



# Waivers: Common Rule, Privacy Rule, and FDA Regulations

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# Presentation Outline

- Full Disclosure: Informed Consent & HIPAA
- Informed Consent: Required Elements
- Documentation of Informed Consent in VA Research
- HIPAA Authorizations
- HIPAA Waivers and Alterations
- Waiver or Alteration of Informed Consent
- Exception to Informed Consent
- Waiver of Documentation of Consent
- Case Studies



# Setting the Stage: Informed Consent and HIPAA Review

# Full Disclosure: Informed Consent & HIPAA

- Unless informed consent is waived by the IRB, **the Common Rule** requires that investigators obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to involving a human being as a subject in research
- With very few exceptions, **FDA regulations** require that investigators obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to involving a human being as a subject in research
- **The Privacy Rule** (Health Insurance Portability and Accountability Act of 1996 - HIPAA) describes when written authorization is required before the use or disclosure of health care information that is not for a "permissible purpose" (i.e., treatment, payment, or healthcare operations) and specifies exceptions allowed by the regulations.

# Informed Consent: Required Elements

- Common Rule Requirements:

- Eight basic elements as described in 38 CFR 16.116(a)
- Six additional elements as described in 38 CFR 16.116(b)

- Additional FDA Requirements:

For clinical trials, the following statement must be provided to each human subject as part of the informed consent process, "A description of this clinical trial will be available on <http://www.clinicaltrials.gov> as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

- Additional VA-specific elements (VHA Handbook 1200.05, Paragraph 15(c) and 15(d)(7))

- Information on any payments the subject is to receive for participating in the study;
- Information on any real or apparent conflict of interest by investigators where the research will be performed;
- A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations;
- When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research (see para 15d(7)).

# Documentation of Informed Consent in VA Research

- Unless a waiver or alteration is approved by the IRB, the written informed consent form must contain the elements of informed consent described in VHA Handbook 1200.05 as approved by the Institutional Review Board (IRB).
- Use of the VA Form 10-1086 (Research Consent Form template) to document informed consent for VA studies involving human subjects is not required.
- The IRB approval date must be documented on the informed consent form.
- Informed consent document must be signed and dated by:
  - Subject or the subject's legally authorized representative (LAR) and
  - Person obtaining informed consent, unless waived by the IRB.

# HIPAA Protects PHI

Privacy Rule states that except as otherwise permitted or required by the regulations, a covered entity may not use or disclose protected health information (PHI) without a valid authorization (45 CFR 164.508)

- PHI is defined as Individually-identifiable health information transmitted or maintained in any form or medium by a covered entity (VHA Directive 1605.01 para 3vv)
- Individually-identifiable health information is a subset of health information, including demographic information collected from an individual, that: (1) is created or received by a health care provider, health plan, or health care clearinghouse (e.g. a HIPAA-covered entity such as VA); (2) relates to the past, present, or future physical or mental condition of an individual, or provision of or payment for health care to an individual; and (3) identifies the individual or where a reasonable basis exists to believe the information can be used to identify the individual (VHA Directive 1605.01 para 3ee)

# Individually Identifiable

- The VA takes into account both the Common Rule (38 CFR 16.102(f)) and the Privacy Rule (45 CFR 164.514(b)(2)) definitions of identifiable data (VHA Handbook 1200.12 paragraph 6a).
  - Common Rule: The identity of the subject is or may readily be ascertained by the investigator or associated with the information
  - Privacy Rule: The presence of one or more of the 18 HIPAA identifiers\* results in a dataset being considered “individually identifiable”

\*Refer to the accompanying handout for a list of the 18 HIPAA identifiers

# HIPAA and Research

Research on human subjects requires an authorization except in the following instances:

- Reviews preparatory to research (VHA Handbook 1200.05 para 23c)
- Research on decedent's information (45 CFR 164.512(i)(1)(iii))
- Limited data sets with a data use agreement (VHA Directive 1605.01 para 2e(5)
  - Similar to a de-identified dataset except that it may contain dates, state, city; and full 5 or 9-digit zip codes
- IRB or Privacy Board approval of an alteration to or waiver of HIPAA authorization (VHA Handbook 1200.05 para 23b and 45 CFR 164.512(i)(1)(ii))

