LYME DISEASE BIOBANK

A BAY AREA LYME FOUNDATION PROGRAM

Lyme Disease Biobank Applicant Instructions – Unblinded Discovery Panel

Overview

The Lyme Disease Biobank (LDB) is a collection of human biological samples to facilitate research in the field of Lyme disease (LD) and other tick-borne infections (TBI). This multiyear initiative launched in 2014, and whole blood, serum, and urine were collected from individuals with suspected acute LD presenting with or without an erythema migrans (EM) or annular rash (cases) and unaffected individuals (LD negative controls from endemic regions). A case report form (CRF) was used to collect information about symptoms, EM (if present), current medications, history of LD and other TBI, medical history, and demographics. Photographs of EM were also taken (if present). Testing was performed, in a blinded fashion, to confirm the presence of *Borrelia burgdorferi*, *Anaplasma phagocytophilum*, *Babesia microti,* and *Borrelia miyamotoi* in the samples by qPCR. Serologic assays (ELISA followed by Western immunoblotting, and C6 peptide analysis) were also performed. Through four seasons of collection, ~450 participants have been enrolled at three sites (East Hampton, NY, Boston, MA, Martha's Vineyard, MA, Marshfield, WI). Each participant's donation provides samples for ~50 research projects, with aliquots of whole blood (1 and 2 ml), serum (250 µl), and urine (1 ml). Blinded and deidentified samples are available to qualified investigators through an application process. An unblinded discovery panel of 12 samples (5 cases and 7 controls) is available for projects earlier in development. Summary demographic information, clinical data, and testing data are available with the discovery panel. Additional data are available upon request.

Application and Review Process Unblinded Discovery Panel

Each potential sample user (herein "applicant") must submit an application that includes a description of their assay/research, whether they have tested in human samples, and how the unblinded panel will help advance their research program. Applicants must also submit their CV. Applications can be reviewed without Institutional Review Board (IRB) approval, however IRB approval or exemption from the applicant's IRB is required prior to releasing samples. The LDB PI will conduct an administrative review to ensure applications are complete and may ask applicants for additional information to clarify or strengthen their application.

The LDB PI will then review the application and make a recommendation to the Board for approval. The LDB PI may seek advice from an ad-hoc pool of experts (the LDB Peer Reviewer Pool) that includes Lyme disease clinical experts, diagnostic experts, immunology experts, pathogen detection experts, and others with appropriate expertise. Individuals in the reviewer pool are required to sign a *Conflicts of Interest, Confidentiality, and Non-Disclosure Policy* prior to participating in a review. Applications will be recommended for approval based on technical merit, potential to advance LD (or other TBI) diagnostics, their likelihood to increase knowledge of LD and other TBI, and alignment with LDB goals and objectives. The LDB Board of Directors will make the final determination as to which applicants will be approved to receive the discovery panel samples. The PI will notify all applicants of the status of their applications, and comments may be provided to the applicants to help them strengthen their applications for future submissions.

Pricing

Samples will be priced in a cost-recovery model. The unblinded discovery panel is $450. Costs for shipping and sample retrieval will be passed on to the investigator.

Process for Approved Applicants to Receive Samples

Deidentified samples will be released upon receipt of an executed Sample and Data Access Agreement that includes a Material Transfer Agreement, full payment (unless otherwise arranged), and a letter indicating that the proposed analysis plan was approved, granted an exemption, or determined to be non-Human Subjects Research by the applicant's IRB. Once these terms are met, the LDB PI will contact the biorepository to order release of the discovery panel to the approved applicant. *Note: Applications can be reviewed without IRB approval, however IRB approval or exemption is required prior to releasing samples or data to approved applicants*.

Approved applicants must abide by the terms in the Lyme Disease Sample and Data Access Agreement, including acknowledging the LDB in any presentations or publications and sharing summary results with the LDB.

Please contact Liz Horn, PhD, MBI, at liz.horn@lymebiobank.org with any questions.