



ROBERTS WESLEYAN COLLEGE

Institutional Review Board Request for Waiver or Alteration of Consent

Prin. Invest. NAME	
STUDY TITLE	

1.	Is this research regulated by the FDA? Note: Most research that involves a drug, device, supplement, biologic, or botanical is FDA-regulated.	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, STOP – do not submit this form. FDA regulations do not allow the waiver/alteration of consent except in emergency use or emergency research. Contact the Office of Research Compliance for assistance.		
2.	What are you requesting? <input type="checkbox"/> Waiver of the requirement to obtain informed consent <input type="checkbox"/> Waiver or alteration of one or more of the elements of informed consent. Identify the element(s):	
3.	Is this request for (choose ONE): <input type="checkbox"/> All subjects <input type="checkbox"/> Some subjects. Identify group of subjects and provide rationale:	
Choose ONE reason (4a or 4b) to support a waiver or alteration of informed consent:		
4a.	<input type="checkbox"/> The research involves no more than minimal risk to the subjects. Explain: <input type="checkbox"/> The waiver or alteration will not adversely affect the rights or welfare of the subjects. Explain: <input type="checkbox"/> The research could not practicably be carried out without the waiver or alteration. Explain: <input type="checkbox"/> Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Explain:	
4b.	<input type="checkbox"/> The research or demonstration project is to be conducted by or subject to the approval of <u>state or local government</u> officials and is designed to study, evaluate, or otherwise examine: <input type="checkbox"/> Public benefit or service programs <input type="checkbox"/> Procedures for obtaining benefits or services under those programs <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs. <input type="checkbox"/> The research could not practicably be carried out without the waiver or alteration. Explain:	