# How is an Authorization Documented for VA Research

- VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, must be used for HIPAA authorizations for new VA studies\*
- When a written authorization is required, the Privacy Rule requires that the authorization be signed and dated by the individual to whom the information or record pertains or their personal representative
- The IRB does not approve the Authorization, but reviews it to ensure consistency with other study-related documents
- The Privacy Officer must review and sign off on the HIPAA Authorization
- VA Form 10-0493 can be found at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-0493-fill.pdf>

\*All studies approved on or after March 12, 2015 (compliance date with VHA Handbook 1200.05)

# Main Act: Waivers

# HIPAA Waiver/Alteration

An investigator requesting a waiver of HIPAA authorization must provide information sufficient to allow the IRB to make the required determinations. In accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(i), the IRB or Privacy Board must document:

- (1) Identification of the IRB of Record
- (2) Date of IRB approval of waiver of HIPAA authorization
- (3) Statement that the waiver of HIPAA authorization satisfies the following criteria:
  - (a) The use or disclosure of the requested information involves **no more than minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements:
    - (1) An adequate plan to protect the identifiers from improper use and disclosure;
    - (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - (3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information is permitted by the Privacy Rule;

# HIPAA Waiver/Alteration (continued)

An investigator requesting a waiver of HIPAA authorization must provide information sufficient to allow the IRB to make the requirement determination. In accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(i), the IRB must document the following:

- (b) **The research could not practicably be conducted without the waiver;** and
- (c) The research could not practicably be conducted without access to and use of the requested information
- (4) A brief description of the PHI for which the IRB has determined use or disclosure to be necessary
- (5) Identification of the IRB review procedure used to approve the waiver of HIPAA authorization (either convened IRB review procedures or expedited review procedures)
- (6) Signature of the Chair of the IRB, or a qualified voting member of the IRB designated by the Chair, on the HIPAA authorization waiver document

# Example of a Waiver/Alteration of HIPAA Form

- [VA Central IRB Form 103](#)

## Available Optional Forms for Research: Waiver of HIPAA Authorization and Revocation of Authorization

- Two VA Forms are available which can be used to help resolve issues with documentation when the
  - IRB approves a waiver of HIPAA authorization for research, or the
  - Subject wishes to revoke authorization for use and release of individually identifiable health information for research.
- These two VA Forms are not currently required for use as per VA or VHA Handbooks or Directives
- VA Form 10-0521: IRB Documentation of Waiver of HIPAA Authorization for Research is located at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-0521-fill.pdf>
- VA Form 10-10116, Revocation of Authorization for Use & Release of Individually Identifiable Health Information for VHA Research is located at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-10116-fill-4-11-2014.pdf>

# Common Rule: Waiver/Alteration of Informed Consent for Public Benefit

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and (2) The research could not practicably be carried out without the waiver or alteration

(38 CFR 16.116(c) and VHA Handbook 1200.05 paragraph 15e)

# Common Rule: Waiver/Alteration of Informed Consent for Minimal Risk Research

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(38 CFR 16.116(c) and VHA Handbook 1200.05 paragraph 15e)

# Revised Common Rule: Waiver/Alteration of Informed Consent

- Requirements for waiving/altering informed consent for research involving public benefit and service programs conducted or subject to the approval of state or local government remains substantially unchanged
- Requirements for waiving/altering informed consent for minimal risk research - One additional requirement has been added:
  - (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the requested waiver or alteration; (iii) **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;** (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (38 CFR 16.116(f)(3))

# Revised Common Rule: Waiver of Informed Consent (Caveat)

- IRB cannot waive or alter any of the elements required for Broad Consent (38 CFR 16.116(f)(2))
- IRB cannot waive consent for the storage, maintenance, or secondary use of identifiable information or specimens if a subject has refused to agree to Broad Consent (38 CFR 16.116(f))
- With the exception of Broad Consent, the IRB can approve a complete waiver of informed consent if the required criteria have been met.

