INFORMED CONSENT: WAIVING WITH CONFIDENCE

OHRP CONFERENCE:
“BEYOND THE BASICS OF INFORMED CONSENT”

SHERATON SOCIETY HILL HOTEL
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Sometimes you can “wave” with confidence,

Sometimes not so much
Objectives, Goals and Discussion

1. Review Usual requirements of the consent process
2. Review of regulatory requirements regarding waiver and alterations
3. "Practicable" and "Adversely Affecting" a subject’s rights
4. Waivers of consent, waivers of documentation of consent, and alterations to the consent
5. HIPAA waiver and alteration of authorization
Objectives, Goals and Discussion

6. Subject populations and approval of waivers and alterations of consent
7. Investigator’s role and responsibility when requesting waivers and alterations
8. IRB’s role in evaluating, approving, or disapproving, waivers and alterations to the consent process
9. State and local laws, regulations, statutes and cultural context
10. Sample IRB forms
11. Case Studies and Examples
What is required of the Consent Form and Consent Process?

Usual requirements of the consent process (summarized);

In accordance to

45 CFR 46.111, Criteria for IRB Approval, parts (a)(4) & (5);

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
What is required of the Consent Form and Consent Process?

45 CFR 46.116 (summarized)
Except as provided (elsewhere in this policy), no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence...
General Requirements for Informed Consent

45 CFR 46.116 (a)

45 CFR 46.116 (a) will include eight (8) basic elements (summarized)

1. statement the study involves research, explanation of the purposes, the expected duration of participation, description of the procedures to be followed, and identification of any procedures which are experimental;
2. any reasonably foreseeable risks/discomforts,
3. any benefits to the subject or to others which may reasonably be expected,
4. appropriate alternative procedures or courses of treatment, if any,
General Requirements for Informed Consent

45 CFR 46.116 (a)

5. extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. (If research is more than minimal risk) discussion of compensation or medical treatment availability,
7. whom to contact for answers regarding questions, subject’s rights, or if injured,
8. participation is voluntary, they may refuse without penalty or loss of any benefits,
General Requirements for Informed Consent
45 CFR 46.116 (b)

Additional Elements: used as appropriate (summarized)
1. treatment/procedure may involve risks to the subject (embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. costs to the subject that may result from participation in the research;
4. consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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; and
6. approximate number of subjects involved in the study.
Review of OHRP requirements that allow for waiver and alterations to the consent process.

HHS 45 CFR 46.116(c)(1 & 2)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116 (a) & (b), or waive the requirement to obtain informed consent provided the IRB finds and documents that:
Review of OHRP requirements that allow for waiver and alterations to the consent process.

1. 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 or 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.
Review of OHRP requirements that allow for waiver and alterations to the consent process.

Common request to Waive or Alter the consent process;

HHS 45 CFR 46.116(d)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements 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.
Review of OHRP requirements that allow for waiver and alterations to the consent process.

HHS 45 CFR 46.117 (c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the ONLY record linking the subject and the research would be the consent document AND the principle risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; OR
Review of OHRP requirements that allow for waiver and alterations to the consent process.

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.

Examples:
- minimally invasive blood draw,
- questionnaires that are non-intrusive, pose minimal or no risk to a subject’s privacy or collect confidential information.
What is the definition of “Practicable”?

When is it, or when may it NOT be “practicable” to obtain and document a subject’s consent?

Consider some commonly accepted definitions of the term "practicable":

(a) Feasible;
(b) Capable of being effected, done or put into practice; and
(c) That may be practiced or performed; capable of being done or accomplished with available means or resources.

When an IRB considers an investigator’s request to waive or alter consent, the IRB should confirm the criteria of not being “Practicable” are met.
Practicability, and Adversely affecting the subject’s rights and welfare

What is many times an investigator’s definition of “Not Practicable”?

Consenting subjects is inconvenient,
Consenting subjects will be a financial burden,
Why should I consent them since they won’t understand the project anyway?
Does not have the time or staffing,
The consent form is too long!
Practicability, and Adversely affecting the subject’s rights and welfare

What about adversely affecting the research subject’s rights?

What should the IRB consider?

