Boston Children's Hospital

Date: Monday, March 17, 2025 12:58:44 PM Print Close

IRB-P00034142 General Information

Title: Sample Humanitarian Use Device (HUD)

General Information

1 * **Protocol Title:**
Sample Humanitarian Use Device (HUD)

Maximum of 230 characters may be entered.

2 **Full Title - If protocol title exceeds the 230 characters limited from field above, enter full title here. Otherwise, leave blank.**
Sample Humanitarian Use Device (HUD)

3 * **Provide a brief summary (in lay terms) of the research protocol. This should be a short description of the study that is understandable to a lay person. If applicable please include the burden and epidemiology of the disease/condition along with any unmet needs of the population.**
Brief summary

4 * **Principal Investigator (PI):** Matthew Stafford

4.1 * **To serve as a PI you must qualify under one of the following eligibility requirements. (Residents, interns, fellows and postdoctoral candidates are not permitted to be PIs). Please select the appropriate category that applies to you.**
Physicians, Dentists and Psychologists credentialed through the hospital with the BCH medical staff registrar as an active medical staff member and having an appointment of Instructor or higher at Harvard Medical School.

If Other patient services professionals:

4.1.1 **Research is part of your scope of employment responsibility and not to meet a training or degree requirement. Please explain how this research falls within the scope of your responsibilities at the hospital.**

4.1.2 **You have training and experience and confirmed clinical research competencies. Please explain your training and experience in clinical research.**

4.1.3 **Are you employed at Children's as a nurse or do you have nursing credentials through Boston Children's Hospital?**
Please note if this is checked yes, in accordance with the policies of the Nursing Department your protocol will be sent to the Nursing department for both scientific review and departmental sign off.
◯ Yes ◯ No

5 * **Is the person who will be primarily responsible for conducting the study at BCH different from the PI?**
◯ Yes ● **No**

If YES:

5.1 **Please add the person(s) who will be primarily responsible for conducting the study.**

Name	Appointment with Children's Hospital?
There are no items to display	

6 * **Has the PI, or if question #5 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human participants at BCH?**
● **Yes** ◯ No

7 * **Type Of Submission:**

- ○ New Research Activity
- ○ **New Research Activity Limited to Secondary* Use of Biological Material and Data
- ○ Establishment of Human Biological Specimen Repository/ Data Registry (only) – repositories/registries are defined as a prospective collections of specimens or data that are processed, stored, distributed to multiple investigators for use in research.
- ○ Request for Exemption
- ○ Individual Patient Expanded Access
- ● **Humanitarian Use Device (HUD)**
- ○ Reliance on Another IRB
- ○ Projects that lack immediate plans for involvement with human participants, their data and/or their specimens (i.e.training grants)

*** Use this form only if:*
1) specimens/data are not identifiable or
2) specimens/data are identifiable but recorded by PI in de-identified format or meet the waiver of HIPAA authorization criteria listed below All other uses of secondary specimens/data must be submitted on a new research activity form.

** Secondary means the tissue or data will be or was collected for a primary or initial purpose other than the research (i.e data from medical records, tissue from pathology)*

Waiver of HIPAA authorization (all criteria must be met)
• The proposed use of this data/document/record/specimen presents no more than minimal risk to the privacy of individuals
•The research could not practicably be conducted without the waiver of HIPAA authorization
• The research could not practicably be conducted without access to and use of protected health information with identifiers
• Waiving HIPAA authorization will not adversely affect the participant's rights or welfare

This form may not be selected if the study involves interaction/intervention with participants in order to obtain tissue/data specifically for this research.

