



REQUEST FOR WAIVER OF WRITTEN DOCUMENTATION OF CONSENT

This request form should be used if you wish to obtain a Waiver of Written Documentation of Consent.

SECTION 1 PRINCIPAL INVESTIGATOR (PI) INFORMATION:	
1.	Liberty IRB Tracking #:
2.	Principal Investigator (PI) Name:
3.	Sponsor:

In order to qualify for a waiver of the written documentation of the consent process, the research must meet ONE of the following criteria. **Note: The research does not need to meet both sets of criteria.**

SECTION 2 WAIVER OF WRITTEN DOCUMENTATION OF CONSENT CHECKLIST:		
Criteria Set #1	YES	NO
<ul style="list-style-type: none"> The only record linking the subject and the research is the consent document. 	_____	_____
<ul style="list-style-type: none"> The principal risk is potential harm resulting from a breach of confidentiality. 	_____	_____
<ul style="list-style-type: none"> Each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern. 	_____	_____
<ul style="list-style-type: none"> The research is not FDA-regulated <i>The answer would be Yes if it is NOT FDA-regulated.</i> 	_____	_____



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	YES	NO
Criteria Set # 2		
<ul style="list-style-type: none"> The research presents no more than minimal risk of harm to the subjects. <i>Please explain.</i> 	_____	_____
<ul style="list-style-type: none"> The research involves no procedures for which written document of the consent process is normally required outside of the research context. 	_____	_____
<ul style="list-style-type: none"> The investigator has provided a script of the consent discussion that meets the requirements for the consent process and includes all required and appropriate additional elements of disclosure. 	_____	_____
<ul style="list-style-type: none"> The research is not FDA-regulated. 	_____	_____

SECTION 3 SIGNATURE AND CONTACT INFORMATION

Name of Person Completing this Form _____		Company and Title _____	
Signature _____		Date _____	
Phone _____		Email _____	



LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD



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