Regarding the criterion under HHS regulations at 45 CFR 46.116(d)(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

In order to determine whether a waiver of informed consent would adversely affect the rights and welfare of subjects, IRBs should consider the following points:
Practicability, and Adversely affecting the subject’s rights and welfare

a. Whether there are other federal, state, or local laws that provide rights to potential subjects to require informed consent. IRBs should seek advice from their legal counsel when appropriate to help the IRB with these determinations. This would be especially important for state specific regulations.

b. Whether the subject population, in general, would object if they knew of the waiver and its intent in facilitating research.

c. Whether the subject population, in general, would consider that the waiver has the potential to cause adverse consequences for their welfare or general wellbeing.
Practicability, and
Adversely affecting the subject’s rights and welfare

Examples of adversely affecting the rights of a research subject

a. In general, secondary use of student educational records, with identifiers intact. FERPA prohibits use of this data for institutions funded by U.S. Department of Education. The student or parent must provide permission for use of identifiable records. (some specified conditions may allow their use)

b. Questionnaires about domestic violence, HIV, life style issues (LGBT), genetic testing and insurance.

Possible disclosure of involvement in the research may jeopardize the subject’s reputation or standing in the community.
Waivers and Alterations of Consent

Waiver and Alteration of Documenting Consent

What does it mean to Waive informed consent?

Waiving the requirement for obtaining a subject’s informed consent or parental permission means that the IRB has determined that the investigators need not obtain the subjects’ informed consent to participate in research.

To “WAIVE” consent means: NO subjects are approached to be engaged in the consenting process, permission is OK’d by IRB that the PI’s request meets the “4” requirements to “Waive” consent found in 45 CFR 46.116 (d).
Waivers and Alterations of Consent
Waiver and Alteration of Documenting Consent

What does a Waiver of Documentation of Consent allow?

When an IRB has not waived the requirement for seeking the prospective informed consent of a subject, or parental permission of children who are subjects, the IRB may Waive the requirement for an investigator to document or obtain a signed consent form for some or all subjects.
A request for a “Waiver of Documentation of Consent” means:

The IRB has approved a consent process with subjects that do not require the documented agreement to participate in research by the research subjects.
Waivers and Alterations of Consent
Waiver and Alteration of Documenting Consent

Although documentation of participation in research has been waived, remember:

• The investigators will have some form of contact with the subjects,
• The contact will allow investigators to treat subjects as Autonomous Agents and respect their ability to determine whether or not they agree to participation and the investigator explains or describes the Essential and Additional Elements of consent to the subject.
Waivers and Alterations of Consent
Waiver and Alteration of Documenting Consent

Documentation vs. Process

Important to differentiate between waiver of documentation and waiver of the process of consent.

For any study involving direct contact with a subject, some form of consent is Required.

• In person - written or verbal
• Telephone with IRB approved script
Waivers and Alterations of Consent

Waiver and Alteration of Documenting Consent

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

a. Subject may or may not be given a summary consent, written script of some kind.

b. A subject can decide and inform an investigator whether they want a document linking them to the research project.
What does an Alteration of Informed Consent allow?

An IRB may approve human subjects research for which some of all of the elements of informed consent at 45 CFR 46.116 (a) & (b) have been altered, or for which some elements have been left out. An IRB has allowed an investigator to conduct a consenting process that does not FULLY disclose or discuss the usual components of consent with a subject.

Example: when subjects have full knowledge of what the research intervention or observations involve, and this knowledge may lead the subjects to modify or alter their usual actions if they know they are being observed. (Deception) A debriefing may be required.
Waivers and Alterations of Consent

Waiver and Alteration of Documenting Consent

What about “Passive” or “Implied” consent?

Per OHRP; “Terms such as “passive” or “implied” consent are not referenced in the HHS regulations. However, OHRP is aware that these terms are sometimes used by investigators or IRBs to describe a process in which consent or parental permission requirements have been altered or waived, or for which the requirement to document consent or parental permission has been waived.”
What about research protocols that request waiver of consent, or an alteration to the consent process and involves the collection and use of Protected Health Information?

IRBs may act as or support the Privacy Board, consider that waiving or altering the consent process can also include waiver or alteration of HIPAA Authorization.
What are the requirements to waive or alter HIPAA Authorization that IRBs and Privacy Boards must consider?

