**Renal Anhydramnios Fetal Therapy (RAFT) Trial**

 **Concept Sheet Submission Form**

**Please fill out all the lettered and numbered sections below**

(*this form will not be accepted unless all of the fields are completed*)

*This form is intended for use for all collaborations. Where* ***“***[ ] **”***appears, click on box to add* “[x] ”*.*

**A. GENERAL INFORMATION**

1. Date of submission: **Click here to enter a date.**
2. Lead investigator(s): **Click here to enter text.**
3. Study Title: **Click here to enter text.**
4. Contact Person (if different from lead investigator): **Click here to enter text.**
5. Institution: **Click here to enter text.**
6. Address:

**Click here to enter text.**

1. Telephone number: **Click here to enter text.**
2. Email address: **Click here to enter text.**
3. Submission Type: [ ]  Initial [ ]  Revised [***Click box to add*** [x] ]

[ ]  Addendum/Expansion of previously approved concept (Proposal #\_\_\_\_\_\_\_\_\_)

1. **Summary of Changes:** If submission is an amendment or addendum (to a previously approved) existing concept sheet, please summarize all changes or expansion. **If submission is a revision (to a previously deferred/rejected), investigators must submit a separate document that responds to the reviewers’ questions and/or comments.** (**NOTE:** In addition to the summary and/or responses, please highlight or track all changes to the previously submitted concept sheet.)

**Click here to enter text.**

1. Guidelines (pages 10 – 11) have been reviewed: [ ]  Yes [ ]  No
* By submitting this Concept, you agree to abide by the RAFT Publication Policy (see Appendix). The policy includes submitting manuscripts accepted for publications to NIHMS for PMCID number, if not using a NIH-approved PMC journal.
* Productivity (e.g., preliminary data analysis, presentation, and/or publication) of approved Concepts is required within 6 months of approval; otherwise the topic may be reassigned.
* Lead authors are responsible for completing an annual progress report (or as requested) for all approved RAFT concept sheets

|  |
| --- |
| **For Internal Use Only (DO NOT REMOVE)** |

Proposal#: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ Processing: [ ] Expedited-Scientific [ ] Regular

**The completed RAFT Concept Sheet Submission Form should be sent electronically to Jena Miller or Meredith Atkinson (****jmill260@jhmi.edu****;** **matkins3@jhmi.edu****)**

**B. CONCEPT INFORMATION**

1. Topic (Select all that apply):

|  |  |  |
| --- | --- | --- |
|  | [ ]  *Maternal complications* |  |
|  | [ ]  *Maternal outcomes*[ ]  *Fetal complications* |  |
|  | [ ]  *Neonatal complications* |  |
|  | [ ]  *Neonatal dialysis*[ ]  *Neonatal Outcomes* |  |
|  | [ ]  *Amniotic fluid biomarkers* |  |
|  | [ ]  *Genetics* |  |
|  | [ ]  *Proteomics* |  |
|  | [ ]  *Amnioinfusion technique* |  |
|  | [ ]  *Imaging* |  |
|  | [ ]  *Natural history* |  |
|  | [ ]  *Other:*  |

1. Sites involved in the proposed study:

[ ]  All RAFT Sites

[ ]  Other, please list the clinical sites by name

**Click here to enter text.**

1. Will this project require the withdrawal of amniotic fluid specimens from the RAFT biorepository?

 [ ]  Yes [ ]  No

1. If “Yes,” the deadline date you will require specimens (mm/dd/yy): **Click here to enter a date.**
* Following approval of the concept, requestor will complete a Biospecimen Access Committee (BAC) Biospecimen Access Request Form. The form can be requested by an email to: achbiorepository@jhmi.edu with “BAC Biospecimen Access Request Form Needed” in the subject line.
* MTA and Data Usage approvals may also be required, depending on the nature of the request.
* If samples will be sent outside of Johns Hopkins Medicine for analysis, the requestor will need to complete an external transfer request to the JHM Human Biospecimen Transfer Committee, website here:

<https://www.hopkinsmedicine.org/institutional-review-board/guidelines-policies/guidelines/transferring-human-biospecimens-to-outside-organizations>

***Potential Funding Source*** (pending application, planned application or funded effort)

1. Are you planning to submit an application for funding (i.e., R01, K23): [ ]  Yes [ ]  No

If yes, please specify and complete questions **a & b** below:

**Click here to enter text.**

1. Your grant submission deadline: **Click here to enter a date.**
2. Is a letter of support from RAFT needed? [ ]  Yes [ ]  No
* **Please inform Jena Miller (****jmill260@jhmi.edu****) and Meredith Atkinson** (**matkins3@jhmi.edu**) **about the outcome of the grant submission within 1 year following approval of concept sheet proposal.**
* **The lead investigator is responsible for notifying the RAFT team.**
1. RAFT Liaison: **Click here to enter text.**
2. Institution: **Click here to enter text.**
3. E-mail Address: **Click here to enter text.**
4. FAX Number: **Click here to enter text.**
5. Mailing Address:

 **Click here to enter text.**

**C. STUDY DESIGN (2 – 3 pages)**

Use the following organization to present your study plan and take whatever space is necessary to completely respond to each section. Complete in 12 point font only. Please submit electronic copies in WORD, RTF, or PDF format.

1. **Lay Language Summary** (Please *provide a one paragraph summary of the study and its impact on participants, written for a 10th grade reading level. If this concept results in a publication, RAFT will request an update to this lay summary. )*

**Click here to enter text.**

1. **BACKGROUND** *(a brief description of the rationale for the sub study including references)*

**Click here to enter text.**

1. **SPECIFIC AIMS AND HYPOTHESES** *(Specimens and data provided by RAFT may only be used to complete the aims described in this concept. Additional testing and use of data, including transfer to another investigator, outside the scope of the stated aims and not explicitly stated in the concept are not allowed. Additional testing and data use require review and approval from the Executuve Committee. In addition, upon approval of the proposed CS a Data Use Agreement form will be sent by the RAFT Data Coordinating Center and must be completed by the Lead Investigator.)*

**Click here to enter text.**

1. **STUDY DESIGN** (*summarize the type of study, inclusion criteria, and sample size)*

**Click here to enter text.**

1. **SPECIFIC INCLUSION AND EXCLUSION CRITERIA**

**Click here to enter text.**

1. **LABORATORY METHODS** *(Indicate the laboratory that will perform assays and if applicable, summarize how new studies will generate data, etc. If not applicable, check the N/A box.)*

**Click here to enter text.**

[ ]  N/A

1. **QA/QC PROCEDURES** *(for studies generating new laboratory data: summarize laboratory QA/QC procedures, participation in recognized program, past publication, etc., relevant to the proposed investigations or testing. If not applicable, check the N/A box.))*

**Click here to enter text.**

[ ]  N/A

1. **STATISTICAL METHODS/ DATA ANALYSIS AND SAMPLE SIZE CALCULATIONS**

*(Include a statement about statistical power. Where appropriate, indicate which variables are needed from the RAFT database and anticipated support needed from RAFT. Include how data will be reported: on paper, what database, what file structure)*

**Click here to enter text.**

Primary outcome variables:

Secondary outcome variables:

Other variables:

1. **Expected time points:**  [ ]  N/A [ ]  ALL time points

[ ]  Prescreening [ ]  Screening [ ]  Amnioinfusions

[ ]  Neonatal timepoints [ ]  >=14 days [ ]  30 days [ ]

[ ]  60 days [ ]  90 days [ ]  [ ]

1. **DATA REQUESTED**

Are you requesting a dataset to perform the analysis at your institution? [ ]  Yes [ ]  No

**Please note that in order to receive RAFT data, a fully executed data use agreement (DUA) must be obtained.** The data use agreement is submitted after the concept sheet is approved by the Publications Committee. Please note that it may take at four (4) weeks or more to obtain a fully executed data use agreement.

1. **PROPOSED TIMETABLE FOR STUDY COMPLETION:**

**Click here to enter text.**

**D. SAMPLE SPECIFICATIONS**

**Shipping procedures and pricing**

**Samples from the Biosample Repository:**

* There is no charge to distribute/aliquot biospecimens
* Biorepository does charge for external courier fees and shipping supply costs (generally ~$150 for a shipment of 192 specimens, total charge will depend on number of samples requested)
* Requesting investigator will provide a shipper account number (e.g. FedEx or UPS) so that the repository can bill the shipment
1. Sample Type\*: [ ]  Amniotic fluid
2. Are previously thawed sample acceptable? [ ]  Yes [ ]  No (**specify reason below**)

