TARGET Ancillary Study Submission and Review Procedures

Investigators are encouraged to propose and conduct ancillary studies related to the TARGET Trial. Ancillary studies refer to studies that are distinct from the main TARGET Trial, but propose questions and test hypotheses that are congruent with the goals and purposes of TARGET. Such studies may require tests or data that are not routinely obtained in the main TARGET Trial protocol, or may involve analyses of trial data in ways not planned in TARGET. Ancillary studies may involve some or all TARGET subjects and clinical sites, depending on the eligibility criteria of the study, sample size needed, or interest of the participating TARGET sites and investigators.

Ancillary studies will enhance the scientific value and productivity of TARGET, and help ensure the continued interest of the diverse group of investigators who are critical to the success of the trial. These studies provide an exceptional opportunity for investigators, either within or outside TARGET, to conduct additional projects leveraging the existing infrastructure of the ongoing trial. In general, ancillary studies will require additional funding from the NIH or other sources. For investigators interested in applying for NIH funding, the preferred mechanism for TARGET ancillary studies is the Clinical Observational (CO) Studies in Musculoskeletal, Rheumatic, and Skin Diseases (R01), PAR-15-115. Discussions about the appropriateness of an individual project for this mechanism, and about other NIH funding mechanisms, can be pursued with NIAMS program officer, Dr. Jim Witter (witterj@mail.nih.gov).

Application Review Process

To protect the integrity of the TARGET Trial, all ancillary studies must be reviewed and approved by the TARGET Ancillary Studies Committee (TASC), and funding demonstrated, before gaining access to TARGET data, samples or participants. New ancillary study proposals should be sent to the TASC for review and approval. The TASC will consist of TARGET investigators as well as a member of the Data Safety Monitoring Board. The TASC will review the proposal and make a recommendation to the TARGET Executive Committee (EC). Final approval/disapproval will then be made by the EC.

Ancillary study forms can be obtained by calling or emailing the TARGET project manager, Alyssa Wohlfahrt (617-525-8784, awohlfahrt@partners.org) or via the TARGET website (in development-http://www.targetra.org/). Applications will be accepted on a rolling basis. Complete ancillary study applications will be reviewed by the TASC with a standard turn-around time of 6 weeks.

The following specifications should be noted while planning for submission of an ancillary study proposal:

- All TARGET ancillary studies must be independently funded by the investigator or by sources obtained by the investigator and justified with an itemized budget. Costs for additional infrastructure support should be included. As an example, for samples that require additional processing, the additional infrastructure needed should be included in the budget.
- At least one TARGET investigator and a member of the administrative core and/or DCC should be included as either a primary investigator or collaborator.
- Proposed studies must not negatively impact the main trial and should comply with the TARGET publication policy.

- Ancillary studies should not confer undue burden upon participants in TARGET, the TARGET DCC, or site personnel.
- Analyses on data or samples after the baseline will not be permitted until the completion of the TARGET Trial.
- All main TARGET Trial data will reside at the DCC and will be released at the agreed upon time points to ancillary investigators .
- Data generated from ancillary studies to the TARGET Trial will be incorporated into the TARGET database when data are requested from TARGET for analyses, or within one year of the close of the ancillary study.
- If DCC resources are to be used, arrangements must be made in advance with the DCC Principal Investigator. In general, costs associated with ancillary study data management and administrative time must be budgeted into the ancillary study.
- All proposed ancillary studies must be submitted to the TASC in time for review, circulation to appropriate committees, and to obtain clearance prior to submission to a funding agency. Studies submitted for approval less than 60 days prior to a funding application deadline may not receive timely approval (with the exception of applications due November 2015).

During the review process, highest priority will be given to studies which:

- Do not interfere with the main TARGET objectives
- Have the highest scientific merit
- Produce the least burden on TARGET participants

Acknowledgement of Terms of Collaboration

Investigators with approved ancillary studies will report to the Chair(s) of the TASC and the EC every year regarding the status of study funding, initiation and terminations dates, success of data collection, and abstracts and manuscripts. By submitting an Ancillary Study proposal for TARGET, investigators agree that:

- Data access and analysis involving post-randomization outcome data will not be permitted until the main trial is complete. If an investigator feels that a proposed analysis and/or publication can be conducted without affecting the randomized portion of the trial, or having a deleterious impact on the conduct of the overall trial, he or she may appeal to the TARGET ASC, SC, and DSMB.
- A written progress report on ancillary studies will be made once a year to the TASC and to the EC.

I, _____, as principal investigator of the TARGET

ancillary study entitled _____

_____

_____, have read and will abide by

the above TARGET Ancillary Study Submission and Review Procedures.

_____ _____

Signature Date