# Revised Common Rule: Alteration of Informed Consent (Caveat )

- Alterations: IRBs can not approve a consent procedure that omits/alters the general requirements of informed consent found in 38 CFR 16.116(a). The consent process must ensure the following:
  - Legally effective informed consent is obtained under circumstances that
    - provide the subject/LAR sufficient opportunity to decide whether to participate;
    - minimize coercion/undue influence and
    - does not include any exculpatory language through which the subject/LAR is made to waive/appear to waive and of their rights or releases/appears to release the investigator, sponsor, institution or its agents from liability for negligence
  - Information is provided to subjects/LARs in a language they can understand
  - Sufficient information is provided to allow them to make an informed decision
  - A short summary of key information related to participation in the study is provided upfront as part of the consent process

# Revised Common Rule: Screening and Recruiting Activities

Use of identifiable information or identifiable specimens without the subject's consent for the purpose of screening, recruiting, or determining eligibility of prospective subjects can be approved by the IRB if the following requirements are met:

- Investigator obtains information through oral or written communication with the prospective subject, or
- Investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

# FDA Regulated Research: Exceptions to Informed Consent Requirements

- Emergency use of a test article
- 10 USC 1107(f) grants the President authority to waive consent for the administration of an investigational new drug to a member of the armed forces during a particular military operation if the President determines that obtaining consent is not in the interests of national security
- Use of an investigational *in vitro* diagnostic device to identify chemical, biological, radiological, or nuclear agents in emergency situations
- Emergency research
  - VA does not conduct planned emergency research  
(VHA Handbook 1200.05 para 3e)

# FDA Exercising Enforcement Discretion with Informed Consent: Minimal Risk Research

Two instances where FDA has stated that it will exercise enforcement discretion with respect to its regulations governing informed consent:

- Effective July 2017, the FDA will not object to an IRB approving a consent procedure that alters or waives informed consent if the IRB finds and documents that:
  - (1) The research involves no more than minimal risk to the subjects;
  - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - (3) The research could not practicably be carried out without the waiver or alteration; and
  - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- FDA intends to revise its informed consent regulations to permit a waiver or alteration of informed consent as described above.

# FDA Exercising Enforcement Discretion with Informed Consent: Leftover Human Specimens

- The FDA will not object to the use, without informed consent, of leftover human specimens\* in investigations that meet the criteria for exemption from the Investigational Device Exemptions (IDE) regulation at 21 CFR 812.2(c)(3), as long as subject privacy is protected using only specimens that are not individually identifiable.
  - Human specimens interpreted to include specimens obtained from specimen repositories, and specimens that are leftover from specimens previously collected for other unrelated research, as long as these specimens are not individually identifiable
- Why was this necessary: Common Rule definition of human subject differs from FDA's definition of human subject
  - Common Rule Definition: A living individual, about whom, an investigator obtains Data through intervention or interaction with the individual, or Identifiable private information (38 CFR 16.102(f)).
  - FDA Definition: a human participant who participates in an investigation, either as an individual or whom or on whose specimens an investigational device is used or as a control (21 CFR 812.3(p)).

# Common Rule: Waiver of Documentation of Consent

- (1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following: (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

(38 CFR 16.117(c) and VHA Handbook 1200.05 paragraph 16c)

# Revised Common Rule: Waiver of Documentation of Consent

## Addition of a third option for waiving documentation of informed consent:

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- (iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(38 CFR 16.117(c)(1))

# FDA Regulated Research: Waiving Documentation of Informed Consent

The IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative, sign a written consent form if it finds one of the following:

That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

*Or*

The IRB finds that the requirements for an exception from informed consent for emergency research are met.

