WAIVERS AND ALTERATION OF CONSENT AND HIPAA

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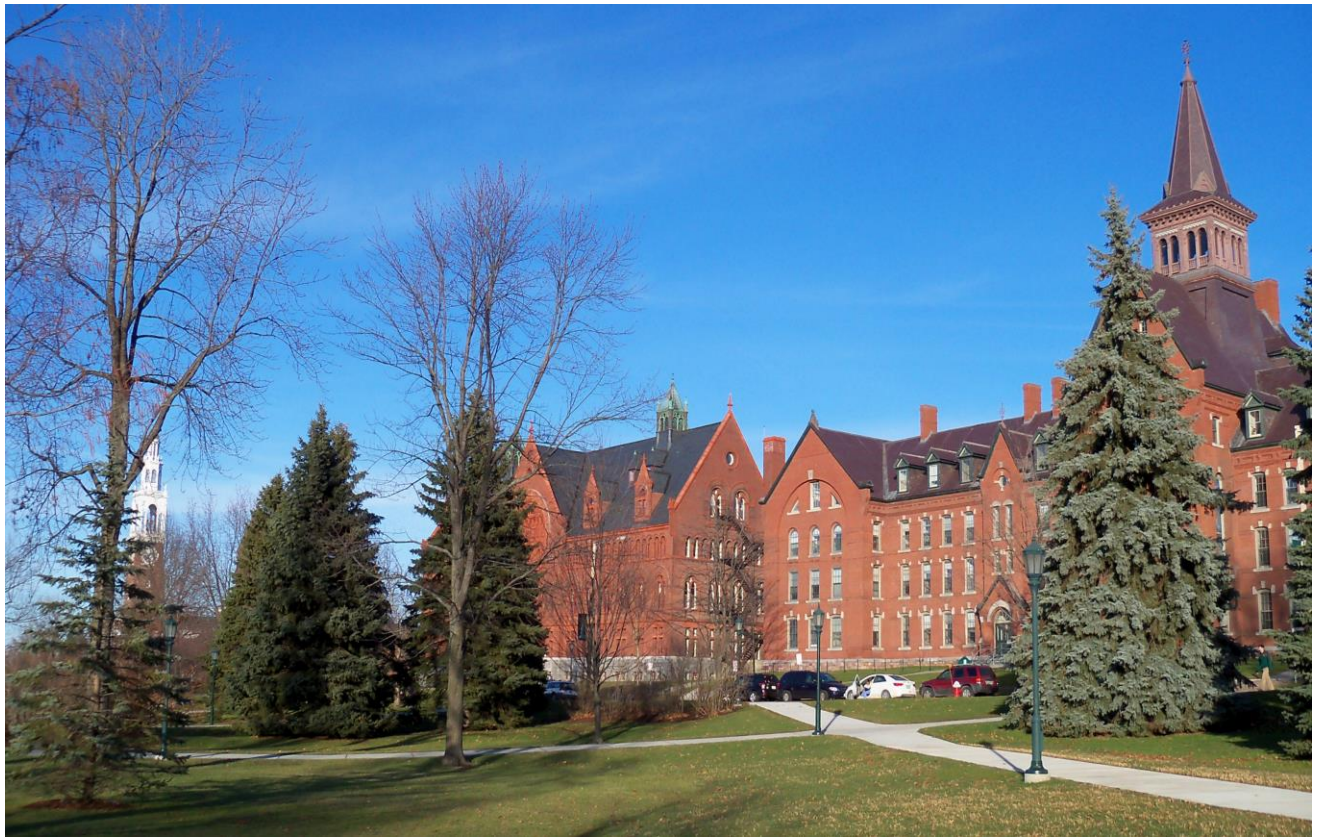
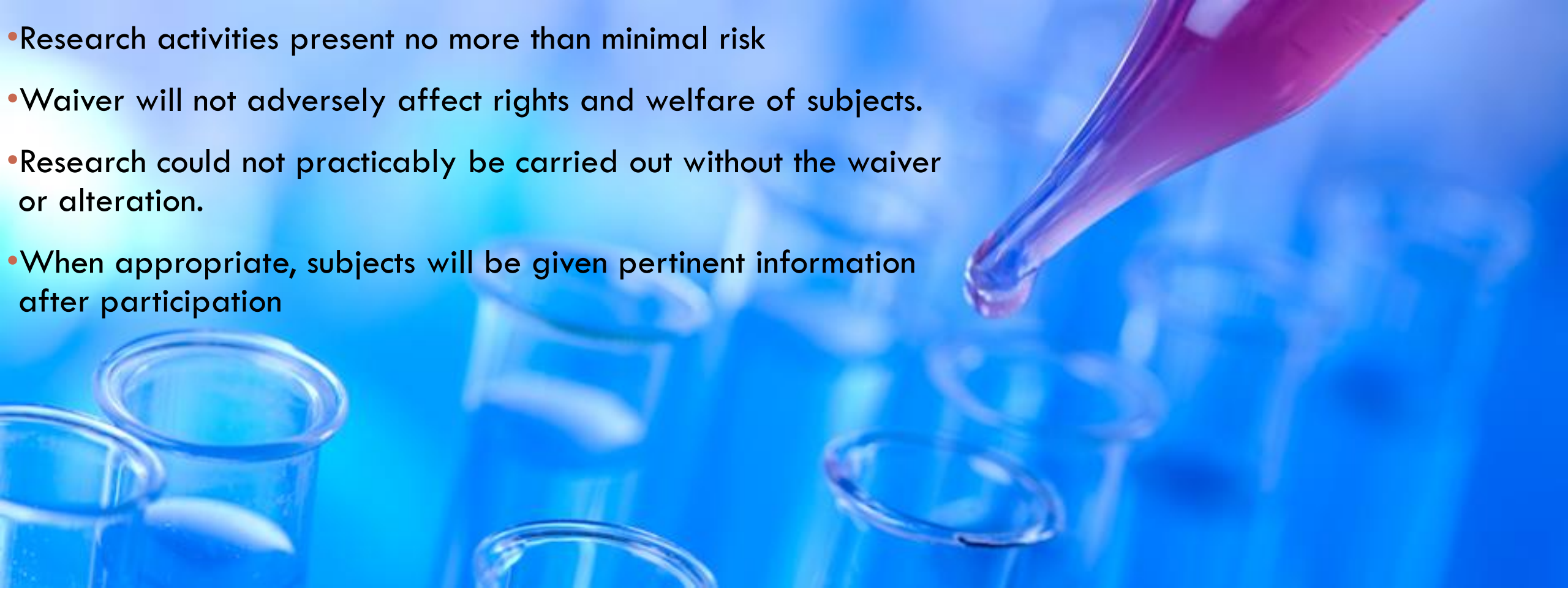
WHAT CAN THE IRB WAIVE?

