Questions about policy interpretation pertaining to clinical disclosure or institutional disclosure need to be directed to the National Center for Ethics in Health Care at (202-501-0364). Questions about the CRB or about epidemiological investigations related to large-scale disclosure need to be directed to the Office of Public Health at (202-461-1000). Questions about quarterly reporting of institutional disclosures need to be directed to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value at (202-461-7254). All other questions should be directed to the Office of the Principle Deputy Under Secretary for Health at (202-461-7008).

5. RECISSIONS. VHA Directive 2008-002, dated January 18, 2008, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working date of October 2017.

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DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides procedures for disclosure of adverse events to patients (or their personal representatives) related to clinical care. **NOTE:** *Information pertaining to adverse events in research can be found in VHA Handbook 1200.5 and VHA Handbook 1058.01.*

2. BACKGROUND

a. VHA believes that there is an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future (see subpars. 21a-21p).

b. The commitment to disclose the occurrence of harmful adverse events to patients is consistent with the VA core values of integrity, commitment, advocacy, respect, and excellence; it demonstrates respect for the patient and professionalism; and it is a foundation to improving care. While any such disclosure must be in keeping with applicable law, the explicit intent is to inform patients about substantive issues related to their care, and not to manage the institution's risk.

c. This Handbook is consistent with The Joint Commission (TJC) standards that patients, and when appropriate, their families be told of "unanticipated outcomes" of care (see subpars. 21j, 21k).

d. Disclosure of adverse events to patients and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients, according to this Handbook, in no way obviate the need to report adverse events (and close calls) as required under VHA Handbook 1050.01 and VHA Handbook 1100.17.

e. Despite the ethical obligation to disclose adverse events to patients, there are legal requirements that establish limits on the information that may be shared and with whom it may be shared. Release of any and all protected health information (verbally or in record form) must always be done according to law and VA standards. Assistance regarding information that may be released is available through the facility's Privacy and Freedom of Information Act (FOIA) Officer(s), as well as the facility's Risk Manager. The following paragraphs describe the most common standards regarding the release of information:

(1) Confidentiality statutes and regulations, such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, limit disclosure of any record containing a patient's personal information to others without the patient's authorization or other legal authority. **NOTE:** *The patient's personal representative is authorized to have access to the patient's protected health information except as noted in this subparagraph and in subparagraph 2e(2) (see VHA Handbook 1605.1).*

(2) Under Title 38, United States Code (U.S.C.) § 7332, VHA may disclose information related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, or infection with the Human Immunodeficiency Virus (HIV) to the patient's surrogate if the patient lacks decision-making capacity and the practitioner deems the information necessary for the surrogate to make an informed decision regarding the patient's treatment. Otherwise such information may not be disclosed even after a patient's death, without a "special authorization" or other exception. Questions about release of such information in the case of an adverse event are to be referred to the facility's Privacy Officer. **NOTE:** *Consultation with VHA's Privacy Officer may also be necessary (see VHA Handbook 1605.1).*

(3) Under 38 U.S.C. § 5705, VHA may not communicate to patients or their personal representatives information that is obtained from quality management activities. Quality management (or "quality assurance (QA)") activities are those that are conducted by or for VA in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or improving the utilization of health care resources in VA facilities. Examples of QA activities include Root Cause Analyses (RCA) or peer reviews for quality management.

f. Disclosure of an adverse event as discussed in this Handbook (or "close calls," as discussed in subpar. 3b) is a separate action from QA review, analysis, or investigation of an adverse event. The purpose of a QA activity is to allow for effective self evaluation in the interest of improving the quality of care. When a disclosure of information is made, the information that is being disclosed must not originate with a QA document; in other words, any information that is shared with the patient regarding the adverse event must come from a source other than a QA document. QA documents may contain information protected under other confidentiality statutes, such as the Privacy Act (see subpar. 2e(1) for limitations related to those statutes). Assistance regarding the release of information that also might be the product of a QA activity is available through the facility's FOIA Officer(s), as well as the facility's Risk Manager. Other specific questions regarding information that may not be disclosed to the patient or representative may be found in VHA Handbook 1605.1.

3. DEFINITIONS

a. **Adverse Event.** Adverse events are untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services provided within the jurisdiction of the Veterans Healthcare System. **NOTE:** *To determine which incidents need to be considered for RCA, consult VHA Handbook 1050.01.*

b. **Clinical Review Board (CRB).** The CRB is a multi-disciplinary board, convened at the request of the Principal Deputy Under Secretary for Health, in response to adverse events that may pose a clinically-significant risk of harm to multiple patients (or members of patients' families), but the probability of harm and/or the severity of the potential harm cannot be determined. The CRB uses a transparent and systematic process to consider whether disclosure is ethically warranted in light of the indeterminate risk.

c. **Close Call.** A close call is an event or situation that could have resulted in an adverse event, but did not, either by chance or through timely intervention. Such events have also been referred to as “near miss” incidents.

d. **Disclosure of Adverse Events.** For the purpose of this Handbook, the phrase “disclosure of adverse events” refers to the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. VA recognizes three types of adverse event disclosure. **NOTE:** *Depending on the nature of the adverse event, the disclosure process may involve all three types of disclosure in a step-wise fashion, or may only involve one or two types of disclosure. See paragraphs 6-9 for additional information on the three types of disclosure, including what must be disclosed, by whom, when, and how.*

(1) **Clinical Disclosure of Adverse Events.** Clinical disclosure of adverse events is a process by which the patient’s clinician informs the patient or the patient’s personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient’s care (see par. 7). **NOTE:** *Clinicians may also be involved in communicating information as part of an institutional disclosure or a large-scale disclosure, but this is not considered a clinical disclosure.*

(2) **Institutional Disclosure of Adverse Events.** Institutional disclosure of adverse events (sometimes referred to as “administrative disclosure”) is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse (see par. 8). **NOTE:** *Facility leaders may also be involved in communicating information as part of a large-scale disclosure, but this is not considered an institutional disclosure.*

(3) **Large-scale Disclosure of Adverse Events.** Large-scale disclosure of adverse events (sometimes referred to as “notification”) is a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue. This process also generally includes public notification and direct communication to key stakeholders (see par. 9).

e. **Epidemiologic Investigation.** An epidemiologic investigation is a study of potentially-affected populations with the intent to ascertain a linkage between health effects (e.g., an infection) and a cause (e.g., an exposure).

f. **Exposure.** Exposure is the proximity to, or contact with, an environmental condition (e.g., an infectious pathogen, a toxic chemical, or radiation) in such a manner that transmission of harmful effects may occur.

g. **Look-back.** A look-back is an organized process for identifying patients and/or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate.

h. **Personal Representative.** A personal representative is a person who, under applicable law, has legal authority to act on behalf of the individual. This may include power of attorney, legal guardianship of an individual, the executor of the estate of a deceased individual, or someone under Federal, state, local, or tribal law with such authority (e.g., parent of a minor). The personal representative generally is the patient's surrogate for the informed consent process (see Title 38 Code of Federal Regulations (CFR) §17.32(e) for authorized surrogates for informed consent; see VHA Handbook 1605.1 for details on personal representatives).

i. **Subject Matter Expert (SME) Review Panel.** The SME Review Panel is a panel convened to conduct fact-finding, including, as needed, site visits, literature reviews, and risk assessment regarding events that have the potential for a large-scale disclosure.

j. **Surrogate Decision Maker ("Surrogate").** A surrogate decision maker (surrogate) refers to an individual authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity (see VHA Handbook 1004.01 for information about surrogate selection, priority, and the surrogate's role in health care decision making).

