

TrialNet Living Biobank Initiative

Instructions for Applicants

The Living Biobank initiative has been developed to enhance the TrialNet ancillary studies program. In accordance with ancillary study policies for access to TrialNet subjects ([Subject Access Policy](#)), all living biobank applications must be reviewed and approved by the Ancillary Studies Committee prior to initiation. If a proposed study might cause deviation in the study protocol, or may interfere with the subjects' interest or participation in TrialNet, then the study must be additionally reviewed and approved by the TrialNet Steering Committee before formal approval is granted. Applications must be submitted using the [Subject Access Application](#).

Access to the living biobank requires support from the TrialNet network, which will be facilitated by the TrialNet Coordinating Center (TNCC). The scope of TNCC support will vary depending upon the nature of each proposal. Services may be limited to sample procurement, or extend to include laboratory processing, specimen storage, additional data capture or non-laboratory procedures, and/or statistical analysis support. Awardees should plan to enter into a contractual agreement with the TNCC for funding of services related to a successful proposal.

Living biobank applications must include a comprehensive study budget for all requested TNCC services. Please refer to the [Living Biobank Cost List](#) for general specimen collection costs, site reimbursement costs, and TrialNet administrative costs. Please consult the TNCC for cost estimations for specialized requests not covered within the price list. Contact information is provided on the following page.

The following supplementary information has been provided to aid interested researchers in the design of living biobank proposals:

Protocol Design Tools

Please refer to the Natural History protocol synopsis, visit schedule, and subject consort diagram to ensure that desired subject populations are followed within the Natural History study and are available for study. Applicants are encouraged to contact the TNCC with questions regarding study feasibility or design.

- The [Natural History Protocol Synopsis & Assessment Schedule](#) has been provided for informational purposes. Living biobank proposals may include specimen collections at protocol-specified study visits or at any time point in between. Blood volumes should be referenced to ensure that daily and 8-week blood volume limits are not exceeded.
- The [Natural History Subject Consort Diagram](#) displays the characteristics of the current Natural History population available for living biobank studies, including subject autoantibody status, glucose tolerance, and Type 1 diabetes risk.
- A [TrialNet Ancillary Studies List](#) has been provided to avoid proposals which duplicate current efforts.



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IRB Information

The Natural History Study Monitoring Consent Form includes language which allows participating sites to contact subjects for additional specimen or data collections. Please refer to the [Model Natural History Monitoring Consent Form](#) for additional details.

TNCC Contact Information

For all inquiries related to the living biobank initiative and application process, please contact:

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