- Informed consent
- Documentation of informed consent (verbal)
- Assent
- HIPAA Authorization





- Research activities present no more than minimal risk
- Waiver will not adversely affect rights and welfare of subjects.
- Research could not practicably be carried out without the waiver or alteration.
- When appropriate, subjects will be given pertinent information after participation

HOW AND WHEN CAN THE IRB WAIVE OR ALTER THE CONSENT PROCESS?

THE IRB MAY GRANT A FULL OR PARTIAL WAIVER

Full Waivers

All subjects and study activity qualifies for a full waiver of consent

Partial Waivers

Only a portion of the study qualifies for the waiver

Only certain subjects qualify for a waiver

FDA REGULATED STUDIES

The FDA *does not* allow waivers of consent or documentation of consent except:

I. Subject is in a life threatening situation
II. Military operation
III. Public Health Emergency

WAIVER OF CONSENT AND HIPAA

Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

"TELEMEDICINE CONSULTATION FOR NEWBORN NEUROLOGICAL EXAMINATION"

Objective

A retrospective study investigating the current use of telemedicine to reduce time to transportation for therapeutic hypothermia (TH) for newborn infants with hypoxic-ischemic encephalopathy, and the subsequent course of treatment and outcomes at UVMMC.

- Data was previously collected for clinical aims
- PI requires the collection of identifiers from the medical record (MRN, DOB)
- Data will be recorded with a code
- Data will be destroyed after analysis

IRB DETERMINATION - EXEMPT 4

APPROVED WAIVER OF CONSENT & HIPAA AUTHORIZATION

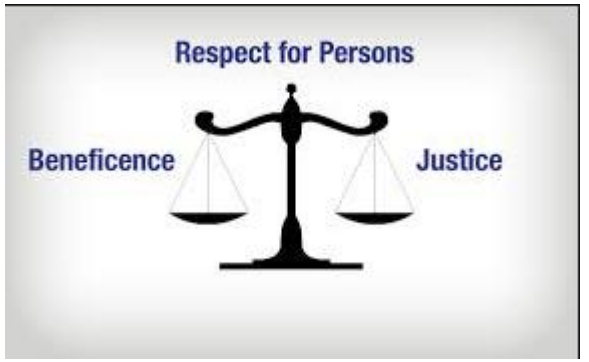
Justifications

- The research will not adversely affect the rights and welfare of subjects as it will not impact the future care of these subjects.
- The research could not practicably be carried out without the use of PHI as the DOB must be confirmed and linked to subjects who received hypothermia therapy for HIE

Justifications

- No more than minimal risk to the entire population
- Many parents have moved out of the area and written consent would be impossible to obtain from this large population
- Restricting this review to subjects who can be contacted would significantly limit the power of the study

PROSPECTIVE WAIVERS OF CONSENT



- The IRB Committee is always cognizant of one of the fundamental principles in research - Respect For Persons

- The concept that all people deserve the right to fully exercise their **autonomy**. Showing respect for persons is a system for interaction in which one entity ensures that another has agency to be able to make a choice.

- When asking the IRB for a waiver of prospective consent all five criteria in 45 CFR 46.116(f) must have ample and scientifically based justifications

PROSPECTIVE WAIVERS OF CONSENT

The IRB requires a strong justification on why the researcher can't get consent when prospectively they have access to the subject

- Is the eligible population difficult to consent
- Scientifically will this limit the data set?
- Justify why consent cannot be obtained by the legally authorized representative

Explanations that "it would be too inconvenient" or "this is just a chart-review study" are not by themselves appropriate justifications for "impracticability"

EXAMPLES OF ACCEPTED JUSTIFICATIONS

- Identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received.
- The size and population being researched. The proportion of individuals likely to have relocated or died since the time of the personal information was originally collected.
- Difficulty of contacting individuals directly when there is no existing or continuing relationship between the organization and the individual.
- The risk of introducing potential bias into the research thereby affecting the generalizability and validity of results if all subjects are not included.

EXAMPLES OF ACCEPTED JUSTIFICATIONS

- All subjects are required for validity. Incomplete participation would result in biased, invalid data.
- Without 100% participation it might not be a representative population or the results might be skewed.
- The risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or in certain circumstances.
- The 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 their consent.