4. SCOPE

This Handbook establishes the procedures surrounding the disclosure of harmful or potentially-harmful adverse events to patients in order to ensure uniform practice across all VHA facilities when such events occur.

5. ADVERSE EVENTS THAT WARRANT DISCLOSURE

a. Disclosure is warranted for harmful or potentially-harmful adverse events, defined broadly to include:

(1) Adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage (or that are reasonably expected to result in death or serious and/or permanent disability), or that are "sentinel events" as defined by TJC.

(2) Adverse events that have had, or are reasonably expected to have, an effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of a diuretic (a medication that dramatically increases urine output), disclosure is required because a perceptible effect has, or is anticipated to occur.

(3) Adverse events that precipitate a change in the patient's care. For example, a medication error that necessitates extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or a surgical procedure that necessitates further (corrective) surgery.

(4) Adverse events with a clinically-significant risk of serious future health consequences to patients, even if the likelihood of that risk is small. For example, a known, accidental exposure of a patient to "ionizing radiation," "a toxin," "an organism," or "infectious entity" associated with a rare, but recognized serious short-term or long-term effect (e.g., blood borne pathogen infection or increased incidence of cancer). In some cases, however, no definite exposure of this type can be determined. Only an increased risk of exposure is known or thought to exist. In

such cases, disclosure needs to be decided with careful deliberation considering the best interests of the patient, and weighing the risks and benefits of disclosure relative to the probability of serious future health consequences. If, after disclosure in such cases, it is later determined through the look-back process or subsequent investigation that harm did not occur, or that the risk of harm is actually negligible, disclosure of the new risk information must be made to the patient. Caution must be exercised in differentiating “clinically significant” risk of harm from harm that is only “plausible” or “hypothetical.”

(5) Any event that requires an unexpected treatment or procedure to be initiated without the patient’s consent (e.g., if an event occurs while a patient is under anesthesia, necessitating a deviation from the procedure the patient expected). Patients have a fundamental right to be informed about what is done to them and why.

b. Where adverse events occur that have a potential to affect, or may have already affected multiple patients at one or more VHA facilities, the process for large-scale disclosure must be followed (see the process providing the ethical and clinical considerations outlined in App. B and App. C).

c. Disclosure of adverse events other than those that fall under the previous descriptions is optional and at the discretion of the providers involved. Cases need to be considered individually and in relation to the specific circumstances.

d. Disclosure of “close calls” to patients is discretionary, but is advisable at times, such as when the patient or family become aware that something out of the ordinary has occurred.

(1) For example, a nurse sets up a patient for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, abruptly stops the transfusion just before the blood enters the patient’s vein. The patient deserves an explanation, even if this is not considered a clinical disclosure of an adverse event.

(2) Although the disclosure of a close call to the patient is optional, reporting close calls is required under VHA Handbook 1050.01.

e. There may be times when a complication that was anticipated and discussed in the informed consent process occurs. Such complications need to be discussed with the patient or patient’s representative as part of ongoing clinical care. However, since “disclosure” suggests revealing or exposing information that is otherwise not known, complications that were discussed in the informed consent process are not considered adverse events that require disclosure under this Handbook, unless the complication is deemed to be untoward or preventable. Any serious complication may still require further investigation as described in VHA Handbook 1050.01.

6. COMMUNICATING ADVERSE EVENTS

a. The process for disclosing an adverse event depends on the nature and circumstances of the event. VA recognizes three types of adverse event disclosure: clinical disclosure of adverse

events, institutional disclosure of adverse events, and large-scale disclosure of adverse events (see pars. 7, 8, and 9).

b. The process of adverse event disclosure is not necessarily a singular event but may involve a series of conversations. For example, as more information is learned in a particular case, a clinical disclosure may need to be followed by an institutional disclosure, which itself may involve multiple conversations. In some cases, the disclosure process may ultimately involve all three types of disclosure.

c. Whenever a potential harm is disclosed to a patient, it may be necessary, after an investigation has been conducted, to follow up with the patient to inform the patient whether the potential harm that was initially disclosed did or did not, in fact, occur (e.g., a patient who is initially told that the patient may have been exposed to a blood-borne virus as a result of improperly sterilized equipment, must be informed of investigation results that would have a significant impact on the patient's health or wellbeing).

d. For the patient who is deceased, incapacitated, or otherwise unable to participate in the process of adverse event disclosure, any clinical or institutional disclosure must be communicated to the patient's personal representative and may involve others, as designated by the personal representative in accordance with VHA Handbook 1605.1.

e. Any release of information regarding a deceased Veteran whose clinical records are covered by 38 U.S.C. 7332, must be made in accordance with applicable law. *NOTE: For additional guidance, refer to VHA Handbook 1605.1 and confer with the facility Privacy Officer, as necessary.*

f. In some cases, it may be apparent that an adverse event has occurred, but its cause is not clear. In those situations, the Veteran and/or the Veteran's personal representative needs to be told what has occurred and what is known about the problem. They need to be informed as to whether the problem is being investigated and if additional information will be provided to them once a review is completed.