8 * **Is this protocol related to child health (including perinatology, prenatal assessments, childhood antecedents of adult disease, and long-term follow up of pediatric disorders)?**

● **Yes** ○ No

9 * **Is this protocol related to cancer (primarily concerning malignancies, oncology patients, or involving use of malignant tumors)?**

○ Yes ● **No**

Note: If YES, your protocol will require review by the Dana Farber IRB instead.
For details, see: IRB Policy 2.14, "Reliance Agreement with Dana-Farber Cancer Institute (DFCI)"

10 * **Are you planning to use the Institutional Centers for Clinical and Translational Research (ICCTR) Study Operations Support?**
NOTE: the ICCTR was formerly the Clinical Research Center

○ Yes ● **No**

ICCTR Study Operations Support includes some of the following services:

- *project management (including protocol development, trial operations, and close out activities)*
- *study coordinator support*
- *research nurse or nurse practitioner support*
- *regulatory support- IRB or FDA*
- *data management (including database builds)*
- *development of case report forms*
- *data entry*
- *recruitment and retention of research participants*
- *administration of surveys and interviews*

- *biospecimen collection and tracking*
- *medical record abstraction*
- *multi-institutional clinical trial support*
- *development of data safety monitoring plans and data safety monitoring boards or committees*

11 * **Does this protocol generate study related charges in Epic that will be billed to the patient or insurance, and/or study fund?**
This includes experimental imaging, DEXA, blood samples, investigational products or devices.
Examples: A minimal risk study where the participant will answer surveys and receives physical therapy that is paid for by the study, an industry sponsored study where investigational product is given to a participant and paid for/donated by the sponsor, a federally funded study where MRIs and DEXA scans are paid for by the grant and not by the participants.

◯ Yes ● **No**

Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

12 * **Does this protocol require the department/Clinical Research Finance to invoice a sponsor (industry, foundation, or federal cooperative agreements)?**
Includes protocols with automatic payments by the sponsor, and cooperative group agreements where the study team has to provide an invoice to the prime institution
Example: An industry sponsored study where the team must invoice for milestones and/or other invoiceable items, a subcontract from CHOP where BCH must send invoices to CHOP directly.

◯ Yes ● **No**

Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

13 * **Will your study require research orders built in Epic?**
Research orders are required for the following: All ETU supported studies, Research imaging, Medications dispensed by IDS, all Research Labs including custom lab panels or studies intending to use research collects for sample collection. Study teams must request order builds for any of the above. Using clinical orders and placing a note in Epic that the order is for research is not acceptable.

◯ Yes ● **No**

If Yes:

13.1 Please select the category:

- ☐ ETU visits and/or lab processing
- ☐ Investigational Medication
- ☐ Research Collects
- ☐ Research Collects - will require processing or storage or shipment
- ☐ Research Imaging
- ☐ Standard of care medication administered as part of study protocol
- ☐ Other

If Other:

13.1.1 Please describe:

14 * **Will your study utilize the ETU?**

◯ Yes ● **No**

Note: If this study uses any ETU service, including laboratory processing, please submit a CROC Intake Form

15 * **Who is responsible for the protocol design?**

- (●) **Sponsored Designed/Initiated**
- ( ) Investigator Designed/Initiated
- ( ) Collaboration/Jointly Designed

If Investigator Designed/Initiated:

15.1 Was the protocol peer-reviewed?

( ) Yes ( ) No

IRB-P00034142 Research Team

Research Team

If the person you need to add to your protocol cannot be found using the “Add” buttons below, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that the person be added to the Research Staff. CHeRP Support will need the following information:

- First Name
- Last Name
- CHID# (if applicable)
- BCH Department (if applicable)
- Email Address

1 Research Staff - Children's Hospital Employees only:

	Last Name	First Name	BCH ID	Role	Editor	CC on Correspondence	Required Training Completed	Training Expiration	CHeRP Training	Date Modified	Date Created
View	Kuniholm	Ashley	123524	Admin Contact	yes	yes	yes	1/13/2028	yes	12/4/2019	12/4/2019
View	Ripton	Jessica	221454	Co-Investigator	yes	yes	yes	6/10/2024	no	3/17/2025	3/17/2025

2 *NOTE:* Accounts are no longer required for non-BCH researchers. These individuals remain under the jurisdiction of their home institution’s IRB and should not be listed here. If you think there is a special circumstance, please contact your IRB Administrator.

