

## iPHFR IRB Application Information

This document contains suggested wording/responses to common IRB questions regarding the iPHFR. It is just a guideline to facilitate the IRB application in individual institutions joining the iPHFR. Not all questions/answers are required by every IRB. Please note that all information contained herein must be individualized per institution by the PI applying for IRB approval with wording appropriate to their center procedure and practices.

### General Information

**Protocol Title:** International Pediatric Heart Failure Registry (iPHFR)

**Brief summary (in lay terms) of the research protocol:**

The iPHFR is an observational registry of children who are diagnosed with heart failure. The iPHFR will examine: 1) clinical information about children presenting with heart failure; 2) severity of heart failure based on symptoms and other organ involvement; 3) medicines used for treatment of heart failure; 4) events that occur in children with heart failure; 5) outcomes of children with heart failure.

**Principal Investigator (PI):** *insert name here*

**Type Of Submission:** *will depend on the choices on your IRB application*

**New Research Activity**

New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients

**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

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

No

**Research Team:** *fill out as appropriate for your centre*

### Funding Sources

Select funding category. No sponsor.

### Financial Disclosure

**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?**

No

**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.**

No

**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?**

No

**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.**

No

**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?**

No

**The CCI 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?**

No

**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?**

No

### **Protocol Design**

**Is this a multicenter study?:** Yes

**Is the person who will be primarily responsible for conducting the study different from the PI?:** No

**Has the PI previously served as a PI of a protocol involving interaction/intervention with human subjects?:** Yes (*answer appropriately for yourself*)

## **Subject Information**

### **Enrollment Numbers**

**Specify the number of subjects enrolled at Hospital, or at sites relying on IRB review, that are required to complete data analysis.** (*Enter appropriate number for your centre*)

**If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, please indicate the total number of subjects to be recruited at Hospital or at relying sites. If not applicable, please leave blank.** (*leave blank*)

**If this is a multi-center study, please specify the total number of subjects required to be enrolled across all sites, including Hospital and reliance sites, for data analysis.** 1000+

**If this is a multi-center study and a larger number of subjects must be enrolled across all sites to account for such things as screening failures, drop-outs, and lost to follow-up, please indicate the total number of subjects to be enrolled. If not applicable, please leave blank.** (*leave blank*)

### **Types of Subjects**

**Gender:** Males and Females

#### **Age**

- Neonates (up to 30 days)
- Infants (between 30 days and 2 years)
- Children (between 2-12 years)
- Adolescents (between 13-17 years)

**Specify entire age range:** birth to 18 years

**Special Populations** (*none need to be specified*)

#### **Neonates**

**All research involving neonates must meet one or more of the following categories. Please check as appropriate. This research:**

Includes procedures do not substantially jeopardize the life or health of the neonate (this category is limited to minimal risk research only).

**Study Location:** *(answer depending on the choices on your IRB application; should reflect inpatients and outpatients)*

## **Recruitment and Remuneration**

### **Recruitment**

**Describe plans for recruitment, including identification of potential participants, who is responsible for recruitment and how and when subjects will be recruited.** Patients with a new diagnosis of heart failure referred to a heart function/cardiomyopathy service for consultation and care will be identified in the outpatient cardiology clinic(s) or the inpatient cardiac ICU or cardiology ward. Patients will be approached to participate by a member of the heart function/ cardiomyopathy team involved in the patient's care. *(use medical locations and team names appropriate for your center)*

**Will you need to search through hospital medical records for the initial screening for potentially eligible subjects?** No

**If applicable, how will prospective subjects' healthcare providers (e.g., physician, dentist, etc.) be involved in the recruitment and/or be notified of their individual patients' participation in the study?** Patients will be approached by the patient's healthcare provider and/or his/her delegate.

**Describe measures that will be implemented to avoid participant coercion or undue influence.** Not applicable

**Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?** No

### **Remuneration**

**Will subjects/families receive a form of payment, compensation or reimbursement?** No

**Please answer the following information regarding ClinicalTrials.gov registration.**

**Into which of the following category(s) does this protocol fall (check all that apply):**

(f) Protocol does not meet any of the criteria above (a-d) and research will not be registered on clinicaltrials.gov

## **Research Data, Documents, Subject Reports & Consent/Assent Forms: Storage**

**Where will research data, documents and subject reports be sent and stored? Check all that apply.** *(check what is appropriate as per your center IRB application)*

Hospital Medical Record

Departmental Medical Record

Separate Research Record  
Subject/family will receive results  
Sponsor, Collaborator and/or Coordinating Center

**Will data include patient identifiers (name, medical record, SS #)?** Yes

**Specify:** Date of Birth, dates of admission/discharge, date of death

**Where will the signed informed consent and assent be stored? Check all that apply.** (*check what is appropriate as per your center IRB application*)

Hospital Medical Record  
Departmental Medical Record  
Separate Research Record  
Sponsor, Collaborator and/or Coordinating Center  
Medical Record at another institution, hospital, physician's office, etc.  
Research Registry  
Not Applicable

### **Medical Expenses for Research Related Adverse Events**

**How will the cost of reasonably foreseeable medical care in the event of a research related adverse event be covered?** This is an observational registry and there are no anticipated medical costs associated with participation in this research registry.