7. CLINICAL DISCLOSURE OF ADVERSE EVENTS

Clinical disclosure is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the course of care. A clinical disclosure is appropriate for all adverse events that cause only minor harm to the patient, except those minor harms that are discovered after the patient has completed the associated episode of care and that have no implications for the patient's future health. A clinical disclosure is also appropriate for more serious adverse events as the appropriate first step in a process that may ultimately require an institutional or large-scale disclosure. While clinical disclosure of adverse events is considered a routine part of clinical care, clinicians must be sensitive to any limitations on sharing information from the Veteran's health record (see subpar. 2e). In general, clinical disclosure of an adverse event proceeds as follows:

a. Clinical disclosure of adverse events that cause minor harm may be performed by any member of the clinical team involved in the patient's care. However, clinical disclosures relating

to events where the harm is more than minor must be performed by the responsible practitioner (i.e., the licensed independent practitioner who has primary responsibility for the patient during the current episode of care), or that practitioner's designee. If a harm is significant enough to require an incident report or local equivalent, it should be considered more than minor.

b. During the clinical disclosure process, one or more members of the clinical team:

(1) Provides preliminary factual information, to the extent it is known, to the patient or the patient's personal representative,

(2) Expresses concern for the patient's welfare, and

(3) Reassures the patient or personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. *NOTE: A general statement to this effect is recommended. Statements should not be made regarding specific actions VA may undertake because those steps may not be possible to implement, or may be subject to change.*

c. A registered nurse, social worker, chaplain, patient advocate, or other staff may be present to help the patient or personal representative cope with the news and to offer support, if needed.

d. The patient (or patient's personal representative) must be provided with contact information of the designated VA health care staff, as needed, to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

e. Clinical disclosure needs to be made face-to-face with the patient or the patient's personal representative whenever possible and practical. In the infrequent instances when it is necessary to convey a clinical disclosure by other modalities (e.g., telephone contact or letter), documentation of the communication needs to include the reason it was not done in person. Disclosure needs to take place in a suitable environment to ensure privacy, and without interruption to provide adequate time to ensure that the patient's questions and concerns can be addressed.

f. Clinicians are expected to conduct clinical disclosures as a routine part of care. Clinical disclosures are not the occasion to discuss rights or compensation under 38 U.S.C. § 1151 and/or the Federal Tort Claims Act.

g. Clinical disclosure must be initiated as soon as reasonably possible and generally within 24 hours of occurrence. Clinical disclosure is not required for minor harms that are discovered after the patient has completed the associated episode of care when there are no implications for the patient's future health. Under such circumstances, the benefits associated with respecting the patient's right to information about their health care are generally outweighed by the burdens associated with unnecessarily worrying or confusing patients with inconsequential information.

h. **Documentation of Clinical Disclosures**

(1) Specific documentation in the Computerized Patient Record System (CPRS) is not required for all clinical disclosures. Requiring documentation of clinical disclosure for all minor

events would create a barrier to making such disclosures a part of routine practice. However, as a general rule, documentation of a clinical disclosure is required when harm is more than minor, as evidenced by the fact that an incident report or local equivalent has been created. If the facility uses an incident reporting system (or local equivalent), an incident report that meets the criteria of a QA record is to be considered a confidential QA document and is not to be referenced in CPRS documentation (see subpar. 2e(3) regarding quality management activities).

NOTE: *It is not required that facilities establish a “template” note or a note title for documenting clinical disclosures.*

(2) Clinical disclosures are not to be documented using the CPRS note template for institutional disclosure.

8. INSTITUTIONAL DISCLOSURE OF ADVERSE EVENTS

a. Institutional disclosure of adverse events (sometimes referred to as “administrative disclosure”) is a formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in or is reasonably expected to result in death or serious injury. Serious injury may include significant or permanent disability, injury that leads to prolonged hospitalization, injury requiring life-sustaining intervention, or intervention to prevent impairment or damage, including, for example “sentinel events” as defined by TJC (see subpar. 21j). Such adverse events require institutional disclosure regardless of whether they resulted from an error.

(1) When an adverse event, has resulted in or is reasonably expected to result in death or serious injury, an institutional disclosure must be performed regardless of when the event is discovered. This disclosure is required even if clinical disclosure has already occurred. If an initial clinical disclosure has been made, it is important to determine what role, if any, the treating clinician(s) will play in the institutional disclosure process, as well as in the ongoing care of the patient.

(2) Institutional disclosure must be initiated as soon as reasonably possible and generally within 72 hours. This timeframe does not apply to adverse events that are only recognized after the associated episode of care (e.g., through investigation of a sentinel event, a routine quality review, or a look-back). Under such circumstances, if the adverse event has resulted in or is reasonably expected to result in death or serious injury, institutional disclosure is required, but disclosure may be delayed to allow for a thorough investigation of the facts provided.

b. Institutional disclosure of adverse events needs to take place after organizational leaders (e.g., the Facility Director, Chief of Staff, Associate Director for Patient Care Services, members of the treatment team, and/or others as appropriate), have conferred with Regional Counsel and have determined what is to be communicated, by whom, and how.

c. When initiating an institutional disclosure, institutional leaders invite the patient or personal representative to meet. **NOTE:** *The facility Risk Manager or Patient Safety Manager, treating practitioner, a mental health professional, or other VHA personnel deemed appropriate, may be included in this conference at the discretion of facility leadership.*

d. Institutional disclosure ideally need to be made face-to-face with the patient or the patient's personal representative, unless it is neither possible nor practical. In the rare instances when an institutional disclosure must be conveyed by other modalities (e.g., telephone contact or letter), documentation of the communication must include the reason it was not done in person. Disclosure needs to take place in a suitable environment, without interruption, allowing adequate time to ensure that the patient's questions and concerns can be addressed.

e. If the patient is not capable of understanding either the situation or the information provided in a disclosure, and does not have a personal representative as defined in VHA Handbook 1605.1, the facility must make the institutional disclosure to a family member involved in the patient's care, if available. *NOTE: The facility's or VHA's Privacy Office or Regional Counsel need to be consulted for additional guidance regarding necessary authorizations and any limitations on what information may be provided as part of the institutional disclosure.*

f. A request made in advance of the discussion by a patient or personal representative to bring an attorney must be honored, but may influence the choice of participants on behalf of the institution.

g. Institutional disclosure of adverse events must include:

(1) An expression of concern and an apology, including an explanation of the facts to the extent that they are known.

(2) An outline of treatment options, if appropriate.

(3) Arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the circumstances and within the constraints of VA's statutory and regulatory authority.

(4) Contact information regarding designated staff who are to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

(5) Notification that the patient or personal representative has the option of obtaining outside medical or legal advice for further guidance.

(6) Offering information about potential compensation under 38 U.S.C. § 1151 and the Federal Tort Claims Act where the patient is a Veteran or under the Federal Tort Claims Act where the patient is a non-Veteran. This needs to include information about the procedures available to request compensation and where and how to obtain assistance in filing forms. Such information must be provided, even when not considered relevant, if requested by the patient or personal representative. There should be no assurance that compensation will be granted, as the adverse event may not give rise to and meet legal criteria for compensation under 38 U.S.C. § 1151 and the Federal Tort Claims Act.

(7) Ongoing communication whereby the Risk Manager or organizational leaders engage the patient or personal representative to keep them apprised, as appropriate, of information that emerges from investigation of the facts related to the adverse event.

h. Documentation, such as reports of contact or incident reports may be kept in a separate file at the facility's discretion and entitled "Adverse Event and Close Call Report." This information must not be retrieved by a patient identifier and must be identified by a case number.

