IMEDCONSENT™

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook sets forth procedures related to the use of the iMedConsent™ software program.

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

a. Establishes requirements for use of the iMedConsent™ software program.

b. Assigns responsibility to Department of Veterans Affairs (VA) medical facilities to maintain the standardized library of iMedConsent™ forms, and to provide and maintain equipment necessary for the proper use of the software.

3. RELATED ISSUES. VHA Handbook 1004.1 and VHA Handbook 1004.2.

4. RESPONSIBLE OFFICE. The National Center for Ethics in Health Care (10E) is responsible for the contents of this Handbook. Questions may be referred to (202) 501-0364.

5. RESCISSIONS. None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of March 2014.

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IMEDCONSENT™

1. PURPOSE

This Veterans Health Administration (VHA) Handbook sets forth procedures related to the use of the iMedConsent™ software program.

2. BACKGROUND

a. VHA is a recognized leader in the use of computer technology to promote and ensure high quality patient care.

b. In February 2004, the VHA National Leadership Board (NLB) mandated national implementation of iMedConsent™.

c. iMedConsent™ is a software package that supports electronic access, completion, signing, and storage of documents, such as informed consent forms and advance directives. iMedConsent™ includes an extensive library of patient education documents, anatomical pictures and diagrams, and drug monographs. The nationwide installation of iMedConsent™ was completed in September 2005.

3. DEFINITIONS

a. **Additional Information Field.** The additional information field is a content field in the consent form creator portion of iMedConsent™. This field contains facility-determined text that is added to every consent form that is generated using iMedConsent™ at that facility. Text that is added to the "Additional Information" field is not overwritten with the release of national software updates.

b. **Administrative Rights.** Administrative rights permissions in iMedConsent™ enable the designated administrative user(s) to perform advanced functions, such as adding local forms, adding text to locally-controlled fields, and generating specialized usage reports.

c. **Administrative Users.** Administrative users have administrative rights to perform advanced functions in iMedConsent™.

d. **Advance Directive.** An advance directive is a written statement by a person, who has decision-making capacity regarding preferences about future health care decisions in the event that individual becomes unable to make those decisions (see VHA Handbook 1004.2).

e. **Crises, Warnings, Allergies and/or Adverse Reactions, and Directives (CWAD).** CWAD notes are displayed on the Cover Sheet of a patient's computerized record, and can be edited, displayed in greater detail, or added to (see VHA Handbook 1907.01).

f. **Dialog Medical.** Dialog Medical is the vendor of the iMedConsent™ software package.

g. **Electronic Signature Pad.** The electronic signature pad is an electronic device that is used to capture written signatures electronically.

h. **Electronically Captured Signature.** The "Electronically Captured Signature," is a term used to refer to a written signature captured using an electronic signature pad and affixed to a document. ***NOTE:*** *An electronically captured signature should not be confused with an electronic signature which is a computer data compilation of a symbol or series of symbols.*

i. **"Facility-Specific Procedure Notes" Field.** The "Facility-Specific Procedure Notes" Field is a content field in the consent form creator portion of the iMedConsent™ program. Utilizing this field, iMedConsent™ administrative users may add text to the description of the procedure or treatment described in individual consent forms. Text added to the "Facility-Specific Procedure Notes" field is not overwritten with the release of national updates.

j. **iMedConsent™.** The iMedConsent™ is a commercially-available software package that has been customized for use within The Department of Veterans Affairs (VA). The software supports electronic access, completion, signing, and storage of such documents as informed consent forms and advance directives. VA has purchased an enterprise license for iMedConsent™. The name of the software package is sometimes informally abbreviated as "iMed."

4. SCOPE

a. iMedConsent™ must be used to generate, sign, and store consent forms for clinical treatments and procedures except as noted in subparagraph 10.a. of this Handbook. Use of the program must be supported in all VA medical centers, Community-Based Outpatient Clinics (CBOCs), and other VA health care environments with access to VA's Computerized Patient Record System (CPRS).

b. Practitioners must use the Spanish-language translations in iMedConsent™ to facilitate the informed consent discussion when appropriate.

c. Practitioners may utilize the patient education materials, anatomical pictures and diagrams, and drug monographs contained in the iMedConsent™ library, as appropriate.

d. Practitioners may use iMedConsent™ to help Veterans complete VA Form 10-0137, VA Advance Directive: Living Will & Durable Power of Attorney for Health Care.

e. The forms and documents in the iMedConsent™ library must be maintained as described in section 11 of this Handbook.

