DOWNSTATE
HEALTH SCIENCES UNIVERSITY

IRB Member Orientation Session II

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Informed Consent Requirements (Common Rule)

Requirements of Informed Consent (1)

45 CFR 46.116 (a): General requirements

a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall **obtain the legally effective informed consent** of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative **sufficient opportunity** to discuss and consider whether or not to participate and that **minimize the possibility of coercion or undue influence**.

(3) The information that is given to the subject or the legally authorized representative shall **be in language understandable** to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative **must be provided with the information that a reasonable person would want to have** in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

Requirements of Informed Consent (2)

45 CFR 46.116 (a): **General requirements**

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) **No informed consent may include any exculpatory language** through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Requirements of Informed Consent (3)

45 CFR 46.116 (b): **Basic Elements**

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study **involves research**, an explanation of the **purposes of the research** and the expected **duration of the subject's participation**, a description of the **procedures to be followed**, and identification of **any procedures that are experimental**;

(2) A description of any **reasonably foreseeable risks or discomforts** to the subject;

(3) A description of any **benefits** to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which **confidentiality of records** identifying the subject will be maintained;

(6) For research involving **more than minimal risk**, an explanation as to whether any **compensation** and an explanation as to whether any **medical treatments** are available **if injury occurs** and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of **whom to contact for answers** to pertinent questions about the research and research **subjects' rights**, and whom to contact in the event of a **research-related injury** to the subject;

Requirements of Informed Consent (4)

45 CFR 46.116 (b): **Basic Elements**

(8) A statement that **participation is voluntary, refusal to participate will involve no penalty or loss of benefits** to which the subject is otherwise entitled, and the subject **may discontinue participation at any time without penalty or loss of benefits** to which the subject is otherwise entitled; and

(9) **One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

(i) A statement that **identifiers might be removed** from the identifiable private information or identifiable biospecimens and that, after such removal, the **information or biospecimens could be used for future research** studies **or distributed to another investigator** for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; **or**

(ii) A statement that the subject's **information or biospecimens** collected as part of the research, even if identifiers are removed, **will not be used or distributed for future research studies.**

Requirements of Informed Consent (5)

45 CFR 46.116 (c): **Additional Elements**

c) *Additional elements of informed consent*. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve **risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;**

(2) **Anticipated circumstances under which the subject's participation may be terminated** by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) **Any additional costs** to the subject that may result from participation in the research;

(4) The **consequences of a subject's decision to withdraw** from the research and **procedures for orderly termination of participation** by the subject;

(5) A **statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;**

(6) The approximate **number of subjects** involved in the study;

(7) A statement that the subject's **biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;**

Requirements of Informed Consent (6)

45 CFR 46.116 (c): **Additional Elements**

(8) A statement regarding **whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions**; and

(9) For research involving biospecimens, **whether the research will (if known) or might include whole genome sequencing** (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Informed Consent Requirements (FDA)

Requirements of Informed Consent (1)

21 CFR 50.25(a): **Basic Elements**

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Requirements of Informed Consent (2)

21 CFR 50.25(a): **Basic Elements**

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Requirements of Informed Consent (3)

21 CFR 50.25(b): **Additional Elements**

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) The approximate number of subjects involved in the study.

Requirements of Informed Consent (4)

21 CFR 50.25(b): **Additional Elements**

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

Requirements of Informed Consent (5)

21 CFR 50.25(c): **Applicable Clinical Trials**

When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: **"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."**

Informed Consent Requirements (SUNY RF Payment Consent)

SUNY RF Informed Consent

SUNY RF Human Subject Payments Policy

Required for research payments (including travel reimbursement) of either

1) $600 or more in a calendar year, or

2) more than $100 per study visit

Informed Consent Requirements (Other Considerations)

Other Considerations Related to Informed Consent

Other informed consent requirements (see Downstate IRB template for details)

Exception From Informed Consent (EFIC) for Planned Emergency Research or Clinical Trials

