

Version Number: 2	Research & Development Policy 151-06	Supersedes Document Dated: N/A
Effective Date: 03/15/2010	Impaired Decision Making Capacity (IDMC)	Expiration Date: 03/14/2014

In this policy the reference to VA Medical Center shall apply to all research involving human subjects that is conducted completely or partly in the Syracuse VA Medical Center and its affiliated CBOCs, the Canandaigua VAMC and its affiliated CBOCs, and the Bath VAMC and its affiliated CBOCs.

Instructions to Investigators Regarding Impaired Decision Making Capacity (IDMC)

The July 31, 2008 VHA Handbook 1200.5, Requirements for Protection of Human Research Subjects required procedures regarding subjects with Impaired Decision Making Capacity (IDMC). All consented subjects will need to be screened for IDMC using the IDMC screening form. All protocols that need to enroll subjects with IDMC require pre-approval for this by the IRB. Research involving these populations frequently presents greater than minimal risk; may not offer direct medical benefit to the participant; and may include a research design that calls for washout, placebo or symptom provocation. There is a specific process for obtaining and documenting the determination of IDMC. This standard operating procedure will provide the specific procedural information that investigators need in order to include subjects with IDMC in their studies. (See below for a description of individuals who can serve as a legally authorized representative and provide surrogate consent.)

Outline of the seven process steps with respect to subjects with IDMC:

- I. Application (Human Subject Research Protocol Review Request Form or the Amendment Form, as appropriate) with submission of Consent Form with surrogate signature line.
- II. Review and Approval by IRB
- III. IDMC screening (pertains to all consented subjects not just for studies with IDMC approval)
- IV. Medical evaluation
- V. Practitioner consultation with Service Chief/ Acting Service Chief or COS
- VI. Progress note documenting IDMC
- VII. Surrogate Consent

IDMC Process Step I

Initial Protocol Review Request For Inclusion Of Subjects With IDMC Based On Three Approval Criteria (noted below):

Application must be made to the IRB for protocols that need to enroll subjects with IDMC. The application must demonstrate how the protocol will meet the three IRB criteria for approval of subjects with IDMC. The application for enrolling subjects with IDMC will be made using the Human Subject Research Protocol Review Request Form or the Amendment Request Form, as appropriate.

A VA Form 10-1086 Syracuse VA Research Informed Consent Template must be submitted for IRB approval. This form has a signature line for the surrogate (legally authorized representative).

The inclusion of subjects with IDMC must be justified to the IRB and IRB approval will be granted based on three criteria:

Criteria (1) Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.

Guidance for Criteria 1. Criteria one says that persons with IDMC must be necessary to the research. If the research can produce valid results without them, then persons with IDMC should not be included. The following sentence in criteria one permits both subjects with IDMC and those who do not have IDMC to be included in the study if there is a compelling reason to do so for the scientific validity of the research. "The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects."

The notification to the IRB for any protocols that may need to include subjects with IDMC must attest to the fact that subjects with IDMC are needed in order to have a representative sample of subjects with the condition/characteristic being studied. (This can include studies with just those with IDMC or both those with IDMC and those who do not have IDMC.) This must be briefly explained as in the following hypothetical examples.

- *"In this study involving the ER, patients may have IDMC because they are physically incapacitated, in great pain or very upset and this is directly related to their reason for being in the ER. Eliminating these individuals would not provide a representative sample of ER cases. A scientifically valid sample could not be obtained without including both subjects with IDMC and those who do not have IDMC."*
- *"In this cancer medication trial patients may have IDMC due to brain metastasis, pain medication or other causes related to the cancer. Eliminating these individuals would not provide a representative sample of cancer cases. A scientifically valid sample could not be obtained without including both subjects with IDMC and those who do not have IDMC."*

Criteria (2) The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.

Guidance for Criteria 2. The investigator must attest to the fact that the research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, the investigator must explain how there is at least a greater probability of direct benefit to the participant.

Criteria (3) Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health care agents (appointed under Durable Power of Attorney for Health Care (DPAHC)) and next-of-kin, or guardians, must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that **their obligation is to try to determine what the subject would do if competent**, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

Guidance for Criteria 3. The investigator must indicate that procedures have been devised to inform the participant's representatives of their roles and obligations as described in criteria three above.

Additional Conditions that must be met for IDMC enrollment approval:

The IRB must make a determination in writing of each of the three criteria listed above. If these criteria are met, the IRB may approve the inclusion of incompetent subjects or subjects with impaired decision-making capacity in research projects on the basis of informed consent from authorized representatives.

Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.

IDMC Process Step II

Review, Approval and Notification of Approval by IRB

The IRB will review the request to enroll subjects with IDMC based on the three criteria and make a determination regarding approval. This determination will be conveyed to the investigator. The IRB will evaluate the Consent form. When approved, a stamped copy of the consent form will be provided to the investigator.

