LANDMark BioBank

Tissue Access Policy

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Tissue Availability and Tissue Access Policy Statements

Tissue Availability

The aim of the LANDMark BioBank (LBB) is to provide access to quality tissue samples for researchers throughout the world to support research investigating biomarkers of diabetes and its complications, improving or creating diagnostic tests and identifying potential new treatments for diabetes and diabetic neuropathy. Tissue collection for the BioBank began in late 2009 at Queensland University of Technology in Brisbane Australia and University of Manchester, UK.

Tissue/clinical data collection

Samples of blood products are banked at the Brisbane site and both blood products and skin tissue are banked at the Manchester site. Clinical and pathological data at baseline and follow-up visits over 5 years is collected at each site, and datasets will be available from the LANDMark study Project Manager (and eventually from a central database accessible from the LANDMark study website).

Timing for release of tissues

Blood Products: Because of the importance to research of clinically annotated tissue samples, a limit has been placed on the quantity of fresh frozen tissues to be released to researchers while 5-year clinical follow data is being collected. A maximum of 50% of any single participant's tissue samples will be released in the first 5 years after accrual. This applies to Guthrie blots, frozen serum, plasma, and buffy coat cells and skin tissue.

Tissue Access Policy

The BioBank welcomes requests for blood product and skin tissue from researchers worldwide. Tissues will only be released, however, to researchers who provide a statement of ethics approval from the Clinical Investigation / Human Research Ethics Committee of their host institution. This applies to researchers who request even a single sample for testing, in order to safeguard participant rights. In order to conserve the limited tissue resources during the first 5 years (2009-2013), frozen blood products and skin tissue will only be released to highly rated projects, and there will be no access for commercial, pharmaceutical or biotechnology companies or international researchers without LANDMark or JDRF-approved collaborators. A level of priority access is available to individuals or

groups providing services in kind to tissue sample collection and storage processes. Such individuals should contact the Project Manager before making an application.

All projects, whether previously reviewed or not by peer review committees, will undergo a peer review by the LANDMark BioBank Tissue Access Committee (TAC) in order to determine the standard of the proposed research project, the likelihood of successful outcomes and the quantity and types of tissue(s) requested. The committee retains the right to prioritise projects and will not necessarily support all funded or fundable projects to protect the longevity of this limited resource. This ruling applies irrespective of the types or numbers of specimens sought from the BioBank.

Guidelines for Applications for Tissue and Data Access

Timing: A Letter of Intent may be submitted at any time. Full applications must be submitted one month from request. Meetings will be scheduled within 6 weeks of receipt of an application.

Procedure:

1. A Letter of Intent (LOI) must first be provided to the Project Manager, containing:

a) Your name, institution, mailing and email addresses, telephone / fax numbers
b) The types of cases required and approximate numbers for each type
c) Statistical justification for the number and types of cases required
d) A statement of the aims / hypotheses of the proposed research
e) A brief description of the technical approach.
f) Evidence that the proposed measurement technique(s) can be used on the specimens requested
g) Clinical and outcome data required
h) Funding available to project
i) Copy of ethics approval to conduct proposed research, or details of pending approval

This LOI will be reviewed on receipt, and if the Project Manager determines that the BioBank can meet your needs, and the TAC determines there are no apparent technical problems, you will be asked to submit a full application, subject to the above timing constraints. This application must be made within one year of submitting the LOI, otherwise a new LOI must be submitted prior to the full application.

2. *Pilot/Small Projects* are subject to the same guidelines as full applications, projects requiring only a small number of specimens and/or which would have low impact on the LBB holdings may be assessed via an expedited application process. Full peer review will be waived, and the application will be dealt with by the Project Manager without TAC involvement based on scientific merit, impact on holdings and value of research to the LBB and JDRF. In general, pilot projects will involve limited numbers of specimens or data, for example 1 to 4 participants blood product samples. These test specimens will be supplied *without* clinical annotation, and in the expectation that if the pilot is successful, a full application will be lodged later. Approval for pilot projects will be for one year only. A copy of approval of the proposed work by a Human Research Ethics Committee will need to be provided to the LBB prior to release of material.

3. Full Applications - Procedure:

I. Before making an application, researchers may wish to confer with the Project Manager to discuss the appropriateness of LANDMark BioBank specimens for the proposed study.

II. Guidelines and application forms can be obtained from the Project Manager. At least 2 weeks before the application is submitted, applicants must send an LOI to the Project Manager. This LOI will be provided to the TAC for comment. In the case that DNA or RNA is to be produced from buffy coat cells by researchers, the amount produced is likely to far exceed the immediate requirements of the project for which tissues were provided. Consequently, excess materials must be returned to the BioBank by arrangement, on production. When resources permit, the BioBank will undertake production of DNA/RNA for release to researchers.

