Startup Checklist

Steps that must be completed prior to initiation of *My Life, Our Future* at your site include those listed below. For your convenience, check off the items once completed.

__ 1. Execute the *My Life, Our Future* Project Agreement with ATHN
   a. This may be done concurrently with IRB submission
   b. Submit signed Project Agreement to ATHN, via email at MLOF@athn.org
   c. Upon receipt of signed Project Agreement, your site will receive a one-time payment to cover IRB submission and project-related costs

__ 2. Obtain IRB approval for *My Life, Our Future* (see below for more information)
   a. This may be done concurrently with Project Agreement execution
   b. Access the My Life Our Future Affiliate Toolkit to obtain all the documents needed for IRB submission. The link to the Toolkit is at the top of the www.athn.org home page - Affiliate Toolkit. The Affiliate Toolkit is in a password protected area of the athn.org website. Upon ATHN receipt of the HTC interest form, ATHN support will notify the contact(s) at your HTC about access to the Toolkit. If you have an athn.org account, you will be notified that your access to this area is granted. If you do not have an athn.org account, the ATHN support instructions will guide you through the steps to create an account and gain access to the ATHN Affiliate Toolkit.
   c. You are encouraged to use our central IRB, Western IRB, if possible. If not, your local IRB can be used. Remote enrollment by Puget Sound Blood Center may be available if your site does not have a study coordinator. For more information, contact MLOF@PSBC.org
   d. Email Puget Sound Blood Center at MLOF@PSBC.org once IRB approval is obtained and include the IRB approval letter and approved stamped consent form.

__ 3. Obtain access to Clinical Manager and Study Manager, the systems you will be using for MLOF. This can be done while your HTC is processing the ATHN agreement and waiting for IRB approval.
   a. Determine which HTC staff will need access to Clinical Manager and Study Manager for the MLOF project.
   b. Get to know your ATHN Administrator. Your ATHN Administrator will assist in getting staff access to Clinical Manager and Study Manager and will be able to demonstrate key functions of these systems.

__ 4. Once the Project Agreement is executed and IRB approval obtained, at least one *My Life, Our Future* Coordinator from your site must participate in a MLOF Startup Webinar. Participation by the primary Clinical Manager user is highly recommended
   a. The Startup Webinar will provide details about enrollment, use of Clinical Manager and Study Manager, sample collection and shipping, how to fill out study forms, results reporting, etc.
   b. Webinar registration information will be emailed to all *My Life, Our Future* Coordinators as they are scheduled. Once your site has executed the Project Agreement and obtained IRB approval, you may register for the webinar.

Upon completion of the Startup Webinar, your site will be cleared to initiate *My Life, Our Future,* and Puget Sound Blood Center will send your site the laboratory materials

Startup Checklist

IRB submission

The documents listed below are part of the Affiliate Toolkit and are provided for submission to IRB. They have been reviewed and approved by Western IRB.

- Certificate of Confidentiality
- Protocol
- Consent/Assent Form
- Adolescent and Child Information Sheets
- Media Consent Form (needed only if you plan to prepare patient testimonials, photos, interviews)
- Recruitment materials – choose which work for your site
    - Letter/Email Verbiage
    - Telephone Verbiage
    - Booklet Information Brochure
    - Trifold Information Brochure
    - Recruitment Flyer
    - Slim Jim
    - "Genotyping for Progress" *HemAware* Article
    - My Life, Our Future website (www.mylifeourfuture.org)

Helpful tips for getting started

- Ensure staff is available and trained to perform project activities
    - Review steps for executing Project Agreement and submitting to IRB
    - Discuss your site's patient recruitment methods and enrollment process
    - Practice sample processing and shipping steps
    - Identify study coordinator and back-up coordinator (record keepers and project admin)
    - Review key contact information for ATHN and PSBC (see below)
- Determine if you are able to spin/freeze NaCitrate tubes or have laboratory resources to do so
- Create project rollout plan/processes
    - Determine how you will assess eligible patients
    - Develop processes to track recruitment, enrollment, and declines/refusals to participate
      Review instructions on how to use Clinical Manager and Study Manager for MLOF. These instructions are also part of the Affiliate Toolkit.

- Note: The Study Manager is compatible with Internet Explorer 9, Firefox 12+, Safari 5+, and Chrome 22+

Support is available

- For assistance with your IRB submission, email Puget Sound Blood Center at MLOF@PSBC.org
- For assistance with the Project Agreement, email MLOF@athn.org
- For assistance in using Clinical Manager or Study Manager or in accessing to the Affiliate Toolkit, email support@athn.org

mylife ourfuture
Genotyping for Progress in Hemophilia

Startup Checklist