5.2 Waiver or Alteration of Informed Consent and HIPAA Authorization

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for granting a waiver or alteration of informed consent with or without waiver of HIPAA authorization in research.

2.0 Policy

It is the policy of the Organization that:

- 2.1. Waiver or alteration of the requirement for informed consent may be approved, provided that the IRB finds and documents the criteria specified in 45 CFR 46.116(f) have been met.
- 2.2. Waiver of authorization under the HIPAA Privacy Rule may be approved, provided that the IRB (acting as the Privacy Board) finds and documents the criteria specified in 45 CFR 164.512(I)(2)(ii) have been met.
- 2.3. Waiver of the requirement for informed consent from parents of minor subjects (parental permission) may be approved provided that the IRB finds and documents the criteria specified in 45 CFR 46.408(c) or 21 CFR 50.55 have been satisfied.
- 2.4. Waiver or alteration of the requirement for informed consent for FDA regulated clinical investigations may be approved, provided the IRB finds and documents the criteria specified in 21 CFR 50.22 have been met.
- 2.5. The IRB will acknowledge an exception to FDA's general requirements for informed consent for emergency use of a test article in accordance with 21 CFR 50.23(a), and HRPP policy 6.4 (Emergency Use of a Test Article).
- 2.6. Exception from informed consent requirements for emergency research involving an FDA regulated test article must be in full compliance with the requirements of 21 CFR 50.24, and HRPP policy 5.6 (Exception from Informed Consent Requirements for Emergency Research).
- 2.7. Complete waiver of informed consent is not allowed for research involving subjects who are prisoners. The Organization will allow the alteration of informed consent provided the criteria at 45 CFR 46.116(f) and 45 CFR 164.512(I)(2)(ii) are met, and prisoners are clearly informed in advance that their participation in research will have no effect on their parole, if such notification is relevant [45 CFR 46.305(a)(6)].

3.0 Criteria for Waiver or Alteration of Consent under HHS regulations and HIPAA regulations

- 3.1. The IRB may allow a waiver or alteration of informed consent and HIPAA authorization provided the requirements of 45 CFR 46.116(f) (and 45 CFR 164.514(I)(2)(ii) if applicable) are met; specifically:
  - 3.2.1. The research involves no more than minimal risk to the subjects (45 CFR 46.116(f)(3)(i)).
    - 3.2.1.1. For research subject to the HIPAA Privacy Rule, criterion the IRB must find that 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: (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 protected health information will not be reused or disclosed to any other person or entity (45 CFR 164.512(l)(2)(ii)(A))

Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(j)). The Organization interprets "daily life" to be the "daily life of the average person in the general population" as opposed to the daily life of the subject.

- 3.2.2. The research could not practicably be carried out without the requested waiver or alteration (45 CFR 46.116(f)(3)(ii)); (45 CFR 164.512(l)(2)(ii)(B)).

Note: In some research projects it would not be practicable to perform the research if informed consent was required. For example:

1. The sample size required is so large (for example, with epidemiological studies) that including only those samples/records/data for which informed consent could be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
2. The subjects for whom records would be reviewed may be lost to follow-up. Individuals likely to have relocated or died may be a significant percentage of the proposed subject population, thus decreasing the statistical power of the study if informed consent was required.
3. Disclosure of the study purpose would bias the research subjects so that study results are not meaningful.
4. 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 informed consent.
5. There is a risk of inflicting psychological, social, or other harm by contacting individuals or families with particular conditions.

Finally, it should be noted that, in general, investigator inconvenience or cost does not determine "impracticality" and there should be a clear rationale why the research could not be conducted with a population from whom informed consent could be obtained.

- 3.2.3. 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 (45 CFR 46.116(f)(3)(iii)).
  - 3.2.3.1. For research subject to the HIPAA Privacy Rule, the IRB must find that the research could not practicably be conducted without access to and use of the protected health information (45 CFR 164.512(l)(2)(ii)(C)).
- 3.2.4. The waiver or alteration will not adversely affect the rights and welfare of the subjects (45 CFR 46.116(f)(3)(iv)).

Note: This justification should be based on the "reasonable person" standard; that is, whether or not a reasonable person in the subject's position would consider the waiver as adversely affecting his/her rights and welfare. For example, a reasonable person would probably not object to innocuous identifiable medical information, such as height or weight being entered into a database without their knowledge or informed consent. The same reasonable person might, however, object if the identifiable information was sensitive (e.g., previous psychiatric treatment, HIV status, age at first pregnancy). It should also be recognized that in some cultures any waiving of informed consent may well be interpreted by the community as adversely affecting the rights and welfare of members of that community.