21 CFR 56.109(c)

# Documentation of Informed Consent in VA Research: Waiving the Signature of the Individual Obtaining Consent

- The IRB may waive obtaining the signature and date of the person obtaining informed consent where there is no physical contact with the subject.
  - The IRB cannot waive obtaining the signature and date of the person obtaining informed consent for any other reason in VA research.
  - Signature of the subject or the subject's legally authorized representative cannot be waived if documentation of informed consent is required by the IRB.

# Example of a Waiver of Documentation of Informed Consent Form

- [VA Central IRB Form 112b](#)

# Cheat Sheet: When do I need What?

- **Waiver or alteration of Informed Consent**
  - Requested when you are not able to obtain the informed consent from the subject for all or a portion of the research study or when you need to omit elements required for informed consent.
  - Waiver of Informed Consent for Recruitment/Screening Activities covers access to subject data (medical records or from the subject) and/or specimens to determine eligibility for participation in the study
- **Waiver of Documentation of Consent**
  - Oftentimes referred to as “verbal consent”
  - Requested when you are able to obtain or provide sufficient information for the subject to make an informed decision as to whether they wish to participate in the study or not, but are not obtaining the subject’s signature on the informed consent form.

## Waiver or alteration of HIPAA

- Requested when you are not able to obtain a signed Authorization Form from the subject for all or a portion of the research study or when you need to omit elements required for a valid authorization.



# Bringing it All Together: Case Studies

# Case Study 1:

An investigator at the Old Glory VA is conducting a minimal risk study investigating whether use of a smartphone can improve delivery of physical therapy in Veterans with prosthetic devices already scheduled to begin physical therapy.

- Veteran medical records will be accessed to identify eligible subjects.
- 150 Veterans will be enrolled into a group using a Smart Phone app in addition to their regularly scheduled therapy.
- The study team will conduct face-to-face interviews with Participants and Providers in the Smart Phone App group at the end of the study about their experience with the device.
- Medical records from 500 Veterans located around the country who are also undergoing physical therapy with prosthetic devices will be accessed to serve as controls.
- No interaction or intervention for research purposes will occur with Veterans enrolled in the control group.
- No data will leave the VA.

# Case Study 1: Poll 1

In order to identify eligible Veteran subjects for the study, the study team will need to obtain:

- a. A waiver of informed consent for recruitment purposes
- b. A waiver of HIPAA for recruitment purposes
- c. A waiver of informed consent and HIPAA for recruitment purposes
- d. Neither

# Case Study 1: Poll 2

The study team has requested a waiver of consent and HIPAA for the interviews with Providers at the end of the study. The Providers will be asked to give their opinions about their experiences with the app. Providers will not be asked about individual patients. Should the IRB approve the waiver requests?

- a. Yes
- b. No
- c. I'm not sure

# Case Study 1: Poll 3

The study team has requested a waiver of informed consent and HIPAA to access data from the medical records for the individuals in the control group. Should the IRB approve their request?

- a. Yes
- b. No
- c. I'm not sure

# Case Study 2

An investigator at the Red, White, and Blue VA plans to administer a survey in a minimal risk study to 2000 Veterans with major limb amputation to assess patterns of prosthesis use, function, and satisfaction with the care they received at the VA.

- The study team has requested waivers of consent and HIPAA for recruitment purposes to access the Veteran's medical records to determine eligibility.
- Study packets including the survey and a pre-paid stamped envelope for returning completed surveys will be mailed to eligible participants.
- The study team will call Veterans to make sure they received the packet and ask them if they have any questions about the study, including whether they would like to complete the survey over the phone.

# Case Study 2: Poll 1

The study team has requested a waiver of consent for administration of the survey. Should the IRB approve their request?

- a. Yes
- b. No
- c. No, but the study may be eligible for a waiver of documentation of consent

## Case Study 2: Poll 2

What about HIPAA? Should the study team include a HIPAA authorization form in the mailing or request a waiver of HIPAA for the administration of the surveys?