Research Staff - Non Children's Hospital Employees only:

Last Name	First Name	Role	Email	Required Training Completed
There are no items to display				

3 PI: Matthew Stafford

Required Training Will Expire: 2/2/2025

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed	Date Created
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	2/2/2022	
Continuing Education	EQuIP: Talk/Meeting	8/4/2020	8/5/2020
Continuing Education	Rounds and Discussions with Research Nurses and Coordinators	7/1/2020	7/2/2020
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/22/2018	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/12/2018	
Continuing Education	Continuing Education/Department Meeting	5/2/2018	
Continuing Education	Continuing Education/Department Meeting	6/13/2016	
Training Received at Another Institution		11/15/2015	
Continuing Education	Continuing Education/Department Meeting	10/26/2015	
Continuing Education	Research Protocol Case Discussions	11/15/2012	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/9/2012	5/9/2012
Continuing Education	Continuing Education/Department Meeting	9/30/2011	

Training Program	Continuing Education Description	Training Completed	Date Created
CHeRP Training		12/19/2010	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/15/2009	11/8/2010
Collaborative IRB Training Initiative (CITI Behavioral)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Biomedical)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Non-Interventional)		4/11/2006	11/8/2010
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	4/5/2006	11/8/2010

IRB-P00034142 Funding Sources

Title: Sample Humanitarian Use Device (HUD)

Funding Sources

1 * **Select funding category.**

- ○ Externally sponsored (federal, state, corporate, foundations)
- ○ Internally sponsored
- ○ Externally and internally sponsored
- ○ No sponsor
- ● **Private Donor**

1.1 If internally sponsored - select as appropriate:

- ☐ Department/ Division or Children's foundation funds
- ☐ Internal Children's Grant Award

1.2 Enter any additional information if applicable:

1.3 If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

1.4 Please provide the name of the private donor.

Private donor

Financial Disclosure

1 * **Do you or any person affiliated with the protocol have or expect to have any investment or financial relationship (examples below) with any entity that is providing funds or other support in connection with the protocol?**

◯ Yes ● **No**

If YES:

1.1 Please select the relationships as appropriate.

- ☐ Consulting
- ☐ Payments for protocol/study design
- ☐ Protocol-related payments not included in the research agreement budget
- ☐ Stock or Options
- ☐ Honoraria
- ☐ Scientific Advisory Board Membership
- ☐ Royalties or license fees related to the protocol, or to any test article or device which will be employed in the conduct of the research under the protocol (including any royalties or license fees received through an academic institution, including Children's Hospital).
- ☐ Equipment or other laboratory support
- ☐ Other support for research unrelated to the protocol
- ☐ Support for educational or other academic or medical efforts
- ☐ Other Grants
- ☐ Other

2 * **Do you or any person affiliated with the protocol have or expect to have any proprietary interest related to the protocol, or related to any test article or device that will be employed in the protocol? Include proprietary interests that you have assigned to any entity, including any institution you have been affiliated with.**

◯ Yes ● **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

- ☐ Patent-licensed, in whole or part, to an entity providing funds for the research
- ☐ Patent-licensed, in whole or part, to another entity
- ☐ Other

3 * **Do you or any person affiliated with the protocol have or expect to have any advisory role, appointment, or employment with any entity that is providing funds or other support for the research to be conducted under the protocol?**

◯ Yes ● **No**

If YES:

3.1 Please select as appropriate.

- ☐ Scientific Advisory Board Membership
- ☐ Other Advisory Role
- ☐ Officer
- ☐ Director
- ☐ Employment
- ☐ Other

4 * **Do you or any person affiliated with the protocol have or expect to have any financial interest, financial relationship, or position or advisory role with any other entity that may be affected by the research to be conducted under the protocol (e.g. competitor, customer, collaborator or commercial sponsor affiliate)? Include any entity that may be benefited or harmed, directly or indirectly.**

○ Yes ● **No**

5 * **Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?**

○ Yes ● **No**

6 * **The IRB prohibits special incentives in connection with clinical research, including, finder's fees, referral fees, recruitment bonuses, enrollment bonuses for reaching an accrual goal, or similar types of payments. Will you or anyone else in connection with the conduct of any research under the protocol receive money, gifts or anything of monetary value that is above and beyond the actual costs of enrollment, research conduct, and reporting of results, from the sponsor or any other entity?**