NOTE: The Adverse Event and Close Call Report is protected under 38 U.S.C. § 5705.

i. A patient or the patient's personal representative may ask whether an investigation will be conducted and if the patient or the patient's personal representative will be told of the results of an investigation. In these cases, the patient or personal representative is to be informed that the information is being reviewed or investigated, as applicable. If indicated, the individual providing the information may state that depending on the type of review conducted, information may be available under FOIA; in addition, the patient or personal representative may also be advised that information documented in the course of a QA activity under 38 U.S.C. § 5705 is not releasable. The patient or patient representative is to be referred to Regional Counsel for coordination of document requests, if a tort claim has been filed.

j. As noted previously, documents created in the course of 38 U.S.C. § 5705-protected activities, such as RCA, local incident reports that meet the threshold QA criteria and peer reviews for quality management, may be released only with specific authority and may not be released to patients, their attorneys, or personal representatives. The facts discovered during quality management activities, however, may reveal adverse event information that requires disclosure. Documenting information in records protected under 38 U.S.C. § 5705 is never to be done to shield information to which a patient or personal representative is entitled. In order to be able to reveal such information to the patient or personal representative, the information must be retrieved from a non-QA document, such as one documented in CPRS.

k. **Documentation of Institutional Disclosures.** Documentation of institutional disclosures must be done using the CPRS Institutional Disclosure of Adverse Event Note Template (see App. A). Subsequent communications with the patient or personal representative that relate to the event are to be documented in an addendum to the original note.

l. Each Veterans Integrated Service Network (VISN) is required to submit a report quarterly, and as requested, by facility, of institutional disclosures to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value. The report must include the date of the adverse event, date of institutional disclosure, number of unique patients, whether there was a patient death, department(s) involved, and a brief description of the triggering event for each institutional disclosure.

9. LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS

a. Large-scale disclosure of adverse events (sometimes referred to as "notification") is a formal process by which VHA officials inform patients, or their personal representatives, that they have been or may have been affected by an adverse event involving actual or potential harm to multiple patients, which is deemed clinically significant.

b. Events having potential for large-scale disclosure require coordination with VA Central Office for the purposes of assessment and planning. To initiate this coordination process, the Facility Director, VISN Director, or Program Officer, as appropriate, must submit an Issue Brief within 24 hours of discovery of the event (see App. B).

c. When an adverse event is discovered at or near the time it occurs, clinical or institutional disclosure must proceed as usual if the potential harm to the individual patient is clear.

d. If the adverse event is only recognized after the associated episode of care (e.g., through investigation of a sentinel event, a routine quality review, or a look-back), it is appropriate to wait until the required VA Central Office coordination process for large-scale disclosure is completed before making either a large-scale or institutional disclosure to an individual patient, but only if it is determined that the delay will not negatively affect the patient's health or well being. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure.

e. Decisions regarding large-scale disclosure of adverse events are made by the Principal Deputy Under Secretary for Health, or designee, following a multi-step VA Central Office process that may involve a SME Review Panel and/or the CRB. **NOTE:** *There are legal limitations regarding the type of information that can be released and to whom, particularly with regard to information protected under 38 U.S.C. 7332 (see subpar. 2e(2)). Additional guidance on large-scale disclosure is provided in Appendix B and Appendix C.*

f. A large-scale disclosure to affected patient(s) or personal representative(s) (if the patient is incapacitated, or otherwise unable to take part in the disclosure process), may entail any or all of the following:

(1) An offer to provide follow-up testing and treatment when appropriate. Testing is to be recommended only if it is medically indicated based on the clinical circumstances. **NOTE:** *In addressing the subject of whether family members or personal contacts of patients may also be tested, the facility needs to indicate that testing, either directly or through fee-basis, of non-Veterans is limited to those otherwise eligible for VA care (see 38 U.S.C. §1781). The facility needs to be prepared to advise non-Veterans of local resources for testing and treatment if they do not have an established primary care provider.*

(2) Coordination with VHA facilities to ensure that required clinical follow-up is provided for potentially-affected patients.

(3) Notification by VA Central Office to the Veterans Benefits Administration (VBA) Central Office component when Veterans' benefits may be implicated.

(4) Development of appropriate and effective communications strategies. This includes public affairs strategies such as an announcement through the media (e.g., telephone, mail, newspapers, electronic media); clear and coherent information to patients, providers, and stakeholders; action plans for facilities and clinical providers; briefings for the Secretary of Veterans Affairs and Congress; and establishment of call centers, internet sites or social media.

Large-scale disclosures may be performed by clinicians, facility leaders, and/or other VA officials in person, by telephone, or in writing.

(5) Notification by VA Central Office to facility and VISN leadership whether or not an epidemiologic investigation is going to take place, and establishment of a clear line of authority, access, and accountability.

10. RESPONSIBILITIES OF THE PRINCIPAL DEPUTY UNDER SECRETARY FOR HEALTH

The Principal Deputy Under Secretary for Health is responsible for oversight and coordination of the large-scale disclosure process, including:

- a. Establishing an environment throughout VHA in which senior leaders ensure that there is staff understanding of what constitutes an adverse event and that there is a just culture in which VHA program staff, VISN and facility leadership, and facility staff members feel psychologically safe to report such events.
- b. Ensuring that VHA senior leaders establish an environment in which VHA program staff, VISN and facility leadership, and facility staff provide ethically-warranted disclosures to Veterans and/or their personal representative.
- c. Appointing the Chairperson of the CRB.
- d. Accepting or rejecting the recommendation of the SME Review Panel to disclose, not disclose or to convene a CRB, and providing a written record of this decision to the SME Review Panel and the Deputy Under Secretary for Health for Operations and Management.
- e. If a decision is made to convene the CRB, sending a charge memo to the CRB Chairperson and at the same time and in parallel, notifying the Deputy Under Secretary for Health for Operations and Management and other relevant VA Central Office programs (e.g., the Office of the General Counsel (OGC), Office of Public and Intergovernmental Affairs (OPIA), and Office of Congressional and Legislative Affairs (OCLA)) to begin preparations for a possible disclosure.
- f. Concurring or non-concurring with the CRB recommendations, and communicating that decision to the Deputy Under Secretary for Health for Operations and Management and the CRB Chair.
- g. Requesting further information and/or guidance from the CRB, as needed, prior to making a final decision.
- h. Ensuring that the VBA Central Office component is notified when Veterans' benefits may be affected by a decision to make a large-scale disclosure.
- i. Submitting all Principal Deputy Under Secretary for Health-related records concerning large-scale disclosure to the shared repository for records relating to large-scale disclosure of adverse events (see subpar. 11k).