\*Specimens previously thawed for other initiatives will most likely be shipped. **If unacceptable, give a reason below for requiring specimens not previously thawed.**

**Click here to enter text.**

1. Sample Quantity\*\*: Minimum:

 Optimum:

1. Expected Amnioinfusion Numbers: [ ]  N/A [ ]  ALL infusions

Pre-infusions samples, post-infusions samples, or both? \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Expected Number of unique participants: \_\_\_\_\_\_

**E. STATEMENT OF AGREEMENT**

 I hereby acknowledge and agree that:

* All information that I provide in this Concept Sheet is complete and correct as submitted.
* Use of specimens and/or data is restricted to the aims outlined in Section C of the Study Design.
* IRB approval has been, or will be, obtained before any data and/or specimens are received.
* I will complete a RAFT Data Use Agreement, if this proposal receives approval and data is requested.
* Under no circumstances will I make the RAFT study subject ID number and/or ancillary ID number public whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.
* I will provide the RAFT CCC with a copy of all abstracts and/or manuscripts submitted, and notify RAFT when the abstract and/or manuscript is/are accepted.
* My signature below indicates a complete review, acceptance, and adherence to the guidelines for collaboration, publication, acknowledgment as outlined in this concept sheet submission form.

**Investigator Signature** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your signature indicates that you agree with all the above information and (if you are requesting data or specimens) that you have received local IRB approval or will attain approval before data or specimens are released.

**INSTRUCTIONS FOR SAVING CONCEPT SHEET:**

After completing all of the sections, save the document in the following manner.

Lead Investigator’s last name**\_**title of concept sheet ***Example:*** Miller\_How to submit a concept sheet

**INSTRUCTIONS FOR SUMBITTING REVISED CONCEPT SHEET:**

Submit a concept sheet with tracked changes and a clean version.

If an investigator is submitting responses to a reviewer’s critique and/or Executive Committee questions, the question/concern must be provided prior to the response.

 Responses must include the Proposal #, lead investigator’s name and study title.

**F. ADDITIONAL SAMPLE AND DATA REQUIREMENTS**

1. **For BIOLOGICAL SAMPLES ONLY:** A data file containing lab results and a codebook of specimen received must be submitted prior to the release of study visit data.
2. Use of RAFT specimens may require MTA and Data Usage approvals between the requesting institution and the biorepository, depending on the nature of the request.
3. Request for RAFT data will require a fully executed data use agreement (DUA) between investigator’s institution and Johns Hopkins University. Separate DUAs are required between all institutions with personnel who will have access to the data and Johns Hopkins University.

**Please read the Guidelines in the following Appendix ➔**

**APPENDIX: Guidelines**

***MANUSCRIPTS***

*Authorship guidelines*

*All publications and presentations of studies utilizing samples or data supplied by RAFT* ***must*** *include the following acknowledgement:*

**Funding/Support:** Research reported in this publication was supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health under award R01HD100540.

**Role of the Funder/Sponsor:** The funding organization had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

*Lead authors are responsible for complying with the NIH Public Access Policy, that peer-reviewed manuscripts arising from NIH funding and accepted for publication on or after April 7, 2008 are deposited in PubMed Central (PMC). The PMCID or NIHMSID should be sent to Jena Miller and Meredith Atkinson* **(****jmill260@jhmi.edu****;** **matkins3@jhmi.edu****)** *along with notification of accepted for publication or actual publication of a manuscript.*

***An electronic copy of all published manuscripts should be sent to XXXX to provide an archival record of work resulting from the study:***

***If data analysis for the manuscript has not been carried out at the RAFT DCC****, the first author is responsible for sending the computer programs, final data sets and codebooks that directly relate to tables and figures in the manuscript to the RAFT DCC. The programs and data should be labeled table1.dat, table1.sas (if SAS was used). Data received from RAFT may* ***only*** *be used for the specific aims of the analysis proposed in this concept. Additional initiatives should be submitted via a new Concept Sheet Submission Form.*

***Policy on Approved Use of Data and Specimens***

* *Specimens or data provided by RAFT are intended for the express purpose of performing steering committee-approved research. These specimens and data must* ***not*** *be provided to other investigators or used for additional projects without the written consent of the RAFT Steering Committee.*
* *Unauthorized use of data and/or specimens for work not specifically described in the aims of the concept sheet will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data* ***and specimens.***