- a. Include a HIPAA Authorization Form and hope it is returned with the survey
- b. Request a waiver of HIPAA
- c. This one is tricky, I'm not sure

# Case Study 3

- A VA Investigator is collaborating with DoD on a nationwide study of Veterans returning from war in the past 3 years that have been seen in PTSD clinics about how their experience in the war has affected their ability to reintegrate into civilian life.
- Both VA and DoD will identify eligible participants using their personnel and medical record databases.
- Study packets containing a survey, information sheet/consent form, and pre-paid return envelope will be mailed to 5000 veterans with the goal of receiving 2500 completed surveys. No interaction or intervention with these participants for research purposes will occur.
- The 40-item survey includes 6-8 questions about military sexual trauma, combat exposure, and illicit drug use.
- Information will be obtained from participants' medical record
- The survey will ask Veterans to check a box indicating their desire to be contacted to participate in an interview with the study team. A subset of Veterans (200) who return the survey will be contacted by phone for an interview.

# Case Study 3: Poll 1

Is the administration of the survey eligible for a waiver of documentation of consent?

- a. Yes
- b. No
- c. More information needed

## Case Study 3: Poll 2

The study team has requested that the IRB approve verbal consent from the Veterans that they interview by phone. Should the IRB approve this request?

- a. Yes
- b. No
- c. More information is needed

## Case Study 3: Part 2

The study team realizes that this study could provide a wealth of information to the VA on the needs of Veterans returning from war and revises the study to open it up to all Veterans returning from war in the past 3 years and make it a minimal risk study (both surveys and any interviews).

- The protocol is revised to include the mailing of annual surveys to these Veterans for the foreseeable future as well as storage of the data in a repository for future use.
- The study team requests a waiver of documentation of consent for administration of the annual surveys and for the storage of the data for future use.

# Case Study 3, Part 2: Poll

Should the IRB approve a waiver of documentation of informed consent for the annual surveys and for the future use of the research data?

- a. Yes
- b. No
- c. Hmm.....

# References

- Federal Policy for the Protection of Human Subjects (“Common Rule”): 38 CFR Part 16 (Dept of Veterans Affairs).
- Department of Veterans Affairs, Veterans Health Administration handbooks:
  - VHA Handbook 1200.05, Requirements for the Protection of Human Subjects Research ([https://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=3052](https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052))
- US Food and Drug Administration. (2017). IRB Waiver of Alteration of Informed Consent for Clinical Investigations Involving no more than minimal risk to human subjects. FDA Guidance for Sponsors, Investigators, and Institutional Review Boards. Retrieved from <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf>
- US Food and Drug Administration. (2006). Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are not Individually Identifiable. FDA Guidance for Sponsors, Investigators, and Institutional Review Boards. Retrieved from <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071265.pdf>

# Upcoming Cyberseminars: Tentative Schedule

Date	Topic	Lead Office
30-Jan-18	Records Management	ORD
20-Feb-18	Engagement in Human Subjects Research	ORD
20-Mar-18	MyhealthVet and Secure Messaging	ORD
24-Apr-18	Continuing Review	ORD
15-May-18	Expedited Review	ORD
16-May-18	Overview of the Revised Common Rule	ORO
19-Jun-18	Working with the VA CIRB	ORD
27-Jun-18 and 02-Jul-18	Final Rule: Delay Until January 21, 2019 of General Compliance of the Revised Common Rule and Use of Three Burden Reducing Provisions: What it Means for VA Research	ORD/ORO
17-Jul-18	Waivers: Common Rule, Privacy Rule, and FDA Regulations	ORD
18-Jul-18	Informed Consent: ICFs; Broad Consent; and Posting of ICFs	ORO
18-Sep-18	Overview of the Revised Common Rule and its Impact on the IRB	ORD
19-Sep-18	Exempt Review and Limited IRB Review	ORO
	Transition Provisions and Overview of the revised VHA Handbook 1200.05 <b>or</b>	
16-Oct-18	Myth Busters: Common Misperceptions re. VA Research	ORD
20-Nov-18	In-depth Focus on the revised VHA Handbook 1200.05	ORD
21-Nov-18	External IRBs and FWAs	ORO
18-Dec-18	In-depth Focus on the revised VHA Handbook 1200.05	ORD

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Questions?