Stand-Alone HIPAA Authorizations

HIPAA Authorization for Psychotherapy Notes

Pregnancy Follow-up consent

SUNY RF Payment Consent

Assent (ages 7-12)

Assent (ages 13-17)

Recruitment Authorization Forms

NYS Medical Release Form

Short Forms

HIPAA Research Authorization Requirements

Requirements of HIPAA Authorization (1)

HIPAA Privacy Rule (45 CFR Parts 160, 162, and 164)

The following core elements must be present in plain language for a research authorization to be valid:

(1) A specific and meaningful description of the PHI to be used or disclosed

Note: The minimum necessary rule does not apply to Authorizations; however, Downstate encourages the investigators to limit the PHI to the minimal necessary PHI that is reasonably necessary to accomplish the purpose of the research.

(2) The name or identification of the person(s) or class of person(s) authorized to make the use or disclosure of PHI. For example, who will disclose the PHI? (e.g., UHB, NYC H+H, Kings County, other hospitals, practice groups, etc.)

(3) The identification of the persons or class of persons to whom the covered entity is authorized to make the disclosure. For example, what internal or external persons or entities will be receiving PHI?

(4) Description of each purpose for which the specific PHI identified earlier is to be used or disclosed

(5) An expiration date or event (this must be a certain date or an event tied to the individual). For example, a statement providing that the authorization will expire on a specific date, after a specific amount of time, or upon occurrence of some event related to the research participant. (e.g., “at the completion of the research”)

(6) The individual’s signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual (e.g., required when recruiting children or cognitively impaired adults).

Requirements of HIPAA Authorization (2)

HIPAA Privacy Rule (45 CFR Parts 160, 162, and 164)

The following statements must be included:

(1) A statement that the individual may revoke the authorization in writing at any time (except to the extent that a provider has taken action in reliance of the authorization), and instructions on how to exercise such right (who does the individual need to write, name and address)

(2) A statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization.

Note: The PI may condition healthcare on the provision of the authorization for research related treatment (e.g., clinical trial), in which case the provider may refuse to provide the research related healthcare if the research participant refuses to execute the authorization.

(3) A statement about the potential for the PHI to be re-disclosed by the research team (e.g., to another organization) and no longer protected by the Privacy Rule

There are **additional requirements** for authorizations for using PHI for **marketing** purposes, **sale** of PHI, or for the use or **disclosure of psychotherapy notes**. Contact the IRB or Privacy Officer for additional information or refer to SUNY Downstate HIPAA (Health Insurance Portability and Accountability Act) Policies and Forms.

For additional information see:

(1) DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes

(2) DMC HIPAA-32 policy: Uses and Disclosures Requiring Patient Authorization.

Waivers and Alterations

STEP 8: SUNY Downstate ORA IRB - Electronic Submissions

Types of HIPAA Waivers:

- Full HIPAA Waiver
- Partial HIPAA Waiver
- HIPAA Alteration

Types of Waivers of Informed Consent Requirements:

- Waiver of the entire process
- Waiver of some of the required elements
- Waiver of documentation (signatures)

IRB Approval:

- All criteria must be met (outlined on form)
- HIPAA Waiver MUST be signed by IRB member

What is “Impracticable”?

SACHRP Recommendations related to waivers

Common definitions of “Practicable”:

- Feasible;
- Capable of being effected, done or put into practice; and that may be practiced or performed;
- Capable of being done or accomplished with available means or resources.

The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent.

Concepts that may help determine whether it is impracticable to perform the research without a waiver:

Scientific validity would be compromised if consent was required. Examples of this might include the following:

- The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
- The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.
- The disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.

Ethical concerns would be raised if consent were required. For example:

- There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
- There is a risk of inflicting psychological, social or other harm by contacting individuals or families.

There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.

Practicability should not be determined solely by considerations of convenience, cost, or speed.

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Thank You!