

WIRB®

WESTERN INSTITUTIONAL REVIEW BOARD®
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Request for a Partial Waiver of Authorization for Recruitment

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) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail		

WAIVER 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 <input type="checkbox"/>	No <input type="checkbox"/>
4.	What identifiers are included on the information you plan to use and/or disclose?		
5.	In what form will the information be maintained? <input type="checkbox"/> Paper <input type="checkbox"/> Electronic		
6.	If the information is in paper format, describe the precautions you have to protect the identifiers from improper use and disclosure:		
7.	If information is in an electronic medium, are passwords required?		
8.	Is access to the information restricted to only those who have a need to know for performance of their job?		
9.	Is this electronic system used to transmit data outside of your site?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10.	If information is transmitted, what safeguards does your system have to prevent inadvertent access to this data?		

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11.	When do you plan to destroy the identifiers? (Identifiers must be destroyed at the earliest opportunity.) <input type="checkbox"/> Subject Contact <input type="checkbox"/> Enrollment <input type="checkbox"/> Study Accrual <input checked="" type="checkbox"/> Other (please specify): <u>Hard Copies maintained in shadow chart at the University of Hawai'i Cancer Research Center of Hawai'i's Clinical Trials Unit.</u>
12.	Other than you and your research staff, who else will have access to this information? Children's Oncology Group
13.	Please explain how your recruitment meets the following criteria: a. Recruitment cannot be practicably carried out without the Partial Waiver of Authorization. <u>Due to the number of interventional studies a pateint may be eligible for, it would not be practicable to obtain individual authorizations for each study prior to access PHI.</u> b. Recruitment cannot practicably be conducted without the participants' PHI. <u>PHI Needed for prescreening purposes to determine pateint eligibility as determined by criteris as atated in COG protocol</u>

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: Hawai'i Pacific Health		
2.	Attn.: David Stumbaugh		
3.	Address: (street, city, state/province, zip, country) 55 Merchant Street, 24th Floor Honolulu, HI 96813		
4.	Phone: (808) 535-7531	Fax: (808) 535-7855	E-mail: DavidSt@kapiolani.org
5.	Mail Stop/Cost Center: NA		
6.	Purchase Order number (P.O.#), if applicable: NA		
7.	Cost of the requested WIRB translation services will be paid by: (if applicable) NA		
8.	Please describe any special billing instructions: NA		
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 recruitment 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