5. RESPONSIBILITIES OF THE FACILITY CHIEF OF STAFF (COS)

The Facility COS must ensure that:

a. Locally-customized forms and data fields contain information that is in compliance with this Handbook, VHA Handbook 1004.1, and any other applicable VHA policies or guidelines.

b. iMedConsent™ usage reports are reviewed.

c. All clinical specialties are using iMedConsent™ to document signature consent as described in this Handbook.

6. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director must ensure:

a. Practitioners have the equipment and resources they need to use the iMedConsent™ effectively.

b. Informed consent workflow has been examined and reengineered when necessary to comply with this Handbook and VHA Handbook 1004.1.

c. iMedConsent™ end-users and administrative users are properly trained.

d. Staff members are made aware of the patient education resources in iMedConsent™ (including the educational documents, anatomical pictures and diagrams, and drug monographs) and are instructed to make use of these materials as appropriate.

e. Practitioners use iMedConsent™ consistent with this Handbook.

f. Administrative users maintain forms in the library as directed in this Handbook.

g. Document processing problems are promptly resolved and/or reported to the vendor when appropriate.

h. Administrative users generate regular iMedConsent™ usage reports for COS review.

i. Facilities use the nationally standardized form and not customize the content of this form (see VHA Handbook 1004.2, Advance Care Planning and Management of Advance Directives).

7. RESPONSIBILITIES OF THE VHA NATIONAL CENTER FOR ETHICS IN HEALTH CARE

VHA National Center for Ethics in Health Care is responsible for:

a. Providing oversight of the iMedConsent™ contract;

b. Maintaining and updating this medical policy; and

c. Ensuring that the iMedConsent™ software maintains compliance with ethical standards and VHA policies related to health care ethics.

8. RESPONSIBILITIES OF THE VHA OFFICE OF HEALTH INFORMATION (OHI)

VHA Office of Health Information is responsible for:

a. Coordinating technical aspects of iMedConsent™ implementation and use;

b. Acting as liaison between the National Center for Ethics in Health Care and the VA Office of Information and Technology (OI&T);

c. Designating a primary technical point of contact within the OHI who will act as the primary contact for IT issues related to iMedConsent™, and who will attend monthly iMedConsent™ Point of Contact (POC) teleconferences; and

d. Coordinating cyber security and other required technical reviews related to software enhancements and new functionalities to the software with OI&T.

9. RESPONSIBILITIES OF THE VHA OFFICE OF PATIENT CARE SERVICES (PCS)

VHA Office of PCS is responsible for:

a. Ensuring that the clinical content in the iMedConsent™ system (i.e., consent form information, patient education documents, and pre- and post-operative instructions) is consistent with VHA policy and reflects current accepted standards of clinical practice through a regular review process using subject matter experts and Field Advisory Committees (FACs).

b. Submitting content changes to the vendor (Dialog Medical) to be incorporated into the software program.

10. INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

a. iMedConsent™ must be used to document patient consent for treatments or procedures that require signature consent, unless:

(1) The patient declines to sign using the electronic signature pad;

(2) There is a temporary system failure that prohibits proper use of the program;

(3) The patient (or surrogate) is giving consent over the telephone, or by fax; or

(4) Use of the program would introduce infection control issues (e.g., patient is in isolation).

b. When iMedConsent™ is not used, signature consent must be documented on a nationally-approved consent form (see VHA Handbook 1004.1).

c. Workflows associated with the informed consent process and documentation must be examined and reengineered to reflect quality standards for informed consent as delineated in VHA

Handbook 1004.1. ***NOTE:*** *A guidance document produced to aid in workflow analysis and reengineering to appropriately incorporate the use of iMedConsent,™ can be founded at: (http://vaww.patientdecisions.va.gov/docs/iMed_Analysis.pdf)* ***NOTE:*** *This is an internal web site and it is not available to the public.*

d. iMedConsent™ must not be used to:

(1) Document consent for services provided by Occupational Health.

(2) Document consent for research, except as specifically authorized by the Office of Research and Development.

e. Spanish-language translations (consent forms and education documents) are available in iMedConsent™. These materials must be used with Spanish-speaking patients (or surrogates) to facilitate the informed consent discussion, when appropriate.

f. A printed copy of the consent form must be offered to the patient or surrogate before and after signatures are obtained.