IDMC Process Step III

IDMC Screening

Below is guidance to include IDMC into the current subject enrollment process:

Step 1 – obtain HIPAA authorization from the participant

Step 2 – administer the IDMC Screening

Step 3 – proceed with the informed consent process

All studies involving consent will include a screening of IDMC. This includes both studies that have previously been approved for inclusion of subjects with IDMC and those that have no plans to include subjects with IDMC. Questions will be utilized to screen for understanding and ability to make an informed judgment in the subject's own best interest regarding whether or not to serve as a study volunteer. The "Protecting Research Subjects With Impaired Decision Making Capacity (IDMC) – IDMC Screening" form will be utilized for this purpose.

It is first assumed that prospective subjects have decision making capacity. The IDMC form is used as a tool for screening and is not intended as a medical assessment of decision making capacity. The investigator or designee, trained in the consent process, will ask IDMC questions of the subject and will sign the form. The form will be maintained in the investigator's study file. Potential subjects who demonstrate impairment in decision making capacity will not be permitted to enroll as subjects unless the IRB has previously approved, for that individual study, enrollment of subjects with impaired decision making capacity. Where prior approval has been granted for enrollment of IDMC cases, the process must be followed as described below in steps IV, V, VI and VII.

IDMC Process Steps IV and V

Medical Evaluation And Practitioner Consultation With Service Chief/Acting Service Chief Or COS

A formal determination if IDMC is made

- (a) The practitioner, in consultation with the chief of service, or COS, may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
- (b) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

IDMC Process Step VI

Progress Note Documenting IDMC

The finding of IDMC must be documented in the person's medical record in a signed and dated progress note in accord with (a) and (b) above.

If the investigator is a practitioner (health care professional as defined below), they can write this progress note: documenting the finding of IDMC, medical evaluation and consultation with the Service Chief/Acting Service Chief or COS.

If the investigator is not a practitioner, the services of a practitioner will have to be enlisted to do this.

IDMC Process Step VII

Surrogate Consent

After a determination of IDMC is documented, the consent process can be conducted with the surrogate using the current IRB stamped approved consent form.

When research is conducted in a VA facility such consent may be obtained from: a health care agent appointed by the person in a DPAHC or similar document; court-appointed guardians of the person, or from next-of-kin in the following order of priority:

- health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document or court-appointed guardian
- legal guardian or special guardian
- spouse
- adult child (18 years or older),
- parent
- adult sibling (18 years of age or older)
- grandparent
- adult grandchild (18 years of age or older).
- *NOTE: The preceding list contains the only surrogate entities who are allowed to provide consent for research purposes.*

All other consent requirements apply as stated in R&D SOP 151-02.

If the research is not conducted in a VA facility, local law applies. In such cases, the IRB will consult with legal counsel to determine which individuals are authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.

If feasible, the practitioner must explain the proposed research to the prospective research subject even when the surrogate gives consent. **Under no circumstances may a subject be forced or coerced to participate in a research study.**

Definitions

The following definitions apply to research. They are taken from 38 CFR 17.32(e) and the VHA Handbook 1400.1 VHA Informed Consent For Clinical Treatments And Procedures.

Competency. In relation to decision-making capacity, competency is a legal determination, made by a court of law, that a patient has the requisite capacities to make a medical decision. This is in contrast to the term "decision-making capacity" which is a clinical determination made by the practitioner.

Decision-Making Capacity. Decision-making capacity for health care decisions has four major components: understanding, appreciating, formulating, and communicating. The first two components represent the patient's ability to understand and appreciate the nature and expected consequences of each health care decision. This includes understanding the known benefits and risks of the recommended treatment options, as well as any reasonable alternative options including no treatment. The latter two components represent the ability to formulate a judgment and communicate a clear decision concerning health care. As used in this Handbook, "capacity" is a clinical determination made by the practitioner, in contrast to the term "competency," which is a legal determination made by a court of law.

Health Care Agent. The individual named in a Durable Power of Attorney for Health Care (DPAHC) document executed by the patient prior to losing decision-making capacity. This individual acts on the patient's behalf to make health care decisions, including the use of life-sustaining treatment when the patient is unable to make such decisions (see 38 CFR 17.32(e), VHA Handbook 1004.2, and Department of Veterans Affairs (VA) Form 10-0137, VA Advance Directive: Living Will and Durable Power of Attorney for Health Care (DPAHC)).

Legal Guardian or Special Guardian. A person appointed by a court of appropriate jurisdiction to make health care decisions for an individual who has been judicially determined to be incompetent. The appointment may be of limited duration. Under VHA policy, legal guardians and special guardians have the same authority to make health care decisions as any surrogate authorized under this policy. *NOTE: Financial or other types of limited guardianship do not always include the authority to make health care decisions.*

Next-of-Kin. A relative (18 years of age or older) of the patient who may act as surrogate in the following order of priority, as specified in Title 38 Code of Federal Regulations (CFR) 17.32: spouse, child, parent, sibling, grandparent, grandchild.

Practitioner. Any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure. For the purpose of this Handbook, the term practitioner includes medical and dental residents, regardless of whether they have been granted clinical privileges.

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The area of using surrogate consent and inclusion of individuals with impaired decision making (IDMC) as research subjects is complex involving issues in semantics, ethics, medical care, regulations and law. This document has not attempted to encompass the breadth of relevant issues but only concentrated on information that is needed for the practical application of procedures to be followed at the VA Medical Center with respect to subjects with IDMC in research.

  
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