RESEARCH PROGRAM OF BCH

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Research First Steps

The goal of this document is to inform those interested in research, how to go about turning an idea into a study. This involves three steps: getting trained to perform research on human subjects, a consultation to identify the goals of the study, and to optimize the methods. Additionally, completing the necessary paperwork for submission to the Institutional Review Board.

Step 1: Online Training

To begin research with Blythedale patients, proper training in studies of human subjects is required.

For those who have not completed this training, we recommend using the Collaborative Institutional Training Initiative at the University of Miami (CITI):

https://www.citiprogram.org/index.cfm?pageID=88

A certificate from CITI, or an equivalent human subject program is necessary.

Source: http://www.childrenandclinicalstudies.org/whydo.php

Step 2: Biostatistical Analysis and Trial Management (BATMAN)

The BATMAN service is intended to help investigators with study design, analysis and funding.

BATMAN can help you:

- Design new research studies
- Plan and write IRB protocols
- Plan and write grants
- Build an easy-to-use database, and teach you how to use it
- Plan and run statistical analysis on your data
- Edit research papers and make graphics to display your data
- Feel less overwhelmed by the process of doing excellent research

Contact Information:
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Step 3: Common Terms & Necessary Forms

Clinical studies often include terms that are unfamiliar to you. Please do not hesitate to contact Lindsey Echevarria, Administrative Coordinator, to assist you as needed.

Protocol:

The main and most important form is the Protocol. The Protocol is the document that describes a study, why the study is being done, how the study will be conducted, and how the results will be analyzed.

Source: http://www.childrenandclinicalstudies.org/whydo.php

The Protocol will describe:

- Why the study is being done;
- What types of children can be in the study;
- When the visits, tests and procedures will take place;
- The types of medicines and dosages to be used;
- How long the study will last;
- How children will be kept safe;
- Possible benefits and risks;
- How privacy will be protected;
- How side effects will be monitored and reported;
- Who will monitor the safety of the study participants and how often; and
- How the results will be analyzed.

Assent:

Even though parents and guardians must consent for their child to join a study, children should have a part in making a decision to join a study, if they are capable of doing so. When a child is asked to have a part in the decision, this is called "assent."

These forms are usually a simpler version of the consent form that parents sign. They have also been reviewed by the same safety group, the Institutional Review Board, to assure that the forms are accurate and at a child's level. Making sure children have a say is important, but remember—not all studies require assent, and the age when assent is requested can vary depending on the study.

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Institutional Review Board (IRB):

Most research done in the United States must have what's called "independent review." Typically a group of experts in research on people, who are separate from the research, reviews it. In the United States these groups of experts are usually called Institutional Review Boards (IRBs).

They review research studies to decide whether or not to allow the studies to be done at the hospital, doctor's office, clinic, or other place for which the IRB is responsible.

IRBs are made up of different types of people: doctors, nurses, ethicists, community people, attorneys, patients, pharmacists, and others.

The IRB's role is to help ensure that the study is well designed, that the risks are as low as possible, and that the rights of study participants are protected. When IRBs review studies in children, they take extra care and follow special rules.

The IRB continues to monitor the study throughout its duration for safety and to make sure it's continuing to be run properly.

Submissions & Dates:

Please submit your Protocol **two weeks** before the upcoming IRB meeting for Administrative Review, and **one week** before the upcoming IRB meeting for final submission.

IRB meetings at Blythedale occur Thursdays, every other month, from 11:00 a.m. – 12:00 p.m.

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IRB Meeting Dates:

- May 12, 2016
- July 7, 2016
- September 15, 2016
- November 17, 2016

Response forms will be distributed 7-10 days after the last IRB meeting.

Forms:

After you have completed all of the above steps, please click the *Research* section of the Blythedale website to find the downloadable forms for your study.

The **mandatory** forms are:

- Main Protocol
- Consent
- Assent (Optional depending on the age and cognition of the child)

The **follow-up** forms are:

- Renewal
- Amendment
- Progress Report
- Termination
- Adverse Event

We are very excited that you are interested in conducting a research study at Blythedale, and we are happy to assist you throughout the process!

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