HIPAA Privacy Rule 45 CFR 164.512(i)(1)(i)

i. Documentation that an alteration or waiver of research participants’ authorization for use/disclosure of information about them for research purposes has been approved by an IRB or a Privacy Board.

This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practically be conducted if research participants’ authorization were required.
ii. The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

   a. an adequate plan to protect the identifiers from improper use and disclosure;
b. 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

c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research *could not practicably* be conducted without the waiver or alteration; and

3. The research *could not practicably* be conducted without access to and use of the protected health information.
What populations of subjects can Waivers and Alterations be used with?

In general, what populations of research subjects can waivers of consent, waivers of documentation of consent, and alterations to the consent process be applied?

a. Adults
b. Children
c. Pregnant Women
d. Prisoners
e. Subjects with diminished mental capacity (Use of Legally Authorized Representative)
What populations of subjects can Waivers and Alterations be used with? Special Considerations

Although these subject types may be involved in research that has a waiver or alteration of consent in place, at time of approval the IRB must remember:

- Research must be No More Than minimal risk with use of the Waiver of Consent.
- IRB review of research with Prisoners requires appropriate representation on behalf of prisoners, and when relevant Prisoners are informed participation will have no effect on parole.
- Review local law and requirements for use of Legally Authorized Representative
What populations of subjects can Waivers and Alterations be used with?  Special Considerations

Subjects enrolled in Exempt IRB approved protocols

Although the regulations at 45 CFR 46.101 list exemptions to when IRB review and approval is not required, this does not mean the IRB or institution cannot require some form of a consent process to take place or be documented.

At the least an oral presentation, and subject acknowledgement to participate should still take place when practicable.
May apply to Exempt Categories 1,2, 3, 5 and 6.
What populations of subjects can Waivers and Alterations be used with? Special Considerations

Research with children and waiver of consent under 45 CFR 408 (c)

In addition to the provisions for waiver contained in 46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is NOT a reasonable requirement to protect the subjects; (EX: neglected or abused children), it may waive the consent requirements in Subpart A, and 408 (b), provided;

1. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and
2. That the waiver is not inconsistent with federal, state, or local law.
What populations of subjects can Waivers and Alterations NOT be used with?

What types of research subjects are IRBs restricted from applying the Waiver of consent allowances to?

- Protocols approved by the IRB as More Than Minimal Risk
- Research involving non-viable neonates
Investigator’s Role and Responsibility

What is the Investigator’s role and responsibility when making requests to the IRB for waivers and alterations to the consent process?

• Clearly describe a research design that an IRB can identify when the PI cannot Practicability conduct the research activities if obtaining the subjects’ fully informed consent is required; and that the subjects’ rights will not be Adversely Affected.
• Being responsive to any questions generated during the IRB review.
• Work with the IRB to meet the needs of protecting human subjects while achieving the goals of the research protocol.
Investigator’s Role and Responsibility

Investigator’s role and responsibility when executing consent process with Waiver of Documentation or Alteration of Documentation.

- Remember: An alteration or waiver of documentation of consent does not mean an investigator is relieved from providing additional information to subjects if or when procedures, risks and benefits of the research change.
- That the data collection and retention process does not otherwise link the subjects to the research project.
- When requested, honor a subject’s request when they desire to be associated with the research through documentation of consent.
What is the IRB’s role?

What is the IRB’s role in evaluating and approving, or disapproving requests for waivers and alterations to the consent process?

• Has the IRB confirmed the PI has addressed the “4” questions found in 46.116 (d) appropriately?
  i. Remember “Practicable; Not Adversely Affecting Subject’s Rights”
  ii. Practicable should not be determined solely by considerations of convenience, cost, or speed.

• Has the IRB properly documented the approval and any contingencies to that approval? (In the minutes and or approval letters)

• IRB may approve waivers and alterations for some, but not all research subjects.

• Consider Quality Assurance post approval evaluations periodically to confirm compliance with terms of waivers and alterations of consent.

• Other considerations?
State and Local laws, Cultural Context

What about State and local laws, regulations, statutes and cultural context?

• Speak with your institution’s legal counsel to determine if there are any additional laws or regulations that may need to be considered prior to IRB approval of the Waiver of Consent, Documentation or Alteration of Documentation.