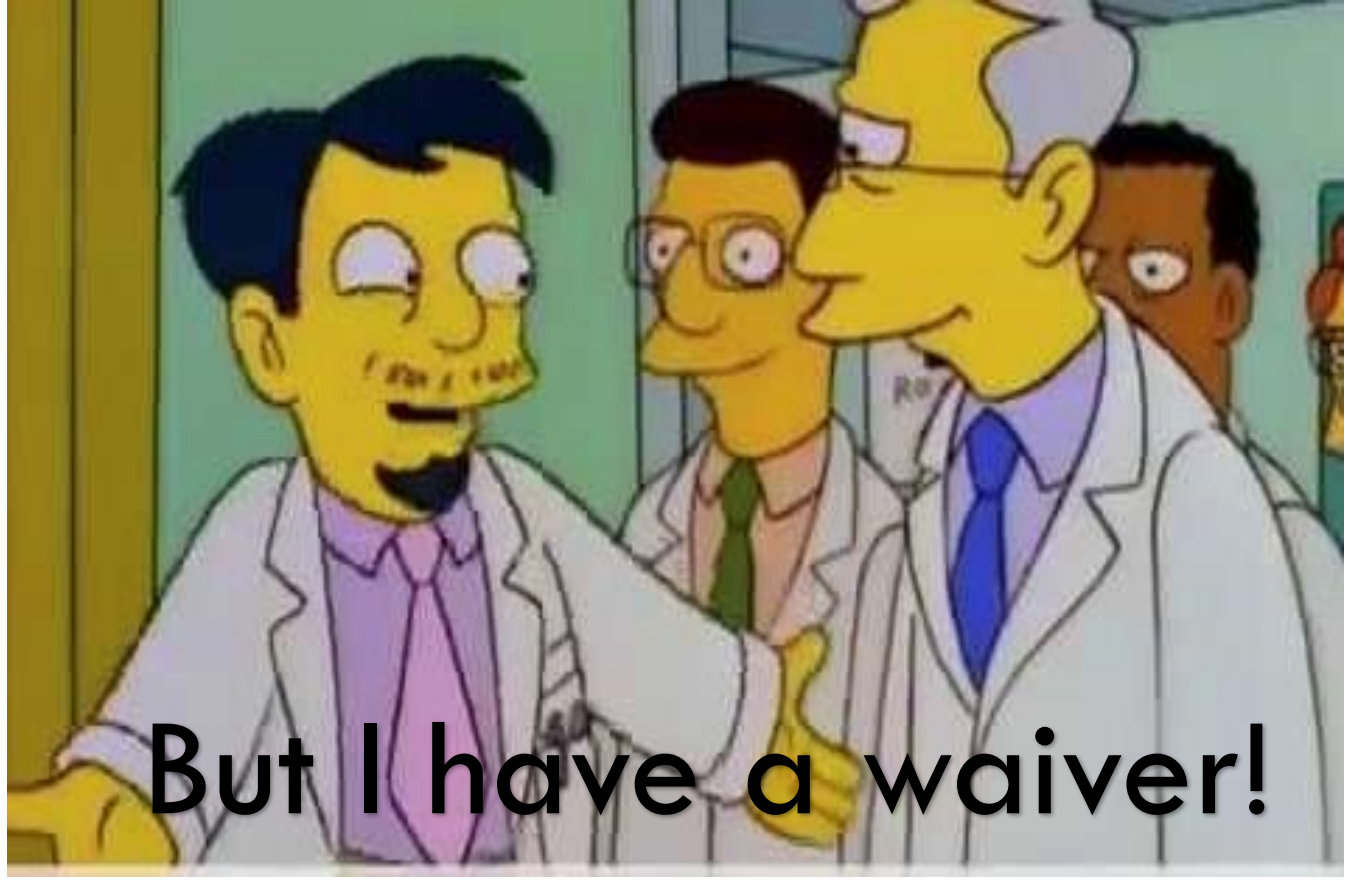
WAIVER OF DOCUMENTATION OF INFORMED CONSENT 45 CFR 46.117(C)

Exempt 2 –
Surveys, Interviews, Educational Tests, or Observation

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

In some research, verbal or implied consent of the subject is sufficient and a signed consent form is not necessary.

When is it commonly used:
Phone screening, online consent, or other situations where written consent doesn't make sense



WAIVER OF DOCUMENTATION OF INFORMED CONSENT 45 CFR 46.117(C)

The requirement for the investigator to obtain a signed consent document from some or all subjects may be waived if:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

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

3. The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk, and there is an appropriate alternative mechanism for documenting informed consent.

"SCHOOL DISTRICT CONSOLIDATION"

Objective:

The research project will examine the efficacy of Act 46 in Vermont specifically in terms of access, equity and community.

Study Procedures:

- Educators will be asked to meet with a group of 2-4 students in person or over Skype
- Answer a series of questions pertaining to Act 46 in Vermont and their perception of the impact of school district consolidation on educational quality in Vermont particularly as it concerns access, equity and community.
- 30-60 minutes of opinions a VT law

WAIVER OF DOCUMENTATION OF INFORMED CONSENT 45 CFR 46.117(C)

Consent process is still documented!