III. Applications must be made on and according to the application form, attaching relevant documents. Completed applications containing all documents and bearing the investigators' signatures **must be provided electronically (pdf file sent by e-mail)** to the Project Manager according to the above timing schedule.

IV. Full applications that have not had prior peer review will be sent out by the TAC to appropriate referees. If a proposal is currently under peer review by a granting agency, the Project Manager can provide a letter stating that the samples requested are available, subject to approval by the TAC once funding is obtained. The TAC would appreciate receiving any available peer reviews for the project.

V. Applications will be reviewed by the TAC, which will assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the biological material currently available. The applicant may be asked to respond to the reviewers' comments in writing. The TAC may suggest some changes to the proposed application and will try to facilitate communication and collaboration between groups working on similar topics. Any member of the TAC with a conflict of interest will be excluded from this review. Reasons will be given for refusal of all or part of the proposed use of material, and this may occur even if the overall grant proposal has approved funding. Conditions on, or restrictions of, use may be made.

VI. Simultaneously, the application will be reviewed by the Project Manager so that a mechanism and timescale for the delivery of the requested specimens and data can be determined.

VII. An acceptance letter will be provided to approved applicants, outlining the conditions on tissue provision as per this policy document. On receipt of a Material Transfer Agreement signed by the applicant(s), and evidence of ethical approval, the project can proceed according to the agreed protocol.

VIII. Any significant deviations from the agreed protocol must be sent by the applicant(s) in writing for approval before proceeding.

IX. Data and biological material will be supplied as soon as possible after a request is approved. The onus is on the investigator to re-submit the application at a later date if additional material is required for the same project.

X. The BioBank will levy cost recovery fees to the applicants for the preparation and shipping of biological materials.

XI. The BioBank reserves the right to withhold the supply of further material if the rate of progress is unacceptable.

XII. Annual progress reports must be sent to the Project Manager for presentation at the TAC meeting that occurs in September each year. The Project Manager will notify all investigators in June that progress reports are due by July 31st.

XIII. At the conclusion of the project, residual materials must be returned or destroyed by agreement of the BioBank, all requested research data will be transferred to the BioBank database, and a final report prepared by the applicants.

Responsibilities of Investigators who use BioBank material

The Chief Investigator(s) of the project must agree:

- To sign the LANDMark BioBank Material Transfer Agreement and not to distribute the material or data to investigators or institutions who are not named in the approved application.

- To include as an author on any resulting publications any BioBank members who fulfil authorship criteria for the study as it progresses. This is required as an outcome measure of BioBank productivity.

- To lodge copies of relevant manuscripts utilising the LANDMark collection with the Project Manager of the LANDMark BioBank, for examination, prior to journal review.

- To acknowledge the JDRF that supports the core activity of the LANDMark BioBank in any resulting publications.

- To submit an annual report on the project by July 31st for presentation to the TAC meeting that occurs in September each year.

- To propose a timeline for monitoring the project.

- To meet the costs involved in preparing and shipping biological specimens and in extracting data from the central database.

- To notify the BioBank of study completion. All studies will be deemed complete after three years unless re-application is lodged.

- To submit all requested research data back to the Project Manager for inclusion in the BioBank database, within 12 months following completion of the project. The research data requested will be decided between the TAC and the researcher. This will facilitate powerful collaborative meta-analyses by the BioBank. It will benefit the researcher providing the data, the BioBank, and LANDMark research.

- To return unused materials to maintain the longevity of the resource, or destroy the material by agreement of the BioBank.

- To obtain a signed MTA from any collaborator to whom they wish to pass on material for use in the approved project. This should be forwarded to the Project Manager with a request that the TAC consider the addition of the collaborator to the project.

Contact Information and Officers of the BioBank (Years 2009-2014)

First Point of Contact for the LANDMark BioBank:

Project Manager
Dr Nicola Pritchard
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Queensland University of Technology
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Members of the BioBank Management Committee

- Dr Nicola Pritchard, Project Manager, Brisbane
- Prof Nathan Efron, CI, Brisbane
- Prof Rayaz Malik, CI, Manchester
- Dr Helen Nickerson, JDRF representative

Members of LANDMark BioBank Tissue Access Committee:

- Dr Nicola Pritchard, Project Manager/Chair
- Dr Helen Nickerson, JDRF representative
- Adjunct Prof Anthony Russell, endocrinology representative
- Dr Dimitrios Vagenas, biostatistics representative
- Professor Nigel Calcutt, molecular pathology representative

Principal Investigators of the JDRF Grant underpinning the LANDMark BioBank:

- Professor Nathan Efron, Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Queensland
- Professor Rayaz Malik, Cardiovascular and Endocrine Sciences, University of Manchester
- Professor Andrew Boulton, Cardiovascular and Endocrine Sciences, Manchester Royal Infirmary
- Professor John Prins, Mater Medical Research Institute, Brisbane