

**KING'S HEALTH PARTNERS
CANCER BIOBANK
MANAGEMENT COMMITTEE, OPERATIONAL
GROUP AND ACCESS SUB-COMMITTEES**

TERMS OF REFERENCE

Version 7.2

April 2017

Document Created October 2006

April 2017

Background

The KHP Cancer Biobank has been collecting information about the breast cancer patients and their disease since the early 1970's and holds over 15,000 tissue samples. Since that time, additional specimens and data from patients with more diverse malignancies, including head and neck, prostate, upper gastro-intestinal, lymphoid and lung tumours, have been incorporated, along with appropriate Access Sub-committees for each, to oversee requests from local, national and international collaborators (structure shown in Figures 1 and 2). This invaluable resource for pioneering research includes patient and tumour data and a range of sample types and preparations (frozen and/or formalin-fixed tumour, tissue microarrays, DNA and RNA and blood). Over 300 peer-reviewed publications have resulted from use of this material and led to greater insight into the development and treatment of cancer.

The KHP Cancer Biobank Management Committee (the "Management Committee") oversees all aspects of governance and management associated with the King's Health Partners (KHP) Cancer Biobank (the "Bank" or the "biobank", comprising the "Tissue Banks" and "Data Banks"). An Operational Group may be appointed to ensure standardisation of processes and procedures to comply with regulatory requirements. Sub-Committees oversee access to tissue and data resources.

1. The Management Committee

Roles & Responsibilities of the Management Committee

1. Ensure that all Bank processes are compliant with national and local legislation, including but not limited to,
 - a. Human Tissue Act 2004
 - b. Data Protection Act 1998
 - c. Freedom of Information Act 2000
2. Review and assess the development of the Tissue & Data Banks with reference to;
 - a. Annual review of the Bank contents and accrual rates
 - b. Annual review of Bank usage
3. Develop the Bank to meet the needs of future technologies
4. Safeguard the finite resources of the Bank by oversight of each Sub-Committee in relation to access and usage of Bank tissue.

Membership of the Management Committee

The Management Committee will consist of a minimum of 8 members appointed by Guy's & St Thomas NHS Foundation Trust (GSTFT) and King's College London (KCL) drawn from the two categories below (with a minimum of 5 members from Category A, and a minimum of 2 members from Category B, at any given time)*:

Category A:**Biobank Representation within Guy's & St Thomas' NHS Foundation Trust**

1. Represent the Bank at Trust Executive level: Facilitate biobank strategic development that has a direct impact on Trust policies and procedures. Report to the Chief Executive, via the Cancer CAG.
2. Represent the Bank to Trust Risk & Quality Committee: Ensure that the biobank procedures are compatible with those of Trust governance. Represent the interests of the biobank in Trust Risk and Quality Committee (TRaQ) policy/procedural decisions.

KHP Representative Members

3. KHP Comprehensive Cancer Centre (CCC): Ensure that the biobank is fully engaged with the strategic goals of the CCC and to promote development to meet future requirements.
4. KHP ICC R&D: To promote biobank resources to potential users and ensure that research developments, which may impact on the biobank collection and processing methods, are reported back to the committee.
5. KCL Biobanks/ Sample Collections: Ensure there is similarity between biobank policies and procedures and those of KCL. To be aware of KCL cancer sample collections that may be of interest to the biobank.
6. Biobank Manager: To co-ordinate and produce an annual biobank report to include collection and project data for each biobank. Alert the Chairman to serious adverse events or incidents. Provide information as requested by members of the Management Committee.
7. Lead Academic Pathologist: Provide advice to the committee on interface between diagnostic histopathology and bank activities. To promote consistency in application review between Access Committees and provide guidance where necessary.
8. Translational research in clinical trials: Regularly report to the committee on developments in clinical trial design that may have an impact on short and long-term biobank resources.
9. Data management: Provide advice to the committee on biobank data security policies and collection of minimum data sets.
10. Academic Leads (or their designate): Provide information to the committee about their

specific biobank. To advise on the impact of policy and procedure changes, in relation to their tumour-type bank.