• Are there laws in your state or region specifically protecting certain populations of subjects?
  i. HIV Positive subjects, prisoners, subjects with diminished mental capacity, children

• Does your investigator interact with subjects that have unique cultural needs?
Sample Forms and Checklists: Waiver Request form

REGULATORY CHECKLIST FOR WAIVER OF INFORMED CONSENT PROCESS
WAIVER OR ALTERATION OF SOME OR ALL ELEMENTS OF INFORMED CONSENT

1. Is study FDA-regulated?  YES ___  NO ___

If YES, STOP. FDA does not provide for any of the following waivers or alterations in this section.

2. Is a waiver of the informed consent process being requested?  YES ___  NO ___

3. Is a waiver or alteration of some or all elements of informed consent being requested?  
(i.e., all required elements of 45 CFR 46.116 will not be applied)  
YES ___  NO ___
4. If YES to either question 2 or 3, the following criteria must be met [46.116(d)]:
   ___ The research involves no more than minimal risk
   ___ The waiver or alteration will not adversely affect the rights and welfare of the subjects
   ___ The research could not practicably be carried out without the waiver or alteration
   ___ When appropriate, the subjects will be provided with additional information after participation

5. May consent procedure or elements of informed consent be waived / altered? YES ___  NO ___
IRB APPLICATION FOR RECORD REVIEWS AND OTHER RESEARCH WHERE WAIVER OF INFORMED CONSENT MAY APPLY (FORM PERTAINS TO REGULATORY CRITERIA RELATED TO HIPAA AND THE COMMON RULE)

P.I. NAME: ___________________________ DEPARTMENT/DIVISION ____________________

STUDY TITLE: ______________________________________________________________

THE IRB MAY WAIVE THE REQUIREMENT TO OBTAIN WRITTEN AUTHORIZATION FROM THE SUBJECT TO USE HIS/HER PROTECTED HEALTH INFORMATION (PHI), PROVIDED THAT THE INVESTIGATOR MEETS THE FOLLOWING HIPAA CRITERIA. PHI IS DEFINED BY HIPAA AS INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (INCLUDING BOTH IDENTIFIERS AND HEALTH INFORMATION) TRANSMITTED OR MAINTAINED IN ANY FORM (ELECTRONIC, PAPER, ORAL COMMUNICATION) THAT RELATES TO THE PAST OR FUTURE PHYSICAL OR MENTAL HEALTH OR CONDITIONS OF AN INDIVIDUAL.
Sample Forms and Checklists: Collecting PHI

1. Please list all protected health information (PHI) to be collected in this study. This includes identifiers and health information. (For example, name, MR# and phone number are identifiers; Specific testing such as medical history and diagnosis are health information).

2. What are the specific sources of the PHI? (i.e., Dr. X’s outpatient records, hospital EMR, Pathology records, etc.)

3. The PHI will be collected by (check all applicable):
   
   ____ Chart/image/database review  ____ Survey/questionnaire (in person)
   ____ Survey/questionnaire (mail)  ____ Interview/group discussion
   ____ Survey/questionnaire (phone)  ____ Observational/prospective review
   ____ Survey/questionnaire (on-line)  ____ Other:
4. Investigators are required to adhere to the “minimum necessary” standard when obtaining PHI without written authorization. Please justify why the PHI you wish to obtain is the minimum necessary to achieve the goals of the research. (This requirement prohibits collection of PHI for which you will not have an immediate, defined use, according to the stated goals of your research study.)

5. Please justify why it is unfeasible to obtain a written authorization from the subjects to use their PHI:

6. The research could not practicably be conducted without access to and use of PHI because: ____________________________
7. Please check off those steps noted below that you intend to implement to ensure confidentiality of subject data and to protect the identifiers or codes that can be linked to identifiers from improper use or disclosure. (Note: Non-Jefferson sanctioned “covered devices” may not be used for the storage of identifiable subject data. See Jefferson Policy #122.35, “Wireless and Portable Device Security Policy.”)

