Baker IDI
HEART & DIABETES INSTITUTE

Rules for Internal use of the Biobank

Please refer to the Biobank's intranet page (http://intranet/science/core_facilities/biobank/) for information about the Biobank and how to access samples/data.

1. Access to samples

- Following discussions with the Biobank Manager and completion of the access request forms all projects must be approved by the Biobank Steering Group.
- This application to the Steering Group should include a detailed protocol describing what the samples will be used for and must define/justify the quantity of material requested.
- Ethics approval (usually via a low risk research application) must also be obtained before any Biobank samples can be released.
- The Biobank is a core service and samples are provided to internal users at a subsidized rate. The agreed fee-for-sample will be transferred from the researchers cost centre to the Biobank cost centre as per the cost-recovery schedule, available on the Baker IDI intranet http://intranet/science/core_facilities/biobank/
- Investigators will be given a de-identified list of potential participant samples which they can then refine according to their inclusion/exclusion criteria. Once selected the samples will be provided by the Biobank Manager.
- Samples (and associated clinical/epidemiological data) may only be used for the purpose described in the application. If researchers wish to test samples using additional methods they must contact the Biobank manager who will assess whether the original application may be amended or if a new application is required. In either case, final approval must be obtained from the Steering Group before the additional work may commence.
- If there is any sample remaining it must be returned to the Biobank with documentation describing how the samples were handled whilst in the care of the researcher (i.e. freezer temperature for storage, number of freeze-thaw cycles, how samples were thawed etc)
- A report describing all the tests done and the results obtained from experiments using Biobank samples must be provided when analysis has been completed.
- If the findings are published the Biobank must be informed of the details and must be appropriately acknowledged in the manuscript (either in methods section, as an acknowledgement or both). Consideration should also be given to whether Biobank staff provided significant intellectual input into the project and credit should be given in the form of authorship when appropriate.
- All Biobank samples are provided in good faith with care taken to supply high quality samples accurate phenotypes. However, samples are provided without warranty of any sort express or implied, and without representation/guarantee that the materials are fit for the described research purpose.
    - *For this reason the Biobank suggests researchers conduct a pilot study with a small number of samples (test samples can be supplied but may not be representative of those in the requested cohort with respect to sample age).*
    - *Such a study should be discussed with the Biobank Manager; ethics approval would still be required and there may be a charge for samples depending on the quantity needed.*

2. Database mining to identify potential participants for clinical studies

1. Following discussions with the Biobank Manager and completion of the access request forms all projects must be approved by the Biobank Steering Group.
2. This application to the Steering Group should include a detailed protocol describing the project and what will be asked of participants.
3. Detailed inclusion/exclusion criteria should be provided (in consultation with the Biobank manager) to enable an accurate search of the Biobank database.
4. Only participants who have explicitly provided consent to be contacted for future research projects will be included in any search of the database.
5. Investigators will be given a de-identified list of potential participants which they can then refine according to their inclusion/exclusion criteria.
6. Ethics approval must also be obtained before the names and contact details of Biobank participants can be released. This may be possible via an amendment of the existing recruitment strategy for projects already approved by ethics.
7. When ethics approval is granted and you have informed the Biobank Manager which participants you wish to contact we will provide you with the contact details.
8. We do not want to 'harass' participants and will generally wait until 6-12 months have passed since they finished in a study before we contact them again. The Biobank therefore needs full details about the results of any contact researchers attempt or make so that our database can be updated. The information we require should be communicated back to the Biobank using the spreadsheet supplied with contact details.
9. Participants should initially be approached with a letter (printed on Baker IDI letterhead) describing the study and inviting them to contact the researcher if they are interested. The Biobank's standard letter format (see attached) is to be used and in most cases the paragraph describing the study should be reviewed by the Biobank Manager as it is to be co-signed by the PI/a senior investigator on the study and the Biobank Manager.
10. The Biobank would like to obtain follow up data (and in some cases another sample) from the participants you plan to approach, even if they are not interested in your project. This is mentioned in the standard letter attached.
11. Contact details of Biobank participants (and associated clinical/epidemiological data) may only be used for the purpose described in the application. If researchers wish to invite people into a different or additional study they must contact the Biobank manager who will assess whether the original application may be amended or if a new application is required. In either case, final approval must be obtained from the Steering Group before the additional work may commence.
12. The cost of this service for Baker IDI researchers starts at $135 per project. This fee may be waived if the project actively recruits participants from its other sources into the Biobank.
13. All non-Biobank participants who agree to donate must complete a Biobank consent form (after reading the Participant Information Sheet) and the Biobank questionnaires.
14. Researchers also agree that they will provide the Biobank with the relevant data for tests that have been conducted (i.e. blood pressure measurements, blood cholesterol/glucose values) in participants who are identified via the Biobank database or who agree to donate a sample to Biobank.
15. All documents describing/listing contact details of Biobank participants must be kept according to Good Clinical Practice guidelines (i.e. confidentiality must be maintained and documents kept secure, either in password protected files or in a locked location if in hard copy)
16. A report describing the results obtained from studies using contact details of Biobank participants must be provided when analysis has been completed (full group data is sufficient).
17. If the findings are published the Biobank must be informed of the details and must be appropriately acknowledged in the manuscript (either in methods section, as an acknowledgement or both). Consideration should also be given to whether Biobank staff provided significant intellectual input into the project and credit should be given in the form of authorship when appropriate.
18. The investigator acknowledges that while every care is taken to supply contact details of appropriate Biobank participants they are provided without warranty of any sort express or implied, and without representation/guarantee that the people listed are (a) still alive and (b) suitable for the described research purpose.

Attachment: Letter for researchers inviting Biobank participants into their study and who the Biobank would like to obtain an additional sample

(To be printed on Baker IDI letterhead; yellow field to be completed by the researcher and un-highlighted)

>Date<

>Title< >First Name< >Surname<
>Participant Address<
>Suburb< >Postcode<

Dear >Title< >Surname<,

Our records indicate that you kindly donated a blood sample to the Alfred and Baker Gene Bank (now called the 'Biobank') in >Year<. When you donated this sample you indicated that you were happy to be contacted for research purposes in future. Based on the information you gave you may be a suitable candidate for a study currently being run by researchers at the Baker IDI Heart and Diabetes Institute (formerly the Baker Heart Research Institute) in collaboration with the Alfred Heart Centre. We would therefore like to invite you participate in this additional research.

The research project >…Study coordinator/Investigator to complete paragraph briefly describing the study in lay terms…<

Enclosed with this letter is a detailed participant information and consent form. If you are interested in participating please read these documents carefully. A member of the research team will contact you to discuss the project further in the coming weeks and will be happy to answer any queries if you have any. If you wish to contact the research team directly please contact > Study coordinator<:

Office:
Mobile:
E-mail:

Thank you for your kind attention and for the initial blood donation you made.

Yours sincerely,

>Principal/Senior Investigator< and Dr Melissa Barber
>Position, Baker IDI Group< Manager, Biobank

PS The Biobank is also interested in collecting updated information about your health and may wish to obtain another blood sample from people who, like you, have donated blood in the past. By collecting repeat data and/or samples we can investigate how time and changes in risk factors affect biomarkers. Even if you cannot participate in the project outlined above, please consider donating another sample to the Biobank. You can make an appointment with the Biobank by calling Sam on (03) 8532 1543.