11. RESPONSIBILITIES OF THE DEPUTY UNDER SECRETARY FOR HEALTH FOR OPERATIONS AND MANAGEMENT

The Deputy Under Secretary for Health for Operations and Management is responsible for:

a. Establishing an environment throughout VHA in which senior leaders ensure that there is staff understanding of what constitutes an adverse event and that there is a just culture in which VHA program staff, VISN and facility leadership, and facility staff members feel psychologically safe to report such events.

b. Ensuring that VHA senior leaders establish an environment in which VHA program staff, VISN and facility leadership, and facility staff provide ethically-warranted disclosures to Veterans and/or their personal representative.

c. Submitting an Issue Brief to the Principal Deputy Under Secretary for Health immediately upon receiving communication from a VISN that an adverse event has been discovered that may require large-scale disclosure (see App. B).

d. Ensuring a coordinated triage process for a review of each potential adverse event that may require large-scale disclosure. The triage process must include designated staff from the offices of: the Deputy Under Secretary For Health for Operations and Management; the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the Deputy Under Secretary for Health for Policy and Services; and other offices and field-based SMEs, as needed, to determine, based on preliminary information, whether the adverse event either:

(1) Involves a negligible or clinically-insignificant risk of harm and, therefore, requires no large scale-disclosure so the issue can be closed; or

(2) Requires referral to an appropriately constituted SME Review Panel (see par. 13) for a more detailed review.

e. Ensuring that potential cases are referred to the SME Review Panel for more detailed review.

f. Providing oversight to the SME Review Panel, summarizing the SME Review Panel findings regarding risk, and submitting a written report and recommendation to the Principal Deputy Under Secretary for Health concerning whether there is a negligible risk of harm and therefore no disclosure is required; or there is a clinically-significant risk of harm and therefore disclosure is required; or there is an indeterminate risk of harm and therefore a CRB needs to be convened to consider whether disclosure is ethically warranted based on factors other than risk alone.

g. Developing, maintaining, and implementing standard operating procedures for the implementation of large-scale disclosures.

h. Implementing a decision by the Principal Deputy Under Secretary for Health to conduct a large-scale disclosure with coordination among appropriate field and Central Office programs

including OGC, OPIA, OCLA, and others. Implementation includes notification of field sites, activation of a site visit team, a review of written materials and statements by OGC, and other appropriate offices (see App. B).

i. Designating and facilitating the Office of Public Health to carry out any required look-back activities and epidemiologic investigations.

j. Conducting an After Action Review of the event with appropriate SME participation and submitting a report to the Under Secretary for Health.

k. Ensuring the establishment of a shared repository for maintaining records related to large-scale disclosure of adverse events. This repository can be accessed: at:

<http://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/10NC/Disclosures/default.aspx> . *NOTE: This is an internal VHA web site and can only be accessed by authorized users.*

12. CLINICAL REVIEW BOARD (CRB)

a. **Chairperson of the Clinical Review Board (CRB).** The Chairperson of the CRB is appointed by the Principal Deputy Under Secretary for Health, and is responsible for:

(1) Convening and chairing the CRB.

(2) Ensuring that CRB deliberations and recommendations follow the process outlined in subparagraph 12b, Appendix B, and Appendix C.

(3) Providing, on behalf of the CRB, written recommendations and justifications to the Principal Deputy Under Secretary for Health that disclosure is recommended or that no disclosure is recommended. If the CRB concludes that there is insufficient information to make a recommendation, the Chairperson is responsible for providing the Principal Deputy Under Secretary for Health with a plan and timeline for a definitive CRB recommendation.

(4) Providing a written statement to the Principal Deputy Under Secretary for Health regarding whether the CRB recommendation regarding disclosure was unanimous and, if not, the number of assenting and dissenting votes and the related rationales.

(5) Ensuring that a CRB recommendation in favor of large-scale disclosure addresses:

(a) Notification to potentially-affected patients, patients' personal representatives, patients' next-of-kin, and other involved parties consistent with information disclosure policies (see subpar. 2e and VHA Handbook 1605.1).

(b) Notification to involved facilities for required clinical follow up with potentially-affected patients, and other involved parties.

(c) The need for inquiry into similar processes at other facilities.

(6) Submitting all CRB-related records concerning large-scale disclosure recommendations to the shared repository for records relating to large-scale disclosure of adverse events.

b. CRB Membership

(1) The CRB is made up of appropriate representatives from the following member offices: Office of the Deputy Under Secretary for Health for Operations and Management; National Center for Ethics in Health Care; Office of Nursing Services; National Center for Patient Safety; Office of Patient Care Services; Office of Public Health; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; and OGC. The SME Review Panel Chairperson also serves as a member.

(2) The CRB Chairperson and each member office, with the exception of OGC, has one vote in the CRB decision. When the Chair of the SME Review Panel represents one of the member offices, the member office still only has one vote in the CRB decision.

(3) The CRB may include non-voting members (e.g., SMEs from VHA programs, the relevant field facility or facilities, program offices, and VHA experts), as needed. The CRB may solicit input from outside experts (e.g., equipment manufacturers), as appropriate.

c. CRB Responsibilities. The CRB is responsible for:

(1) Considering those adverse events where it is unclear whether there is a clinically-significant harm or potential harm to patients as determined by the Principal Deputy Under Secretary for Health following the SME Review Panel's findings.

(2) Reviewing the information and risk assessment provided by the SME Review Panel, seeking clarifications as necessary.

(3) Considering all available clinical, scientific, and epidemiologic information and discussing additional (non-clinical) factors (as described in App. C) to determine whether a recommendation for disclosure of the adverse event to patients and families is appropriate.

(4) Determining if an epidemiologic investigation is recommended.

(5) Ensuring that all documents relevant to the CRB's deliberations are provided to the CRB Chairperson for submission to the shared repository for records relating to large-scale disclosure of adverse events (see subpar. 11k)..

13. SUBJECT MATTER EXPERT (SME) REVIEW PANEL

a. The SME Review Panel is a standing panel that meets as necessary, to review and make recommendations on cases referred by the Principal Deputy Under Secretary for Health concerning adverse events that potentially warrant large-scale disclosure.

b. Led by the Deputy Under Secretary for Health for Operations and Management, or designee, it is made up of appropriate SMEs from the office of the Assistant Deputy Under Secretary for Clinical Operations; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the National Center for Patient Safety; the Office of Patient Care Services; the

Office of Public Health; and other program offices (e.g., Supply, Processing, and Distribution), as needed.

c. **SME Review Panel Responsibilities.** The SME is responsible for:

(1) Conducting fact-finding, including site visits if needed, literature reviews (see subpar. 21q), risk assessments, and summarizing findings regarding risk to patients, and if relevant, members of patients' families.