It should also be noted that the Family Education Rights and Privacy Act (FERPA; 20 U.S.C. §1232g; 34 CFR 99) protects the privacy of personally identifiable information contained within a student's educational record. FERPA applies to all schools (K-12 and postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. Generally, schools must have written permission from the student (or parent if the student is a minor) in order to release any information from a student's education record unless it meets some of the specified criteria for which release is allowed.

- 3.2.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (45 CFR 46.116(f)(3)(v)).

Note: In general, this criterion is designed to address de-briefing after research is conducted. In these situations, it may be ethically required or determined to be respectful to provide the subject with pertinent information pertaining to their participation in research under the waiver of informed consent/authorization granted by the IRB. When this is the case, the subject must be presented with an ICF (ICF) for continued participation in the research. The ICF must include a provision for the subject to withdraw their data and/or samples from use in research should they choose not to continue participation.

4.0 Criteria for Waiver of Parental/Guardian Consent (Permission) under HHS regulations at

45 CFR 46.408(c)

- 4.1. The IRB may allow a waiver of parental/guardian consent (permission) provided the requirements of 45 CFR 46.408(c) are met; specifically;
  - 4.1.1. The research must be designed for conditions or for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects.

  Note: The following are considerations which may justify a waiver:

1. Informing parents or guardians may result in harm to the child. For example, the study involves STD testing of 15-18 year old females which is permitted by state law without parental/guardian permission.
2. The research is important to the health and well-being of adolescents and the subjects are capable of understanding informed consent at an adult level. For example, the research involves asking 15-18 year old females about their sexual practices, prescribing contraception in accordance with described sexual practices and an annual follow up for three years. The questions are reasonably commensurate with questions asked during gynecologic services which the adolescents are permitted by law to receive without parental permission and the prescribed contraceptive methods are also permitted by state law without parental/guardian permission.
   It should also be noted that the Family Education Rights and Privacy Act (FERPA; 20 U.S.C. §1232g; 34 CFR 99) protects the privacy of personally identifiable information contained within a student's educational record. FERPA applies to all schools (K-12 and postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. Generally, schools must have written permission from the student (or parent if the student is a minor) in order to release any information from a student's education record unless it meets some of the specified criteria for which release is allowed.

- 4.1.2. There is an appropriate mechanism in place for protecting the children who will participate as subjects in the research.
  Note: The choice of an appropriate mechanism depends upon the nature and purpose of the research activities, the risks and anticipated benefit to the subjects, and their age, maturity, status, and condition. For example, the appointment of an advocate, provisions for referral to counseling or other safeguards may be necessary.

5.0. Criteria for 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

- 5.1. The IRB may allow a waiver or alteration of informed consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials provided the requirements of 45 CFR 46.116(e) are met; specifically;
  - 5.1.1. 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:
    - 5.1.1.1. Public benefit of service programs
    - 5.1.1.2. Procedures for obtaining benefits or services under those programs
    - 5.1.1.3. Possible changes in or alternatives to those programs or procedures
    - 5.1.1.4. Possible changes in methods or levels of payment for benefits or services under those programs.
  - 5.1.2. The research could not practicably be carried out without the waiver or alteration.
  - 5.1.3. The research is not regulated by the FDA.

6.0. Criteria for Waiver or Alteration of Consent for FDA Regulated Minimal Risk Research

- 6.1. The IRB may allow a waiver or alteration of informed consent in FDA regulated research provided the requirements of 21 CFR 50.22 at met; specifically
  - 6.1.1. The clinical investigation involves no more than minimal risk to the subjects;
  - 6.1.2. The clinical investigation could not practicably be carried out without the requested waiver or alteration;
  - 6.1.3. If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;
  - 6.1.4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
  - 6.1.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

7.0. Responsibilities of IRB/ORA

- 7.1. For research which does not involve PHI, the IRB will review the proposed waiver or alteration of informed consent in accordance with HRPP policy 2.2 (Full Board Review) or HRPP policy 2.3 (Expedited Review).
- 7.2. Research which involves PHI may only be reviewed by the convened IRB, unless the research represents no more than minimal risk to the privacy of the individuals who are the subject of the PHI, in which case it may qualify for expedited review.
- 7.3. The Checklist for Waiver or Alteration of Informed Consent and HIPAA Authorization in Research will be used to determine whether or not a waiver can be granted in accordance with the federal regulations.
- 7.4. Documentation and justification for IRB approval of waiver or alteration of informed consent and HIPAA authorization will appear in the IRB review letter and in the meeting minutes.

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