- Information sheet was created to inform participants of the purpose of the study
- Students will inform the potential interviewees that their responses will be included in a class research project that they will be submitting for a grade and that this project will presented at the Student Research Conference.
- After obtaining initial verbal consent to an interview, students will set up a time and location to meet with their interviewees.

Regulatory for obtaining verbal consent

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- After reading the information sheet any questions that they may have will be answered.
- Participants will then be asked if they wish to proceed with the interview.
- If verbal consent is obtained this will be recorded on the documentation of informed consent which will be kept in a locked file cabinet until the study is completed, at which point the document will be destroyed.

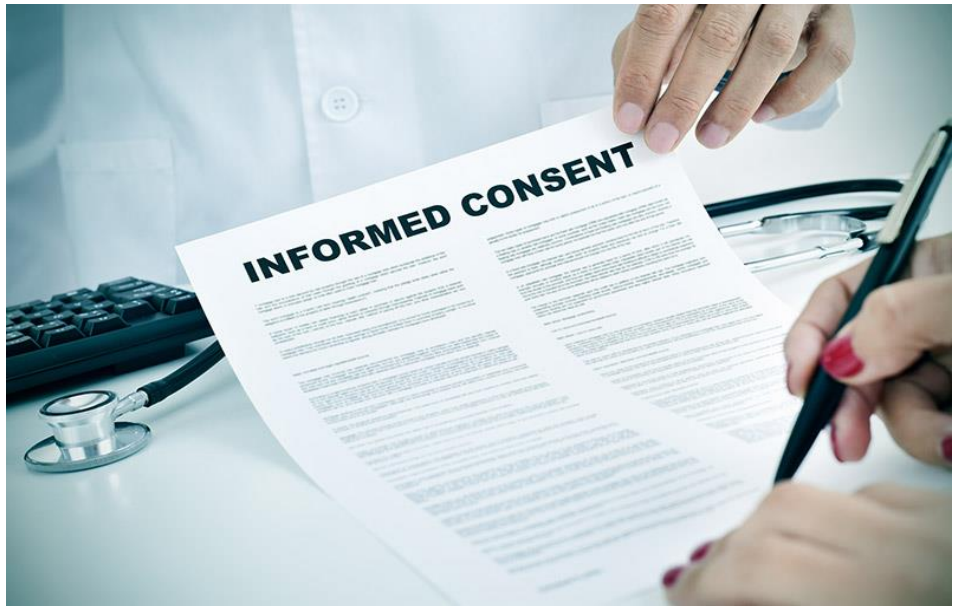
ALTERATION OF CONSENT: 45 CFR 46.116(F)

In some research, an alteration of the individual's informed consent or elements of the process may be waived.

In these cases, some of the elements of informed consent are met but not all.

The protocol involves deception of the subject for a short period.

Information typically held would be the basis for the research and subjects are later debriefed.



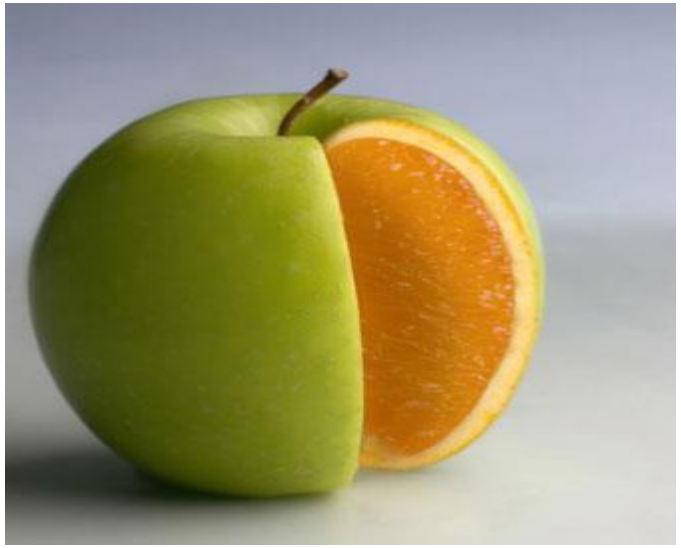
DECEPTION STUDIES

"RELATIONSHIP BETWEEN ATTENTIONAL CONTROL AND ANXIETY AND ITS EFFECTS ON AUTONOMIC AND KINEMATIC PARAMETERS IN ADULTS WHO STUTTER"