Category B:

Independent Members

11. Medical Law/Ethics: Provide general guidance on the legal and ethical framework and values of the biobank; advice on ethical aspects of access applications when required; advice on other legal issues as and when required.
12. Finance/Fundraising Initiatives: To have high-level oversight of the biobank's funding requirements and funding streams. Report to the committee on potential staff funding shortfall; significant changes in running costs and fundraising initiatives to promote financial stability. Engage with fundraising teams to promote the biobank and maximise potential investment.
13. Researcher: Regularly report to the committee on research developments that may have an impact on short and long-term biobank resources. This may include changes in type of material collected or preparation processes.
14. Patient/Lay Representative: Provide a lay/patient perspective on the policies and direction of the biobank. Input into how the biobank engages with past and prospective donors.
15. Independent Biobank Representative:[§] Compare policies and activities between biobanks to enable the Bank to benchmark against a similar facility.

* Numbers to be reviewed at three year intervals

§ Not contracted to King's College London or Guy's & St Thomas NHS Foundation Trust

With the exception of Academic Leads, members may not appoint an alternate to represent them on the Management Committee and act on their behalf.

Observers may attend the Management Committee meetings on occasions by invitation only but will not participate, and cannot act as replacement of, the dedicated members of the committee.

Whilst some roles and responsibilities lie with defined members of staff (such as the Biobank Manager), who are therefore regarded as permanent members of the Management Committee, and others have very specific remits and expertise and may therefore remain on the Management Committee on a long term basis, other members will ordinarily serve for a

period of 3 years in the first instance, with the possibility of being re-appointed for a further 3 years. No more than one third of Management Committee members may be replaced at any one time.

Chairman

The Chairman will be appointed by members of the Management Committee and fulfil either role 1 and/or 2 listed in the Management Committee members (Biobank Representation within GSTFT).

The Chairman will serve for a period of 3 years in the first instance, with the possibility of being re-appointed. Re-appointment shall be for 3 years at a time, and each reappointment shall be subject to approval by the Management Committee.

The Chairman should be:

- Independent and objective. If the Chairman may have reason to access the Bank, there must be another independent GSTFT representative appointed to the relevant Access Sub-Committee to ensure transparency.
- Able to give time and commitment
- Knowledgeable with regard to academic science as well as governance issues

Decision-making by the Management Committee

Quorum

A quorum will consist of at least one third of the total number of members from time to time (rounding down), plus one. (So, for example, if the Management Committee consists of 8 members, a quorum will be $2+1 = 3$.)

Meetings

The Management Committee will meet at least every six months on a date notified in advance to the members.

Resolutions

A resolution in writing signed by all the members of the Management Committee entitled to receive notice of a meeting of the Management Committee shall be as valid and effectual as if it had been passed at a meeting duly convened and held, and may consist of several documents in the like form each signed by one or more members of the Management Committee. An emailed signature shall be sufficient to constitute "signed" agreement to a resolution.

Other**Reporting Relationships**

Through the Chairman of the Management Committee, the custodian (being the Chief Executive of GSTFT from time to time) shall be made aware of the annual accrual and usage of data and any substantive changes in governance or management through the Annual Report. The Chairman or his nominated representative shall report to TRaQ (figure 1).

Administration

The Biobank Manager or designate shall act as secretary to the Management Committee.

The secretary, in co-operation with the Chairman and Lead academic pathologist shall prepare all meeting agendas.

A register of meeting attendance will be kept by the Biobank Manager and may be included in Bank reports.

Operational Group

The Management Committee may form an "Operational Group" to oversee the day to day running of the Biobank. If the Operational Group is brought into existence, it shall be governed by section 2 of these Terms of Reference.