(2) Submitting a written report to the Principal Deputy Under Secretary for Health with one of the following three findings and corresponding recommendations:

(a) There is a negligible risk of harm, considering both the probability of harm and the severity of potential harm; therefore no disclosure is required and the issue should be closed.

(b) There is a clinically-significant risk of harm, considering both the probability of harm and the severity of potential harm; therefore disclosure is required and there is no need to convene a CRB.

(c) There is an indeterminate risk of harm, considering both the probability of harm and the severity of potential harm; therefore a CRB should be convened to consider whether disclosure is ethically warranted based on factors other than risk alone.

(3) Ensuring that all documents relevant to the SME Review Panel's deliberations are provided to the SME Review Panel Chairperson for submission to the shared repository for records relating to large-scale disclosure of adverse events (see subpar. 11k).

14. RESPONSIBILITIES OF THE CHIEF OFFICER FOR PUBLIC HEALTH

The Chief Officer for Public Health is responsible for:

a. Chairing the CRB, as assigned by the Principal Deputy Under Secretary for Health, and in that capacity, fulfilling the responsibilities outlined in subparagraph 12a.

b. Leading, organizing, and conducting any required VHA look-back program and epidemiologic investigation as part of, or following, a large-scale disclosure to patients.

c. Providing support to facilities and VISNs, as requested and as needed, during other disclosure events.

d. Consulting and collaborating with the Centers for Disease Control and Prevention (CDC) and/or other public health authorities regarding adverse events.

e. For adverse events involving exposures, establishing the definitions of positive and negative test results.

f. Overseeing the process of collection of epidemiologic investigation results.

g. Analyzing and reporting of all results from look-back and/or epidemiologic investigations. This includes reports to the facility, VISN, and VA Central Office and determining the messaging of test results to affected Veterans.

15. RESPONSIBILITIES OF THE CHIEF OFFICER, NATIONAL CENTER FOR ETHICS IN HEALTH CARE

The Chief Officer, National Center for Ethics in Health Care, or designee, is responsible for:

- a. Participating in the CRB process.
- b. Interpreting policy questions pertaining to clinical or institutional disclosure.

16. RESPONSIBILITIES OF THE ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR QUALITY, SAFETY, AND VALUE

The Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, or designee, is responsible for:

- a. Participating in the CRB and the SME Review Panel processes.
- b. Providing a representative from the National Center for Patient Safety to participate in the CRB and SME Review Panel processes.
- c. Interpreting and updating the risk management content of this Handbook, as requested by the National Center for Ethics and Health Care.
- d. Completing a quarterly review and analysis of institutional disclosures reported by each VISN office and providing recommendations to appropriate program offices based on analysis of the quarterly review.

17. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK (VISN) DIRECTOR

The VISN Director, or designee, is responsible for:

- a. Ensuring that facility leaders establish an environment in which facility staff understand what constitutes an adverse event and that there is a just culture in which staff members feel psychologically safe to report such events.
- b. Ensuring that facility leaders establish an environment in which ethically-warranted disclosures are provided to Veterans and/or their personal representative. This includes ensuring a collaborative relationship between Regional Counsel and VA medical facility staff.
- c. Submitting an Issue Brief to the Deputy Under Secretary for Health for Operations and Management immediately upon receiving communication from a VA Facility Director or from appropriate reports that an adverse event has been discovered that is not an isolated case but

rather a systems issue affecting multiple patients and thus that may require large-scale disclosure (see App. B).

d. Participating in the Field-VA Central Office process for determining the need for and implementation of large-scale disclosure decisions, as requested (see App. B).

e. Submitting all VISN-related records concerning large-scale disclosure to the shared repository for records relating to large-scale disclosure of adverse events (see subpar. 11k).

f. Providing a report quarterly, and as requested, to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, on the number and types of institutional disclosures provided by facilities within the VISN.

18. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director is responsible for:

a. Promoting an ethical health care environment and culture in which appropriate disclosure of adverse events is routine practice.

b. Ensuring that clinical and institutional disclosures of adverse events are performed openly and promptly with patients and/or their personal representatives.

c. Ensuring the facility policy on disclosure of adverse events to patients is published by December 30, 2012. The facility policy must conform to this Handbook.

d. Ensuring that relevant staff are aware of this Handbook and local facility policy.

e. Ensuring that relevant clinical staff receive training on how to conduct clinical disclosure of adverse events.

f. Promoting an ethical health care environment and culture in which staff members involved in adverse events and subsequent disclosure processes are aware of, and provided with, safe and adequate professional and institutional support in managing the effects of the event.

g. Ensuring that the patient (or the patient's personal representative if the patient is deceased, incapacitated, or otherwise unable to take part in the disclosure process) is provided with contact information for designated VA health care staff, as needed, to respond to questions regarding the disclosed information or clinical events associated with an adverse event.

h. Ensuring that adverse events that may require institutional disclosure are communicated immediately to Regional Counsel.

i. Submitting an Issue Brief to the VISN Director and Regional Counsel immediately following the discovery at the facility of an adverse event that is not an isolated case, but rather a systems issue affecting multiple patients which might require a large-scale disclosure (see App. B).

j. Participating in the VA Central Office fact-finding process, CRB process, large-scale disclosure implementation, look-back and epidemiologic investigations, as requested. This includes ensuring that sufficient resources are available to perform these processes in a proper and timely manner. For example, a case manager may be needed to coordinate clinical, laboratory, communications, and other aspects of the investigations (see App. B and App. C).

k. Ensuring that adverse event disclosures are correctly documented in CPRS, to include:

(1) Ensuring that the new progress note title called “Institutional Disclosure of Adverse Event” is created.

(2) Ensuring that the former progress note title “Disclosure of Adverse Event” is inactivated, so that it will no longer be used. Historical progress notes with the title “Disclosure of Adverse Event” are to remain within the record.

(3) Ensuring that the graphical user interface (GUI) Text Template (Institutional Disclosure of Adverse Event) is associated with the progress note title: “Institutional Disclosure of Adverse Event”.

(4) Ensuring that the progress note title “Institutional Disclosure of Adverse Event” is mapped to the national standard title of “Communication of Adverse Event.”

(5) Ensuring that a User Class and Business Rules are created to restrict the entering of the GUI Template/Progress Note, “INSTITUTIONAL DISCLOSURE OF ADVERSE EVENT” to specific users (e.g., Risk Manager, Patient Safety Manager, Quality Manager, Chief of Staff). Business rules for initial progress note creation should also be applied to the creation and signature of any addenda attached to this progress note. Access restrictions are only to be placed on entering, not on viewing.

