5.4 Waiver of Requirement to Obtain Signed Consent Form

1.0 Purpose

The purpose of this policy is to describe the Organization’s process for waiver of the requirement to obtain a signed Informed Consent Form (ICF).

2.0 Policy

It is the policy of the Organization that:

- 2.1. A waiver of the requirement to obtain a signed ICF for some or all subjects may be approved provided that the IRB finds and documents the criteria specified in 45 CFR 46.117(c) are satisfied.
- 2.2. A waiver of the requirement to obtain a signed ICF for some or all subjects may be approved for FDA regulated research only provided that the IRB finds and documents the criteria specified in FDA regulations at 21 CFR 56.109(c) are satisfied.
- 2.3. For research where the IRB has waived the requirement to obtain signed informed consent, the PI/authorized study personnel must still perform an adequate informed consent process in accordance with HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects).

3.0 Criteria for IRB Approval of a Waiver of Requirement to Obtain a Signed ICF

- 3.1. The IRB may waive the requirement for the investigator to obtain a signed ICF for some or all subjects if it finds any of the following:
  - 3.1.1. The only record linking the subject and the research would be the ICF and the principal risk would be potential harm resulting from a breach of confidentiality (45 CFR 46.117(c)(1)(i)).
    - 3.1.1.1. 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.
    - 3.1.1.2. This justification for waiver applies only to non-FDA regulated research.

- 3.1.2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (45 CFR 46.117(c)(1)(ii)), or 21 CFR 56.109(c)).
  - 3.1.2.1. For research regulated by FDA, the subject will be provided with a written statement regarding the research. This statement can be in the form of an informed consent form without signature blanks, or a narrative.

> Note: Examples of procedures that might meet the requirements of 45 CFR 46.117(c)(1)(ii) and/or 21 CFR 56.109(c) include (but are not limited to) interviews and on-line or in person surveys, routine venipuncture, vital sign measurements as well as some routine diagnostic procedures such as magnetic resonance imaging without contrast and electrocardiography.

- 3.1.3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained (45 CFR 46.117(c)(1)(iii)).
  - 3.1.3.1. Application must describe an appropriate alternative mechanism for documenting that informed consent was obtained.
  - 3.1.3.2. This justification for waiver applies only to non-FDA regulated research.

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

> Note: The existence of a written summary or an unsigned ICF could potentially present a risk to the subject if someone else gains access to the summary or ICF and can link the subject with the research. Therefore, it is unlikely that the IRB would require such a statement or ICF be provided to the subject when a waiver is granted under 3.1.1 above.

4.0 IRB and/or ORA Responsibilities

- 4.1. The IRB or expedited reviewer will review the proposed waiver in accordance with HRPP policies 2.2 (Full Board Review) or 2.3 (Expedited Review).

- 4.2. Documentation and justification for approval of waiver of requirement to obtain signed ICF will appear in the IRB review letter.

DOCUMENT HISTORY:

? Written: 1/12/2016 (Approved: 1/12/2016) - original author not recorded

? Revised: 1/25/2018 - revision not documented

? Revised 12/11/2024 – added (and clarified) types of procedures which might not require written consent outside the research setting (section 3.1.2); added requirement that application describe an appropriate alternative mechanism for documenting that informed consent was obtained under 45 CFR 46.117(c)(1)(iii) (section 3.1.3); minor stylistic changes. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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