○ Yes ● **No**

7 * **Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?**

○ Yes ● **No**

8 **If any of the questions above are checked "Yes", please provide the name of the individual for whom the disclosure is made and describe in further details the disclosure. This section must include a full description of the financial relationship, including but not limited to, a detailed description, as applicable, of any test article of device involved; the advisory role or appointment; the competitor, customer, collaborator; any arrangement related to the research; and so on. Please also include actual amounts of any consulting or other monies received and the time period for which it was received. This section will not be reviewed without a full disclosure.**

9 **Upload any other pertinent documentation.**

Name	Date Last Modified	Version Number	Owner
There are no items to display			

IRB-P00034142 Humanitarian Use Device

Humanitarian Use Device

1 * **Name of Humanitarian Use Device (please include the generic and trade names as applicable)**
Humanitarian Use Device

2 * **Source (supplier or manufacturer) of the device**
Device Manufacturer

3 **Date of HUD designation, if known.**

4 * **FDA assigned HDE number**
HDE000000

5 * **What are the indications for the use of the device(disease or condition that the device is intended to treat or diagnose)?**
Indications for use

6 * **Provide a brief description of the device.**
Description of device

7 * **What is the age range of the subjects?**
Age range

8 * **Describe the contraindications, warnings and precautions for use of the device.**
Contraindications

9 * **Are there any alternative practices, procedures or devices available to treat or diagnose the patient's disease or condition? If yes, please detail. Note: To be eligible for marketing approval under the HDE regulations, the sponsor must show that no comparable device, other than this device or a device being studied under an IDE, is available.**
Alternatives

10 * **Will data be collected on the patients?**
● **Yes** ○ No

If YES:

10.1 **Will the collection of data be on safety and effectiveness and used to support a pre-marketing (PMA) application?**
○ Yes ● **No**

If YES, this is not the correct form - you will be re-directed to the General Information form where you need to change type of submission to "New Research Activity" as the type of your research.

10.2 **Will data be collected for any type of database or data repository?**
● **Yes** ○ No

If YES:

10.2.1 **Please describe.**
Description of registry

10.2.2 **Describe how the data will be stored, confidentiality maintained and who will have access to the data.**
Protection of data

11 * **Who will cover the cost of the device and any procedures associated with using or implanting the device?**
Cost of device

12 Attach the following Humanitarian Device Exemption (HDE) documentation as provided by the sponsor.

12.1 FDA Humanitarian Device Exemption (HDE) approval letter (or similar form from sponsor)

Name	Date Last Modified	Version Number	Owner
HDE approval letter.docx(0.01)	12/4/2019 2:51 PM	0.01	Ashley Kuniholm

12.2 HUD manufacturer's information, including product labeling, clinical brochure and any other pertinent manufacture information materials.

Name	Date Last Modified	Version Number	Owner
Device label.docx(0.01)	12/4/2019 2:51 PM	0.01	Ashley Kuniholm

13 * Explain who will obtain consent, when and how.

Consent procedures

14 * Attach the Humanitarian Use Device consent form or information sheet to be provided to patients. Note if data is being collected in a database or repository to be used for future research or future additional marketing initiatives, please be sure the consent includes information regarding those uses.

Name	Date Last Modified	Version Number	Owner
Consent Form.docx(0.01)	12/4/2019 2:51 PM	0.01	Ashley Kuniholm

Your consent must use the current required format.Click here to download the template.

IRB-P00034142 Additional Documents

Title: Sample Humanitarian Use Device (HUD)

Additional Documents

1 Please upload any additional documents if it is necessary.

Name	Category	Date Last Modified	Version Number	Owner

There are no items to display

NOTE: Please do not upload any documents been previously uploaded in another smartform location. This section should be used for non-patient facing documents that a sponsor requires to be submitted to the IRB. Additional study manuals may be uploaded here as needed per protocol.

PI's Statement

- **I assure the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity, I will seek approval by the Institutional Review Board (IRB).**
- **I assure the IRB that there are appropriate resources (funding, equipment, space, support services) to conduct this research safely and in accordance with all required human subject protection policies.**

* **The PI accepts responsibility for assuming adherence to DHHS, FDA, HIPAA and Boston Children's Hospital's regulations and policies relative to the protection of the rights and welfare of patients/participants participating in this study.**

● **Yes** ○ **No**

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