- List of identifiers will be kept in a separate location from the coded subject data that can be linked to identifiers.
- Subject data will be kept in a locked filing cabinet or desk and in a locked office.
- Subject data will be kept on a password-protected, encrypted on-site computer.
- Subject data will be kept on a Jefferson server. Provide specific physical and/or electronic location:
- Subject data will be kept on a Jefferson-issued or -approved “covered device” as per Jefferson Policy #122.35. Specify type of “covered device” to be used:
- Other (please describe):____________
Sample Forms and Checklists: Collecting PHI

8. Specify those individuals who will have access to identifiable subject data:

9. If a code that links to identifiers will be used, please describe the coding mechanism.

10. Identifiers and/or codes that can be linked to identifiers should be destroyed at the earliest possible time. Please describe your plans to destroy identifiers/codes. However, if there is a health or research justification, for retaining the identifiers/codes, or if it is required by law, please provide justification.

11. If appropriate, how will subjects be provided with pertinent information after research? If not appropriate, please specify why.
12. PI certifies to the following:

_____ The information listed in this waiver application is accurate, and all study personnel will comply with the HIPAA regulations and the waiver criteria. All study personnel have completed HIPAA training.

_____ I assure that the PHI obtained as part of this research will not be used or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval by the IRB before doing so.

Principal Investigator Signature __________________________  Date__________________
Sample Forms and Checklists: Questionnaire Consent

At the beginning of the questionnaire, use the following or similar statement:

By completing and returning this questionnaire you are indicating your consent to take part in this research study. The purpose of this study is.... Completing the questionnaire is entirely voluntary. Not participating (that is, not returning the questionnaire) will not affect your ability to receive continuing care at (name of institution) and you are not giving up any of your individual rights. Your confidentiality and privacy is protected because this is an anonymous questionnaire. If you have questions about this research, call (NAME) at (telephone number).

PLEASE DO NOT SIGN THE QUESTIONNAIRE
Case Study #1

An investigator is seeking IRB approval to conduct a research study to determine the rate at which HIV + patients utilize the Social Services that they are referred to consult.

The PI and research team will conduct a retrospective chart review involving 250 patients receiving clinical care at the PI’s institution. The PI will also collect: Age, Gender, Race, Employment status, marital/partnership status.

• What type of waiver or alteration can the IRB approve?
• Are there any particular concerns the IRB may have and what might they be?
Case Study #2

The investigator who received IRB approval to conduct a retrospective research study to determine the rate at which HIV + patients utilize the Social Services has found, that to date, of those patients referred for Social Support Services in the past, only 27% of the 250 charts reviewed, had noted that patients actually followed through and contacted Social Services.

The PI is now asking to modify the protocol as follows.

- The PI now wants to remind patients at the time of their clinical visit to contact Social Services, provide a “reminder card,” and contact the patients by phone or email to confirm patients have consulted Social Services.

- What type of waiver or alteration can the IRB approve?
- Are there any particular concerns the IRB may have and what might they be?
Case Study #3

A social/behavioral researcher would like to evaluate and modify the curricular activities of 6th grade science students in two different public schools from the same school district, whose students score poorly on annual assessments.

In school “A” the students will continue to receive the already approved science course, and in the second, school “B”, the PI will implement an already proven science program known to improve student learning. The teachers themselves are not participants.

The PI has noted in the protocol that consenting the parents would not allow for sufficient numbers of students to be enrolled in the study to determine measurable changes in outcomes, that rates of parental literacy are low, and that a new school year will start shortly and the PI just doesn’t have time to consent the parents.

• What type of waiver or alteration can the IRB approve?
• Are there any particular concerns the IRB may have and what might they be?
Bibliography: Websites used in support of this presentation are provided below in “link” format.

HHS.gov; Frequently Asked Questions About Human Research
http://www.hhs.gov/ohrp/policy/faq/index.html

HHS.gov; Code of Federal Regulations
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

HHS.gov; SACHRP Letter to HHS Secretary, January 31, 2008
http://www.hhs.gov/ohrp/sachrp/sachrpletter013108.html

NIH: Grants & Funding; Frequently Asked Questions from Applicants

HHS.gov; Health Information Privacy: Research
http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/research.html
Bibliography: Websites used in support of this presentation are provided below in “link” format.

Drexel University, Office of Research, Human Research Protection Program
IRB Forms, Guidance and SOPs
http://drexel.edu/research/compliance/humanSubjects/irb/sopGuidance/

Thomas Jefferson University, Office of Human Research, Division of Human Subjects Protection
http://www.jefferson.edu/university/human_research/irb/forms.html