



Waiver or Alteration to the Consent Process Checklist and Waiver of Consent Documentation Checklist

*Requests for waiver of consent and waiver of documentation of consent are reviewed on a case-by-case basis and are not to be viewed as an option for most research. These exceptions to the requirements are heavily scrutinized by Harrison IRB to confirm that all requirements are met.

Date: _____ Reviewer: _____

Protocol: _____ Sponsor: _____

Research Involving Waiver or Alteration of the Consent Process

Waiver of consent (which includes waiver of the informed consent process AND waiver of the documentation of consent) is only granted in specific cases that meet the criteria found at 45 CFR 46.116(d).

Criteria required to Waive or Alter the Consent Process	Yes	No	NA	Comments
1. The research involves no more than minimal risk to the subjects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. The waiver or alteration did not adversely affect the rights and welfare of the subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. The research could not practicably be carried out without the waiver or alteration.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. When appropriate, the subjects will be provided with additional pertinent information after their participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. The research is conducted by or subject to the approval of the state or local government officials.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. The research or demonstration protocol is designed to study, evaluate or otherwise examine: <ul style="list-style-type: none"> • Public benefit or service programs • Procedures for obtaining benefits or services under those programs • Possible changes in or alternatives to those programs or procedures • Possible changes in methods or levels of payment for benefits or services under those programs 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. The research is not FDA-regulated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments: _____

Waiver of Consent Documentation

Federal regulations allow an IRB to waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if specific requirements are met (45 CFR 46.117(c)).

In cases in which the documentation requirement is waived, Harrison IRB requires the investigator to provide Harrison IRB with a written statement of the information that would be provided to the subjects.

- Written Statement Attached
- NA

When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers having the investigator to provide subjects with a written statement regarding the research.

- Confirm Consent Process
- NA

This regulation does not involve waiver of the informed consent process.

45 CFR 46.117 allows the investigator to alter the requirements for written documentation of informed consent via a “short form” document which does not include all of the required elements.

Criteria required to Waive Documentation of Consent (in addition to Waiving or Altering the Consent Process)	Yes	No	NA	Comments
1. That the only record linking the subject and the research would be the consent document.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. The principal risk is potential harm resulting from a breach of confidentiality.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. The research is not FDA-regulated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. The research presents no more than minimal risk of harm to subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. The research involves no procedures for which written consent is normally required outside of the research context.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments: _____

HIPAA (The Privacy Rule) and The Waiver of Authorization

The Privacy Rule has its own list of criteria that must be met in order to waive a subject's written authorization to use and disclose individually identifiable health information for research. [45 CFR 164.512(i)(2)(ii)]

HIPAA Criteria to Waive Written Authorization	Yes	No	NA	Comments
1. The research involves no more than minimal risk to the privacy of the subjects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. The protocol must include the following: <ul style="list-style-type: none"> • An adequate plan to protect identifiers from improper use and disclosure, • An adequate plan to destroy the identifiers at the earliest opportunity. Identifiers can be maintained if there is a health or research justification or if retention is required by law. The investigator must document such justification. • Adequate written assurances that the identifiable information will not be reused or disclosed except: <ul style="list-style-type: none"> ○ As required by law ○ For Authorized oversight of the research project ○ For other research for which the use or disclosure would be permitted 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. The research could not practicably be carried out without the waiver or alteration.				
4. The research could not practicably be conducted without access to and use of this identifiable information.				

Primary Reviewer Signature: _____

Date of Review: _____

*****Harrison IRB Internal Use Only*****

Reviewed Date of Review: _____

Further Action(s) Required: _____

Reviewed by: _____

Additional Comments: _____