(6) Ensuring that the Institutional Disclosure of Adverse Event Note template (see App. A) is used only to document institutional disclosure of adverse events.

l. Ensuring that information about potential compensation under 38 U.S.C. 1151 and the Federal Tort Claims Act is provided to patients and/or patient representatives as part of the institutional disclosure and large-scale disclosure process.

m. Submitting all VA medical facility-related records concerning large-scale disclosure to the shared repository for records relating to large-scale disclosure of adverse events (see subpar. 11k).

n. Providing a report quarterly, and as requested, to the VISN Director, regarding the number and types of institutional disclosures that have been provided by the facility.

19. RESPONSIBILITIES OF THE FACILITY RISK MANAGER

The facility Risk Manager is responsible for:

- a. Immediately notifying the Associate Director for Patient Care Services, Chief of Staff, or Facility Director about the discovery of a significant adverse event that is brought to the attention of the Risk Manager; especially those that may require institutional disclosure or a decision regarding a large-scale disclosure of adverse events.
- b. Referring providers who have questions about the legal dimensions of disclosure of adverse events to Regional Counsel.
- c. Establishing a regular dialogue with Regional Counsel and requesting that Regional Counsel educate providers, as needed, regarding legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.
- d. Participating in any look-back or epidemiologic investigations required.
- e. Establishing a process for collection, tracking, and analysis of relevant information related to institutional disclosures conducted at the facility for submission to the VISN Director in a quarterly report.

20. RESPONSIBILITIES OF THE FACILITY CHIEF OF STAFF AND ASSOCIATE DIRECTOR OF PATIENT CARE SERVICES

The facility Chief of Staff and Associate Director of Patient Care Services are responsible for:

- a. Immediately notifying the Facility Director regarding the discovery of any significant adverse event that is brought to their attention.
- b. Participating in discussions and institutional disclosures with others (e.g., clinicians, facility senior management team, Regional Counsel, VISN staff, patients, or personal representatives), as appropriate, concerning the adverse event.
- c. Participating in any look-back or epidemiologic investigations required.

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INSTITUTIONAL DISCLOSURE OF ADVERSE EVENT NOTE TEMPLATE

Dialog Preview

INSTITUTIONAL DISCLOSURE OF ADVERSE EVENT

Date/Time of Discussion:

Place of Discussion (Reason for any delay in the disclosure):

Names and Identity of those present:

Discussion points of the adverse event:

Outline of treatment options, if appropriate:

Offer of assistance, including arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support:

Questions addressed in the discussion:

Advisement of 1151 claims process and right to file administrative tort claim:

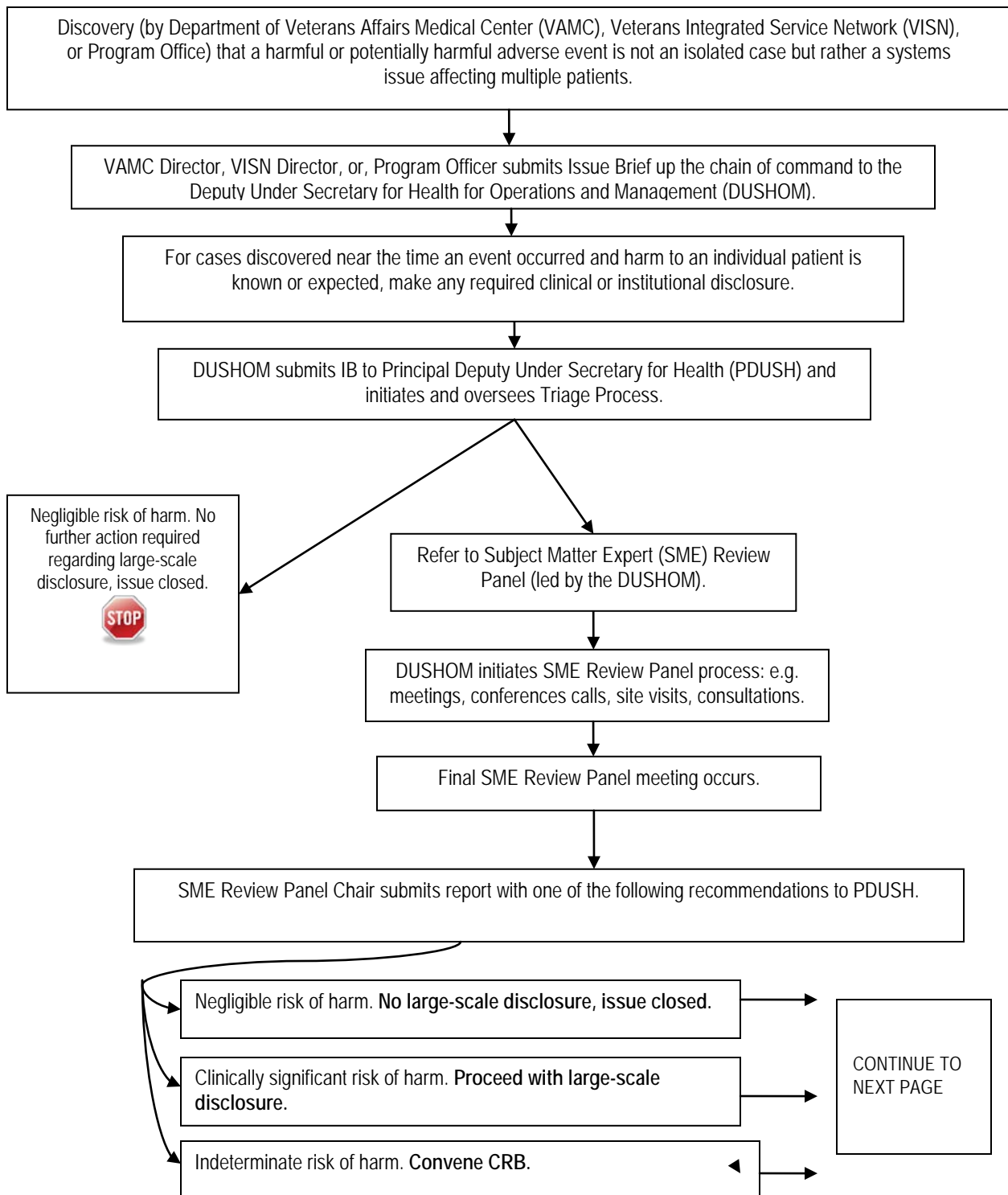
Continued communication regarding the adverse event:

