NF Research Initiative

10/16/17 - Meeting Minutes

1. Agreements

a. Steering Committee Charter

1. **David Miller:**
    a. We are eager to get these reviewed at your local institution's office of sponsored programs so we can know if there are things that need to be changed
    b. We will still amend this to include the idea about how to incorporate new members, and circulate an updated version to all SC members ASAP
        b. **Adrienne Flanagan:** Have we circulated who is going to be in working groups?
    a. **David Miller:** We have had some response, but hopefully that won't preclude having a document that governs the steering committee
    b. **Angie Hirbe**: I think all the documents look fine
    c. **Adrienne Flanagan**: I have not looked at this in detail
    d. **David Miller**: If you're ready to sign this, you're going to want to show it to your representatives at your institution (Office of Sponsored Programs). Everyone should show document to administrators at their local institutions and then we can move forward
    e. **Chris Moertel:** We've already showed documents to administration and we have all the regulatory stuff in progress
        i. Aware that they have an end of the month deadline to get this done
    f. **David Miller:** We'd like to vote on the Steering Committee Charter on November 20th
        i. **Katherine Piculell**: The Steering Committee Charter still needs to get updated with Working Group descriptions and how we would incorporate new members.

2. IRB Strategy

a. **David Miller:**
    1. Ultimate goal: get samples processed for genomic sequencing before we have in-person meeting on Monday, April 23rd in Boston
    2. Want to bring some data to CTF conference in Paris November 2018
    3. It will take several months to get MTA's done, get samples processed and get data back
b. Prospective samples
    1. Do we want a central IRB or we can create a protocol that we share with various institutions?
    2. *Or we can continue to collect samples the way they've been done at individual institutions and this may end up resulting in less bureaucracy*

a. Unanimous opinion of those on this SC call that we can continue to collect samples based on IRB protocols already in place at the various institutions (for prospective collection also)

3. **Angie Hirbe**: WashU IRB is in place - just need MTA
    a. If someone has the right protocol in place we should just move forward
    b. Other institutions can use our protocol as a template
4. **Adrienne Flanagan**: If people have their IRB's we can just work with what we have
    a. **Adrienne Flanagan** asks - Are you planning on doing multi-regional sequencing (multiple areas of each tumor)?
        i. **David Miller:** Genomics working group will make recommendations and SC will decide how to sequence, but this does make sense (due to tumor heterogeneity)

1. We want to generate most useful data that we can
2. It's a good idea to do sequencing for multiple sites

        ii. **Adrienne Flanagan:** Is it ok for people to extract their own DNA and send DNA?
            a. **David Miller**: I would be very happy with that. This is often more feasible and desirable for various institutions to do own extractions. This way people don't have to send more tissue than necessary. We don't want to be a tissue bank.

There may be 2 options (TBD by genomics and pathology work groups):
1. Send X amount of tissue
2. Send X amount of DNA and RNA

        iii. **Adrienne Flanagan:** Prefers one place to do sequencing. If samples are in various places, we can scan tumors to compare with genomics (take a section of fresh frozen to correlate histology with what is being sequenced). Everyone can comment on these scanned samples to look at them.
        iv. **Angie Hirbe:** This is something I want to bring up in Oncology & Pathology working group. We want to connect histologically with genomic data
        v. **Adrienne Flanagan**: For many of the older samples, DNA will be great and RNA will not be as good.
        vi. **David Miller**: My preference would be to do DNA sequencing even if we can't do RNA sequencing.

1. These will be issues addressed in Genomic Working Group (to make a proposal that the SC will approve).

c. Use Case Scenarios for DUA and IRB

1. What is allowable in terms of data sharing?
    a. **David Miller:** A possibility is to have annotated data. For cases where people want access to raw data they have to apply to be a co-investigator.

a. What would people prefer to do in terms of access to the data? Should there be an embargo period? We could waive embargo period and make data readily available to entire consortium
b. **Adrienne Flanagan:** If someone puts in more cases than someone else, that may affect the decision
c. **Angie Hirbe:** It's reasonable to give every site the option to have an embargo period and they can forgo it if they want
d. **Chris Moertel:** Data sharing protocol of Synodos could be an example (David Miller will check with CTF to see how that was written)

3. Working Groups

a. Descriptions of Working Groups
    1. *Oncology & Pathology*
        a. A lot of the work has been done already by Angie Hirbe (registry) and the BCH study team (pathology SOP)
        b. Will meet "as needed" to look at the clinical data points in the registry to make sure there is no disagreement and no omissions
        c. Will review and approve pathology SOP document
        d. Granular issues – quantity of samples etc.
    2. *Genetics & Informatics*
        a. Provide input to the SC about what we are going to do for the genomic analysis in terms of depth of coverage, what samples we need and how the data is going to be processed
    3. These working groups can meet 2 or 3 times in the near future to make a robust proposal for the end of this calendar year. As time goes on, they should not need to meet very often (not a major time commitment)
    4. *Data Use & Publications*
        a. Rules for sharing and accessing data
        b. Policy about a "data embargo" that allows individual sites a period of exclusive access to their data, and then it gets shared
        c. How do we want to handle credit for publications and make sure everyone is treated fairly?
        d. Ongoing role in order to vet future proposals to use the shared data (avoid overlapping projects)
b. Scheduling Working Group meetings
    1. **David Miller** foresees people reading documents very carefully for WG meetings since it will be a more focused scope of work
    2. We've had mixed results with Doodle polls for a recurring meeting
    3. We'll focus on getting some near-term meetings scheduled so that we have progress before the next SC meeting
    4. Focus subsequently on identifying best times for future meetings

c. **Coordinating Center** will schedule meetings for working groups
    1. We'll be administrative support for meetings (follow-up action items, keep minutes, etc)

4. Consortium Membership

a. Since the call in September, we have had requests from people who are interested in joining the consortium
    1. **David Miller:** How do we want to handle the addition of other sites to the consortium? Do we want to have affiliate members who are able to participate and who are not on SC?
        a. **Justin Jordan**: The more samples the better for the data
        b. **Adrienne Flanagan:** Happy with that. No strong feelings about it
        c. **Chris Moertel** – I am an affiliate with Mayo and working with affiliate Children's Hospital Minnesota. Don't want to make this too cumbersome for you, but the more the better, and increasing membership is totally fine.
    2. **David Miller:** Is there anyone who is opposed to idea of bringing on additional members?
        a. As part of participation agreement, we will state that we have consortium members and if other people want to join, they can be in working groups, can collaborate, and after they have been in consortium for a year, they would be eligible to have a seat on SC. We don't want to add too many people to SC right away. There was unanimous agreement on the call that this would be ok.

5. April 23, 2018 In-Person Meeting

a. People will come in over weekend and we can have dinner night before (Sunday evening)
b. Will keep it to a one day meeting so people can leave at the end of the day on Monday
c. Scheduling meeting 6 months out will give us an incentive to generate data making this meeting a milestone
d. **Angie Hirbe:** Ready to go with documents for registry…can still make changes to documents
    1. Huntsman has requested some changes
    2. Would like to finalize things so we can start inputting data
e. To extent possible, would like to get MTA and DUA in place

Meeting Attendees:

David Miller (Boston)

Jesse Hart (Providence, Rhode Island)

Chris Moertel (Minnesota)

Anthony Griffin (Toronto)

Adrienne Flanagan (London)

Justin Jordan (Boston)

Xia Wang (Moffitt)

Angie Hirbe (Wash U)

Lor Randall (Utah)