2. Operational Group**Roles & Responsibilities of the Operational Group**

- Ensure that the Bank is compliant with Human Tissue Authority licence requirements
- Standardise and share good practices across banks wherever possible
- Produce and review policies, Standard Operating Procedures and risk assessments
- Undertake or participate in regular audit activities
- The Operational Group Chair will report to the Management Committee

Membership of the Operational Group

The Operational Group shall comprise all or some of the following:

- Biobank Manager
- Manager/Co-Ordinator/Technical Lead of tissue-type biobank
- Quality Manager
- Academic Lead (as required)

Decision making of the Operational Group

Quorum

A quorum will consist of at least one third of the total number of members of the Operational Group from time to time, plus one; or two, whichever is the greater number.

Meetings

The Operational Group will meet as required, and at least every six months on a date notified in advance to the members of the Group.

Resolutions

A resolution in writing signed by all the members of the Operational Group entitled to receive notice of a meeting of that Group shall be as valid and effectual as if it had been passed at a meeting duly convened and held, and may consist of several documents in the like form each signed by one or more members of the Group. An emailed signature shall be sufficient to constitute "signed" agreement to a resolution.

3. Access Sub-Committees

Roles & Responsibilities Of The Access Sub-Committees

An Access Sub-Committee shall exist in relation to each of the following:

- Head and Neck Biobank
- Breast Biobank
- Thoracic Biobank
- Prostate Biobank
- Upper Gastrointestinal Tract Biobank
- Lymphoma Biobank

(together, the "Access Sub-Committees" and the "Biobanks").

The role of each of the Access Sub-Committees will be to:

- a. Review applications to access the relevant Biobank, with reference to;
 - Scientific merit
 - Study design
 - Requestor's financial resources (i.e. details of grant to fund study)
 - The relevant Biobank's resources
- b. Rate applications with regard to:
 - Strategic value to KHP
 - Collaborative value to KHP
 - Resources requested
 - Impact of research

- c. Members of the Access Sub-Committee shall have a spread of research knowledge; the opinion of 'experts' within specific subject areas will be sought as required.
- d. The full Access Sub-Committee will review:
 - 1. Requests for all material and data (pilot and full studies)
 - 2. Results from pilot studies (with view to approving continued access)
 - 3. Interim study update (time to be determined for individual studies)
 - 4. Extension of studies (which will also require a pilot study stage)
- e. The Academic Lead for each Access Sub-Committee will provide a regular report to the Management Committee on sample accrual and access, study use and research output to the Management Committee.

Membership of the Access Sub-Committees

Each Biobank Access Sub-Committee will consist of a minimum of 8* members appointed by GSTFT and KCL and shall include the following:

- Biobank Academic Lead
- Biobank Manager/Co-ordinator
- KCL or GSTFT Scientist
- GSTFT Oncology Representative
- KCL or GSTFT Consultant Histopathologist
- Epidemiology/ Statistics Representative
- KCL or GSTFT Consultant Clinician
- Independent Scientist[§]

* Numbers to be reviewed at three year intervals

§ Not contracted to KCL or GSTFT

Members may not appoint an alternate to represent them on the Access Sub-Committee and act on their behalf.

Scientist members will serve for a period of 3 years in the first instance, with the possibility of being re-appointed for a further 3 years, with no maximum term.

Academic Lead

The Management Committee Chairman will appoint the Academic Lead for each Access Sub-Committee. The Academic Lead will serve for a period of 3 years in the first instance, with the possibility of being re-appointed for a further period of 3 years, with no maximum term.

The Academic Lead will:

- Review feedback on each access application from the relevant Access Sub-Committee members and, in the light of that feedback, issue a final decision for communication to the applicant
- Give time and commitment
- Be knowledgeable with regard to academic science as well as governance issues
- Report to the Management Committee on all aspects of that Access Sub-Committee's function.

In exceptional circumstances (for example, where the Academic Lead of the Access Sub-Committee is the main applicant for a project) it may be appropriate for the Management Committee Chairman to appoint a deputy for review of an application for access.

Decision-making by the Access Sub-Committee

Quorum

A quorum will consist of at least one third of the total number of members from time to time, plus one.