11. CLINICAL CONSENT FORM ADMINISTRATION IN IMEDCONSENT™

a. Local versions of national consent forms can not be created in iMedConsent™. Administrative users must ensure that local versions of national consent forms do not exist in their local form library, and must instruct practitioners to use only the nationally-approved consent forms.

b. Facilities may add consent forms to their local library for treatments or procedures that are not included in the iMedConsent™ library. However, copies of locally-created clinical consent forms must be sent to the vendor, Dialog Medical using the email address enterprise@dialogmedical.com, before the form is added to the local library. If the newly-added form duplicates a form in the national library, or is otherwise inappropriate, the facility will be instructed to delete the form from their library. Once national versions of consent forms are released, facilities must delete any corresponding locally-created consent form and instruct practitioners to use the national form.

c. All locally-added consent forms must be consistent with Handbook 1004.1. Facilities need to determine local procedures for the review and approval of new clinical consent forms that are not included in the standard iMedConsent™ library.

d. Forms used for purposes other than those described in this Handbook and that are not specifically prohibited in this Handbook may be added to the iMedConsent™ library at the local level. All locally added forms must be reviewed and approved by the local forms committee. ***NOTE:*** *The local forms committee make-up varies from facility to facility, but the committee must ensure that this guideline is followed.*

e. Information added to the "Facility-Specific Procedure Notes" must conform to the requirements in Handbook 1004.1. This text must not include risks, benefits, or alternatives.

Information added to the "Facility-Specific Procedure Notes" field must be approved and regularly reviewed by the local Chief of Service. Appropriate content includes logistical information about the treatment or procedure that is relevant to local practice (e.g., directions to the building where the procedure is performed).

f. Text contained in the "Additional Information" field must be approved and regularly reviewed by the COS or designee. Since this text is added to every consent form, it must only contain information that is relevant to all treatments and procedures performed at the facility. For example, "If you need to cancel or reschedule your treatment or procedure, call 555-1000."

12. ADVANCE DIRECTIVES

a. Although use of iMedConsent™ to help patients complete and electronically store advance directive forms is encouraged, it is not mandatory.

b. Practitioners need to print two copies of the completed, signed advance directive for the patient (or more upon request). ***NOTE:*** *Procedures and requirements for documentation of advance directives are described in VHA Handbook 1004.2.*

13. OPERATIONAL REQUIREMENTS

a. iMedConsent™-related equipment (e.g., servers, workstations, signature pads) must be properly configured and maintained.

b. Printers must be available in areas where iMedConsent™ is used so that the documents created, or available in iMedConsent™, can be easily printed for the patient.

c. Various mobile solutions are in use throughout VHA for wireless or mobile implementation of iMedConsent™. Each facility possesses unique characteristics, which make a "single solution" impractical. Specific equipment needs are to be determined at the facility level by local performance improvement teams. Such equipment assessments need to incorporate a user-based evaluation and include simulated "consenting" scenarios in the desired deployment locations. End-user participation in these evaluations is essential to ensure that the equipment is manageable within the context of the informed consent workflow.

d. Except in the simplest of cases, VA staff must not service mobile carts, unless they have received proper training and instruction from the vendor of the devices. ***NOTE:*** *For concerns regarding compatibility of equipment with iMedConsent™ software, VA staff should contact the vendor, Dialog Medical.*

14. CONTACTS

a. **Technical Issues.** Technical problems or difficulties with the iMedConsent™ software needs to be reported to the vendor, Dialog Medical, at 1-800-482-7963 or at: enterprise@dialogmedical.com.

b. **Clinical Content Concerns and Requests**

(1) Concerns related to the clinical content in the iMedConsent™ program and requests for new content need to be reviewed and approved by the relevant Specialty Chief and submitted to the vendor using email (enterprise@dialogmedical.com). Submission must include the name of the document (or proposed name if new content is being requested), the specialty (or proposed specialty), and a description of the concern or new content request.

(2) The vendor, Dialog Medical, evaluates content requests on a 90-day timeframe (estimated) to determine whether content modification or new content is needed. Dialog Medical provides a summary of actions taken in response to any field request to PCS for review.

(3) PCS is ultimately responsible for ensuring that consent form content is consistent with VHA policy and practice.

c. **VHA Policy.** Questions about iMedConsent™ and policy-related requirements need to be sent to vhaethics@va.gov.

d. **Other Resources**

(1) Electronic Support for Patient Decisions Website: http://vaww.patientdecisions.va.gov. ***NOTE:*** *This is an internal web site and it is not available to the public.*

(2) National Center for Ethics in Health Care Website: http://vaww.ethics.va.gov. ***NOTE:*** *This is an internal web site and it is not available to the public.*

15. REFERENCES

a. Title 38 CFR § 17.32 (2005)

b. VHA Handbook 1004.1

c. VHA Handbook 1004.2

d. VHA Handbook 1907.01