### **Privacy and Confidentiality**

#### **Privacy**

**'Privacy' refers to a person's desire to control access of others to themselves. Describe the steps that will be taken to protect and assure the privacy of the subject. Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).**

Name and medical record will be accessed by the medical doctor and/or nurse who is enrolling the patient in this research project. This information will never be shared with anyone else not on the research team. There is a central data collection center at the United Network for Organ Sharing (UNOS) in the United States. Each center is assigned a code (e.g., ABC 001) and all patients are given codes at the host center so that only an ID number is sent and no private or personal information can be determined about the codes. Aggregate, de-identified data will be given to the participating sites on a bi-annual basis.

#### **Confidentiality**

**Investigators are required to obtain only the minimum data necessary to achieve the research goals. Please justify why the data you are obtaining is the minimum necessary.**

The identifiable data being collected includes date of birth, death, and hospitalizations; all of which are required to determine the age at time of events in pediatric patients and age-related outcomes which are key to the object of the registry (natural history of pediatric heart failure).

**Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.**

*Need to provide your center-specific answer regarding privacy/storage of data locally.*

The limited data set will be housed at the United Network for Organ Sharing (UNOS). Monitors and print outs are in areas that are badge access only. Access to the production databases are on a need to know access only.

**Provide a plan to protect the identifiers from improper use and disclosure.**

*Need to provide your center-specific answer regarding privacy/storage of patient identifiers.*

**Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers. For protocols that may be subject to future continuing and secondary data analysis, the IRB highly recommends providing justification for not destroying identifiers permanently.** Since this is an ongoing registry looking at natural history and outcomes, there is no clear end date that could trigger a timeline for destroying identifiers. Retaining the information is key to the data analysis for the primary outcomes of the registry. Should the registry cease to exist or be dissolved permanently, retained data will be permanently destroyed by the data coordinating center.

### **Protected Health Information and HIPAA Authorization Information**

**Protected Health Information (PHI)** is information acquired by Children's Hospital, including demographic information, that could reasonably identify an individual **AND** Relate to the past, present, or future physical or mental health, condition or treatment of an individual; **OR** Describe the past, present, or future payment for the provision of healthcare to an individual. There are some limited situations when research protocols will not use or create protected health information. For example, educational research conducted in a school setting.

**The following information is considered identifiable PHI under the Privacy Rules regulations. Indicate which of the following will be obtained.**

Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures.

### **Data and Safety Monitoring**

**Please check one of the categories.** This protocol is minimal risk and we are not including a DSMP. *(pick the correct low risk option for your institution)*

### **Risks and Benefits**

## **Risks**

**Provide a description of the foreseeable risks to subjects. Consider all types of risks, including physical, psychological, social/reputation, legal, financial, privacy and breach of a promise of confidentiality.** The only potential risk to the patient is the very minimal risk of loss of confidentiality. Every precaution will be taken to protect the participants' information as outlined above and in the consent form.

**What is the likelihood and seriousness of such risks?** Very minimal.

**Describe provisions for minimizing risks to participants.**

Patients are assigned an acrostic identifier immediately upon entry into the web-based data entry system. The electronic database complies with all national patient privacy regulations and HIPAA. All information disseminated from the registry will be in aggregate form.

## **Potential Benefits**

**Are there potential direct benefits to the research participants?**

No

**Describe how the research may result in knowledge expected to benefit society.**

The aggregate data collected in this registry has the potential to benefit society by providing a better understanding of heart failure in this patient population.

## **Pediatric Risk/Benefit Determination**

**Check the category below that best represents the degree of risk and benefit which children in this study will be exposed to.**

No more than Minimal Risk; No Potential for Direct Benefit

## **Incidental Findings and Dissemination of Results**

### **Incidental Findings**

**Is there a possibility of clinically significant incidental findings being discovered during research procedure?**

No

**Will this research produce individual results for research subjects?**

No

**Will you be able to provide individual results to research subjects?**

No

**Will you be able to provide aggregate results to subjects?**

Yes

**What format will you use to provide aggregate results to families? (check all that apply)**

Copies of peer focused publications, upon subject/family request

**Research Categories and Special Considerations**

**Please select the appropriate research category for your research. A primary category must be selected. A secondary category should be selected only if applicable.**

**Primary Research Categories:** *(pick what is appropriate for your center)*

Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies

**Secondary Research Categories:** *(probably none are applicable)*

**Nursing/Biosafety Resources**

**Will this protocol require any of the following nursing services for any research related direct care requirements?**

No

**Method of Consent**

**Check all that apply:**

Written informed consent/assent/authorization will be obtained from subjects.

*(most centers will have to obtain consent so this should be the default)*

**Waiver of Informed Consent and Authorization Requested**

*This will not be applicable to most centers. If a center wishes to pursue waiver of consent, they will need to word their application as per requirements from their IRB.*