

Steering Committee 11/14/13 Minutes

Present: Maine, Tufts, Duke, Florida, Beth Israel, Northwestern, Tennessee, HealthPartners, Kansas, Nebraska, UT Southwestern, Phoenix, Central Lab, NIDDK

1. Recruitment

- In ~1 month, D2d has completed 100 screenings, 21 baselines and 4 randomizations.
- Common reasons for screen failures include high doses of vitamin D and high/low BMI.
- It is important for site investigators and especially RCs to explain to participants that the allowed amount of supplemental vitamin D and calcium is consistent with current recommendations and the evidence for high dose therapy does not exist. D2dstudy.org has information on this topic to educate the public and research staff. A Talking Points document has been developed and available on the portal.

2. Pre-screening Data Collection to identify and quantify exclusions at pre-screening.

- Data will be collected monthly via Survey Monkey for the previous month. Information collected includes the total number of people prescreened and the reason for not proceeding to screening.

3. Central Lab

- Thanksgiving schedule: All samples must be **shipped by Tuesday 11/26** in order to be received by Wednesday 11/27.

4. Sub-committee Updates

Ancillary Studies

- Right now is a good time to start thinking about any ancillary studies, including what kind of additional samples are needed.
- LOIs and applications need to proceed to grant application in a timely manner and the policy has been updated to included. Revised policy is attached for review and SC approval..
- The NDEP educational materials should be supplied to all participants at their baseline visit as these materials were approved as part of the D2d main study IRB submission. The NDEP Ancillary study has been approved by some IRBs other sites are in the process of obtaining the approval. Once approved participants will be asked to complete the pre and post questionnaires. Approved ancillary studies will be listed on the D2d web portal.

Publications and Presentations

- There has been an update to the policy clarifying tiers 1, 2 and 3. There is also a 9 month limit from approval of proposal to manuscript submission (extensions are possible based on circumstances). The revised policy is attached for review and approval.

Recruitment and Retention

- Each site has been assigned a recruitment advocate. Advocates are expected to keep in regular contact with their sites (2x month), encourage the sites and make recommendations. The advocates will present successes or challenges their sites may be having once a month to the RRS committee.

Support and Education

- Currently working on developing educational materials.

Research Coordinators Subcommittee

- Met once and will work to collaboratively to address issues.
- Eventually the CC will hand the committee over to research coordinators and chairs will be elected.

5. Vitamin D Advocacy Groups

- These groups believe a massive amount of vitamin D intake is necessary and that D2d trying to limit vitamin D intake is unethical.
- In order to assist research coordinators and other staff who may be subject to such questions, a list of talking points will be provided to the sites so they are prepared to respond to such questions.

Action: Committee members review the revised Ancillary Studies Policy and the Publications and Presentations Policy reply to the e-mail with your approval or comments. No reply by Nov. 30, 2013 will be considered a vote to approve.

Next Meeting Date: December 12, 2013 at 12:00 pm EST

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