Meetings

The Access Sub-Committees will meet as necessary to determine access requests. The Access Sub-Committees may have 'virtual' meetings where access requests are circulated by e-mail to committee members for review. Each application will be reviewed by at least 4 members of the Access Sub-committee, except where the accelerated procedure outlined below applies. Access Sub-Committee members should complete an electronic review form and email it to the Access Sub-Committee co-ordinator. Access Sub-committee members must complete their review within 2 weeks of receiving the application from the manager or co-ordinator. The Academic Lead for each Biobank will review the committee members' review forms and report to the Biobank Manager, or the appropriate designate for each Biobank, the comments and overall decision of the access sub-committee. The summarising of review comments and reporting will be undertaken by the Academic Lead within 2 weeks of receipt of the review forms.

Resolutions

A resolution in writing signed by all the members of the Access Sub-Committee entitled to receive notice of a meeting of that Access Sub-Committee shall be as valid and effectual as if it had been passed at a meeting duly convened and held, and may consist of several documents in the like form each signed by one or more members of the committee. An emailed signature shall be sufficient to constitute signed agreement to a resolution.

Accelerated Procedure

Any two of the following three members of the Access Sub-Committee (1) the Academic Lead for the relevant Biobank, (2) the Consultant Histopathologist member, and (3) the Biobank Manager, may approve requests for access to less than ten samples of control material, without requiring approval from the full Access Sub-Committee of the relevant Biobank, so long as that access request, if approved, is then notified to the full Access Sub-Committee within 14 days thereafter. This is an “accelerated procedure” for dealing with control material. Control material includes tissues, cells and derivatives, which are used for optimising technical conditions. Control material has no linked clinical data.

Other

A register of Access Sub-Committee member response rates for each application will be kept by the Biobank Manager and may be included in Bank reports.

