WIRB®
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Request for a Waiver of Consent under the Common Rule And Waiver of Authorization under HIPAA

Sponsor _____ **Sponsor Protocol No.** _____

PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h)]

1.	PI Name:		
2.	PI Company Name:		
3.	PI Mailing Address: (street, city, state/province, zip, country)		
4.	PI Phone: ( )	PI Fax: ( )	PI E-mail:
5.	How would the PI prefer to receive study documents? (check one) ☐ Fax ☐ E-mail ☐ Regular Mail		

I. Waiver of Consent

1.	Describe why this research involves no more than minimal risk to the subjects:		
2.	Describe why this waiver will not adversely affect the rights and welfare of the subjects.		
3.	Describe why this research could not practicably be carried out without the waiver of consent.		
4.	Will subjects be provided with any information on this study after participation? If so, what information will they be given?	Yes ☐	No ☐

II. Waiver of authorization to use and disclose protected health information.

1.	Describe the identifiable health information that will be accessed under this waiver:		
2.	Who will have access to the information?		
3.	Are the persons who have access to the information required to sign confidentiality statements?	Yes ☐	No ☐
4.	What identifiers are included on the information you plan to use and/or disclose?		
5.	In what form will the information be maintained? ☐ Paper ☐ Electronic ☐ Both		

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6.	If the information is in paper format, describe the precautions you are taking to protect the identifiers from improper use and disclosure:			NA ☐
7.	If information is in an electronic medium, are passwords required?	NA ☐	Yes ☐	No ☐
8.	Is access to the information restricted to only those who have a need to know for performance of their job?		Yes ☐	No ☐
9.	Is this electronic system used to transmit data outside of your site?		Yes ☐	No ☐
10.	If information is transmitted, what safeguards does your system have to prevent inadvertent access to this data?			
11.	When do you plan to destroy the identifiers? **(Identifiers must be destroyed at the earliest opportunity.)** ☐ End of Study ☐ _____ years after the end of the study. ☐ Other (please specify): _____			
12.	Other than you and your research staff, who else will have access to this information?			
13.	Please explain how your research meets the following criteria for a waiver: 1. This research cannot be practicably carried out without the Waiver of Authorization. _____ 2. This research cannot practicably be conducted without the participants' PHI. _____			

BILLING INFORMATION: Please tell us who should be billed for this review. ***(If this section is not completed, the PI will be billed)***

1.	Company Name:		
2.	Attn.:		
3.	Address: (street, city, state/province, zip, country)		
4.	Phone: ( )	Fax: ( )	E-mail:
5.	Mail Stop/Cost Center:		
6.	Purchase Order number (P.O.#), if applicable:		
7.	Cost of the requested WIRB translation services will be paid by: (if applicable)		

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8.	Please describe any special billing instructions:
9.	If you have listed someone other than yourself as the billing contact, please attach written verification from that person indicating he or she will pay for these services.

By signing this statement, I am providing written assurance that only information essential to the purpose of this research will be collected, and access to the information will be limited to the greatest extent possible. Protected health information will not be re-used or disclosed to any other person or entity.

Signature of Principal Investigator _____ Date _____