Objective:

This study will assess the effects of social stress on autonomic, behavioral and kinematic changes in adults who stutter versus adults who do not stutter.

The experiments will include a social evaluative threat component that will be *unknown* to the participant when signing the consent form.



DEBRIEFING WITH ALTERATIONS OF CONSENT

The purpose told to the subject about the research study	What was actually being studied in the research study
"Part of this experiment is ***an assessment of your social skills and public speaking ability.*** At the end of the experiment you will be required to deliver an impromptu three-minute speech about a topic. Now I won't be giving you the topic of the speech until thirty seconds before I start the camera and you begin the speech	The task to prepare a speech was included to cause some social stress. The task of preparing a speech in 3 minutes is unreasonably difficult for anyone. The purpose of including this ***stress induction was to be able to compare how you did before and after feelings of stress***".

ALTERATION & WAIVER OF DOCUMENTATION OF CONSENT: 45 CFR 46.116(F) &45 CFR 46.117(C)

Alteration of parental permission and implied consent

"MIDDLE SCHOOL HUMANITIES TEACHERS INTEGRATING SOCIAL JUSTICE EDUCATION & YPAR"

Objective:

The research project is an effort to:

1) Figure out if taking social justice classes has caused any change in the way 6th and 7th graders understand social justice issues

2) Measure how motivated students felt about learning social justice content.

How does the alteration of consent deviate from typical consent procedures?

- Students participate by completing online surveys will provide implied informed assent rather than written informed assent.
- Written parental consent is not required for students completing the online survey.

ALTERATION AND WAIVER OF DOCUMENTATION

Justifications:

- No more than minimal risk
- Students indicate voluntary consent by completing the online survey
- All students will be provided with an information sheet about the research
- Class time will be reserved for questions/discussion with the PI about the project.
- The requirement to obtain parental permission will likely skew the population participating to affect the validity of the results.
- Researchers need to include disadvantaged children in dataset. Obtaining parental permission for these students is difficult because of non-English speaking parents, illiterate parents, or parents who may be less likely to follow through than non-disadvantaged students.

WAIVER, PARTIAL WAIVER OR ALTERATION OF HIPAA AUTHORIZATION 45 CFR 164.512

Disclosure of PHI

LIST OF PHI IDENTIFIERS THAT MAKE HEALTH INFORMATION IDENTIFIABLE

1. Names.

2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geocodes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death

4. Telephone numbers.

5. Fax numbers.

6. Electronic mail addresses.

7. Social security numbers.

8. Medical record numbers.

9. Health insurance plan beneficiary numbers.

10. Account numbers.

11. Certificate/license numbers.

12. Vehicle identifiers and serial numbers, including license plate numbers.

13. Device identifiers and serial numbers.

14. Web universal resource locators (URLs).

15. Internet protocol (IP) address numbers.

16. Biometric identifiers, including fingerprints and voiceprints.

17. Full-face photographic images and any comparable images.

18. Any other unique identifying number, characteristic, or code, unless permitted by the individual

WAIVER OF HIPAA AUTHORIZATION

What is it: HIPAA authorization is not obtained for access to protected health information (PHI)

- When is it commonly used: in conjunction with a waiver of consent for a chart review
- When is it not used: A medical record review for recruitment does not require HIPAA waiver because it is considered "preparatory to research"

WAIVER OF HIPAA AUTHORIZATION

UVM Medical Center and the UVM LUSE Center may use or disclose PHI for research purposes without patient authorization if the IRB (functioning as the Privacy Board) has approved a "Waiver of Authorization."