Figure 1: King's Health Partners Cancer Biobank Governance Structure

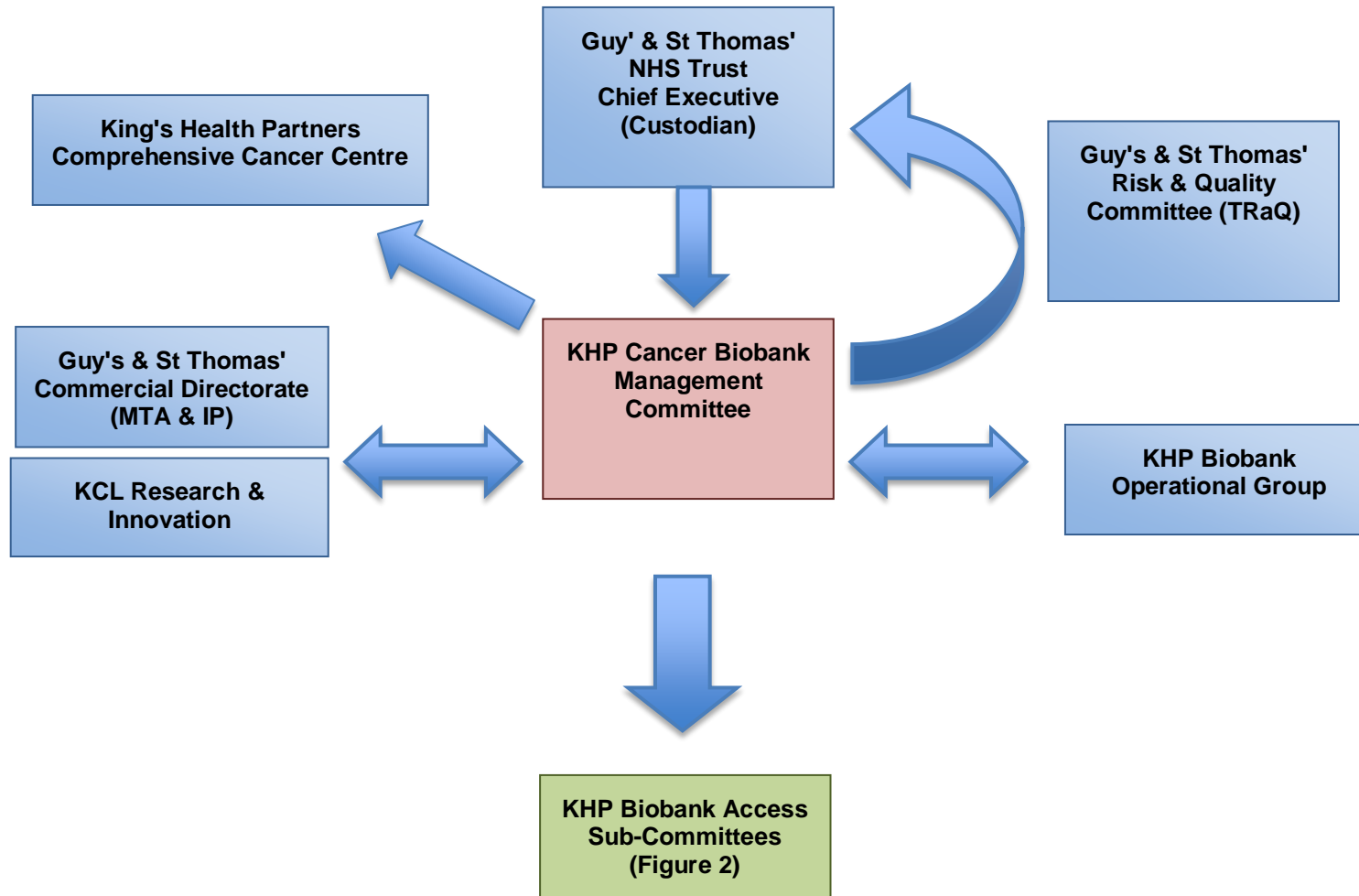


Figure 2: King's Health Partners Cancer Biobank Access Sub-Committees

Breast	Colorectal	Head & Neck	Lymphoma	MPN	Thoracic	UGI	Urology
<p>Academic Lead: Sarah Pinder</p> <p>Co-ordinator: Cheryl Gillett</p> <p>Members: Joy Burchall Michael Douek Cheryl Gillett Anita Grigoriadis Ash Kothari Katherine Lawler John Maher Janine Mansi Henrik Moller Tony Ng Peter Parker Elly Sawyer Julie Scudder Elena Provenzano</p>	<p>Academic Lead: Francesca Ciccarelli</p> <p>Co-ordinator: TBC</p> <p>Members: Gill-Barman Baljit Fuju Chang Mark George Cheryl Gillett Robert Goldin Michael Green Jesper Lagergren Paul Ross</p>	<p>Academic Lead: Eddy Odell</p> <p>Co-ordinator: Rhonda Henley-Smith</p> <p>Members: Teresa Guerrero-Urbano Jean-Pierre Jeannon Andrew Lyons Tony Ng Richard Oakley Kim Piper Ricard Simo Mahvash Tavassoli</p>	<p>Academic Lead: Paul Fields</p> <p>Co-ordinator: TBC</p> <p>Members: Dinis Calado Cheryl Gillett George Mikhaeel Jo Spencer David Wrench</p>	<p>Academic Lead: Claire Harrison</p> <p>Co-ordinator: TBC</p> <p>Members: Richard Dillon Deepti Radia Donal McLornan Bridget Wilkins Kavita Raj</p>	<p>Academic Lead: James Spicer</p> <p>Co-ordinator: Cheryl Gillett</p> <p>Members: Paul Cane Cheryl Gillett Anita Grigoriadis Juliet King Katherine Lawler John Maher Henrik Moller Peter Parker Michael Scheaff</p>	<p>Academic Lead: Jesper Lagergren</p> <p>Co-ordinator: Jesper Lagergren</p> <p>Members: Fuju Chang Rebecca Fitzgerald Cheryl Gillett Nick Maisey Andrew Davies Henrik Moller Peter Parker</p>	<p>Academic Lead: Ash Chandra</p> <p>Co-ordinator: Aida Santaolalla</p> <p>Members: Christian Brown Ben Challacombe Christine Galustian Michelangelo Fiorentino Cheryl Gillett Mieke Van Hemelrijck Henrik Moller John Maher Sarah Rudman Simon Chowdhury Massimo Loda</p>