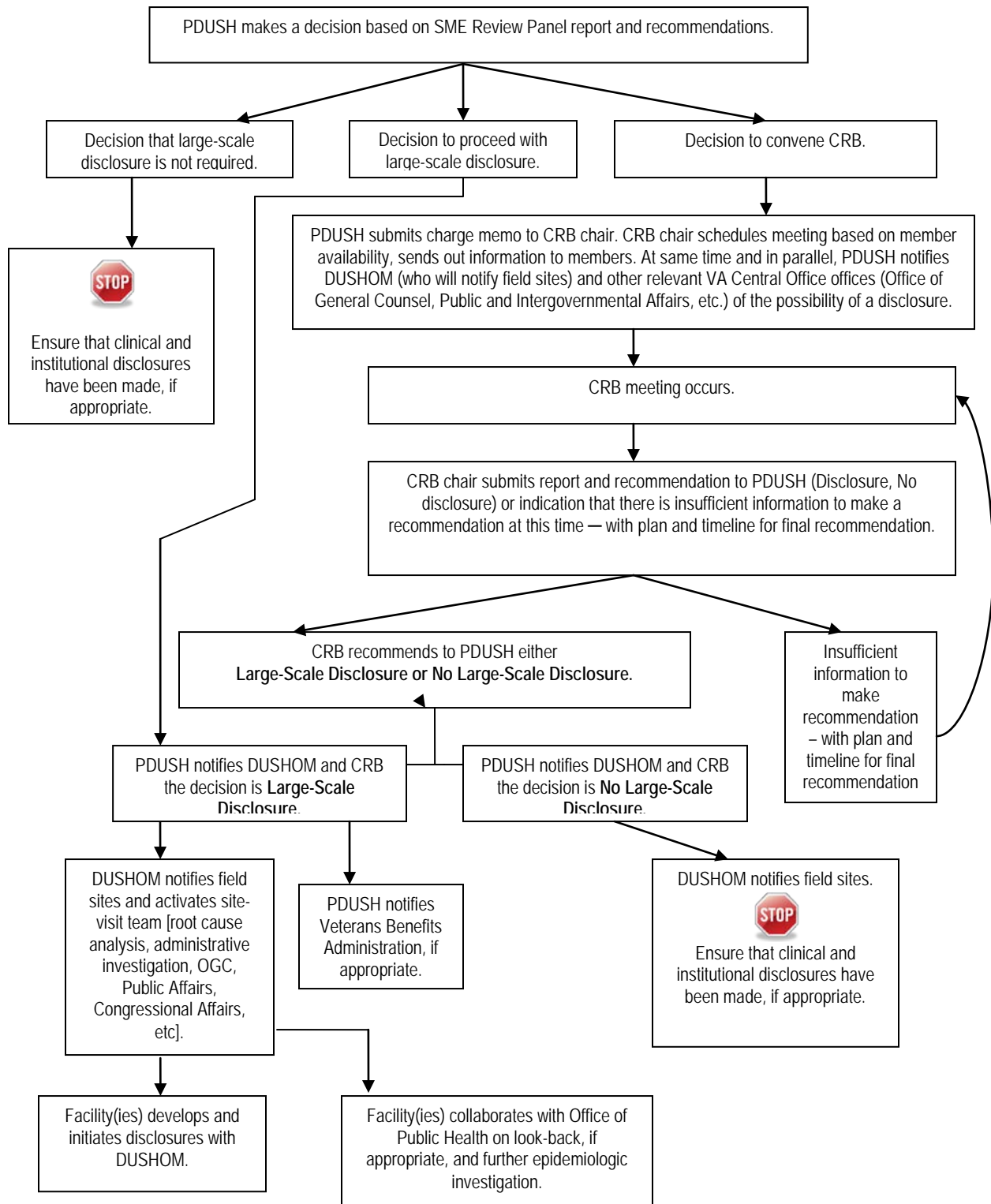
Contact information for individual managing the disclosure:

Close

1. Date and Time of Discussion-Drop-down calendar (required).
2. All elements within the graphical user interface (GUI) Template have a Free Text box for documenting the information.
3. Each of the elements within the GUI Template is a required field that must be completed before the note can be signed by the author.

**PROCESS FOR ASSESSMENT OF ADVERSE EVENTS THAT MIGHT REQUIRE
LARGE-SCALE DISCLOSURE**





**ETHICAL LEADERSHIP DECISION PROCESS FOR
LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS
(FOR USE BY THE CLINICAL REVIEW BOARD (CRB))**

Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm or potential harms to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and severity of harm resulting from the adverse event, as well as a weighing of additional factors, including, but not limited to: salient ethical principles; risk of harm to patients and potentially-affected third parties; benefit and burden of disclosure to patients, including medical, psychological, social, or economic; impact on the institution's perceived integrity and its capacity to provide care and treatment for all patients; as well as applicable policy and relevant precedent. In providing a recommendation about large-scale disclosure to the Principal Deputy Under Secretary for Health, the Clinical Review Board (CRB) needs to include the following considerations in its decision process:

1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION?

- a. What is the probability that a given patient was exposed to the adverse event?
- b. What is the probability that the adverse event will cause a particular patient harm?
- c. What is the nature of the potential harm?
- d. What is the expected severity of the harm?
- e. What is the expected duration of the harm?
- f. Is there treatment available to prevent or ameliorate the harm?
- g. Does the harm have the potential to extend beyond the identified patient, to third parties and what is the probability that the extension of harm would occur?

2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS DECISION?

In addition to the standing members of the CRB, individuals and groups need to be included on a case-by-case basis to ensure that the perspectives of all relevant Department of Veterans Affairs (VA) subject matter experts and stakeholders affected by the decision have an opportunity for input.

3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?

a. Does the decision reflect VHA core values, such as excellence, integrity and accountability? For example, would the decision inspire a high degree of confidence in VHA's honesty, reliability, and sincere good intent? Would the decision demonstrate an understanding of, sensitivity to, and concern for, each person's individuality and importance? Would the decision indicate that VHA is taking responsibility for collective action? That VHA is preserving the organization's reputation and exercising appropriate stewardship of public resources?

b. Does the decision reflect values central to health care provider professionalism? For example, does the decision hold in high regard the dignity and worth of VHA's patients?

c. Does the decision reflect values central to public health practice? For example, does the decision reflect and make use of the best epidemiological evidence to improve population health? *NOTE: On a case-by-case basis, additional values may be relevant.*

4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY LIKELY HARMS?

Although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large-scale disclosure of adverse events likely involves the following considerations:

a. Are there medical, social, psychological, or economic benefits or burdens to the patients, resulting from the disclosure itself?

b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other patients?

c. What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that Veterans and Congress would have in VHA?

NOTE: On a case-by-case basis, additional questions may be relevant.

5. DOES THIS DECISION ESTABLISH A GOOD MODEL FOR FUTURE DECISION MAKING?

a. Is this a good model for how similar questions need to be handled in the future?

b. Has the decision process been followed and documented in a way that can be easily referenced for any similar future cases?

6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION?

- a. Does this decision reflect similar decisions by other large health care systems?
- b. Will the decision be understood and accepted by patients and the public?
- c. Was the process used to make the decision systematic, examining the question from all angles?
- d. Was the process used to make the decision transparent, that is, was the reasoning made clear to all involved?