In order to use or disclose PHI with a waiver of authorization, the IRB or Privacy Board must find:

(a) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following criteria:

(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;

(3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity.

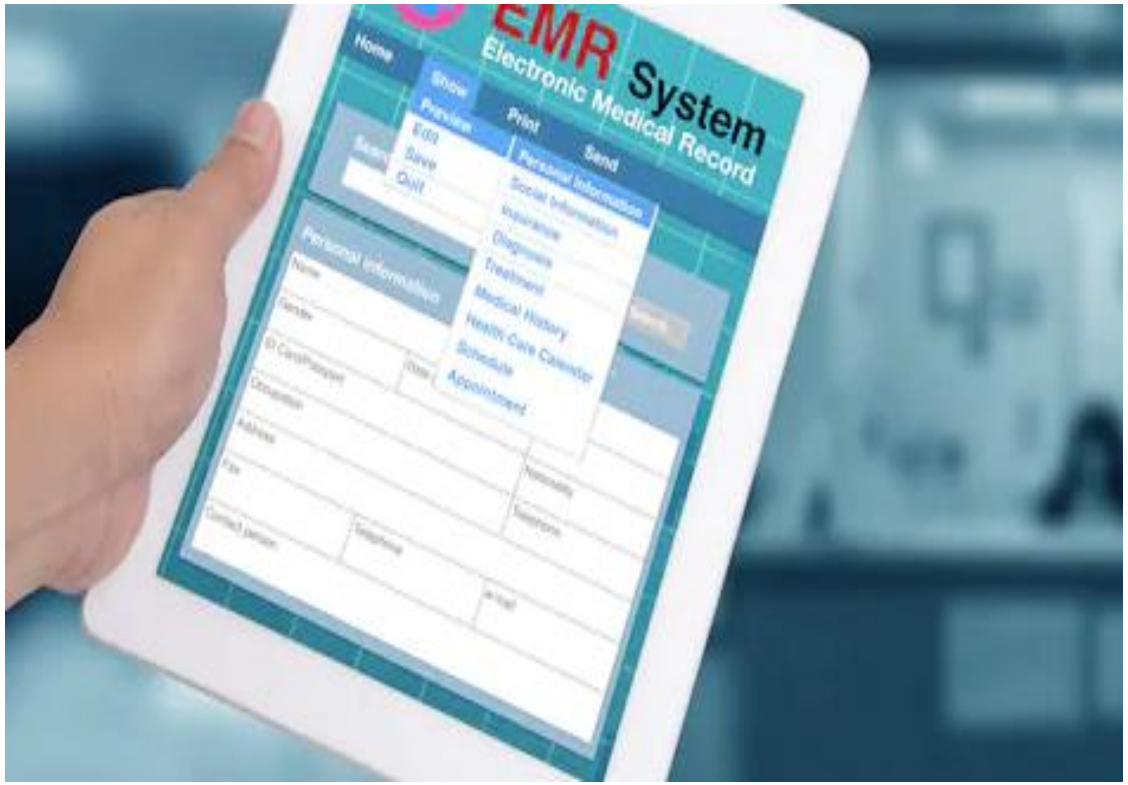
(b) The research could not practicably be conducted without the alteration or waiver; and

(c) The research could not practicably be conducted without access to and use of the protected health information.

WAIVER OF HIPAA AUTHORIZATION

Investigators accessing, recording, and/or obtaining identifiable information must have normal legitimate access

The University of Vermont IRB cannot grant a HIPAA waiver for medical records from entities outside of UVM/UVMMC



PARTIAL WAIVER OF AUTHORIZATION FOR RECRUITMENT PURPOSES

A UVM Medical Center Health Care Provider or his/her agent may, without patient authorization, review the medical records of patients with whom he or she has a current clinical relationship to determine whether they meet the eligibility criteria for enrollment into a research study, and then contact prospective subjects directly by telephone or by letter, explaining the research study and requesting a decision concerning the individual's potential interest in the study.