Brain Tumour Biobank Ireland

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1. GOVERNANCE OVERVIEW

1.1. Background

Brain Tumour Ireland Biobank (BTB) was founded in 2016 by the Department of Physiology and Medical Physics, RCSI (Prof Jochen Prehn), the Neuropathology Department, Beaumont Hospital (Dr Alan Beausang, Dr Jane Cryan and Dr Francesca Brett), and the Neurosurgery Department, Beaumont Hospital (Mr Stephen McNally), with additional financial support of Brain Tumour Ireland (BTI; main funder) and the Irish Institute of Clinical Neuroscience (IICN, equipment support funder).

1.2. Context including Goals

With the support from Brain Tumour Ireland, the RCSI Department of Physiology and Medical Physics, and the RCSI Centre for Systems Medicine (CSM) along with the Departments of Neurosurgery and Neuropathology in Beaumont Hospital established a brain tumour biobank in RCSI and Beaumont Hospital to develop novel biomarkers and treatments for brain tumour patients. Patients undergoing brain tumour surgery have been given the opportunity to consent to have their tissue included in the biobank. This collaboration will enable RCSI and Beaumont Hospital investigators, as well as other national and international investigators to research brain tumours, develop novel biomarker and develop novel therapies for the treatment of brain tumours. Brain Tumour Ireland is delighted to support RCSI (Royal College of Surgeons in Ireland) in the establishment of its brain tumour biobank, which will encourage research aimed at individualised treatments and increasing survival rates for brain tumour patients. By collecting brain tumour cells from patients, the biobank will enable new and targeted therapies for brain tumours to be examined. Only patients who consent can have their tissue used in the biobank, and only tissue surplus to diagnostic requirements can be biobanked.

1.3. BTB Management Team

Prof Jochen Prehn (Department of Physiology & Medical Physics, RCSI)

Dr Alan Beausang (Neuropathology, Beaumont Hospital)

Mr Stephen McNally (Neurosurgery, Beaumont Hospital)

Ms Eilis Griffin (BTI Representative)

Prof David Smyth, RCSI (Ethics advisor)

2. Terms of Reference

2.1. Schedule: Meetings shall be held a minimum two per annum and as required when an access requests are received. Meeting minutes will be deemed accepted 15 calendar days from circulation date.

2.2. Quorum: the BTB Management shall not deliberate and decide validly unless a minimum of 3 members are present.

2.3. Voting Rights: Each member of the BTB Management present in the meeting shall have one vote. Decisions shall be taken by a majority of 50% + 1 of the votes cast.

3. PROCESS

3.1. Patient sample and Data Collection system

Collection: Tissue samples of fresh / frozen brain tumour samples are banked at the RCSI Education & Research Centre (ERC). Formalin-fixed paraffin-embedded brain tumour samples are stored in the Beaumont Hospital Neuropathology Department. Blood, which is separated into Serum and Plasma, is also collected from corresponding patients as well as an overnight first 100mL voided sample.

Database: Central to the bio-collection is the FreezerWorks software, which accommodates the collection and tracking of samples and integration of clinical information. This allows investigators to identify what samples are available and where they are located, as well as linking to the relevant clinical and follow up data.

3.2. Access policy

The Brain Tumour Biobank (BTB) welcomes requests for brain tumour samples from researchers who have an interest in the collective goals of the Bank. Samples will only be released, however, to researchers who can provide a statement indicating that their research is carried out according to the code of good practice in research, the samples will be handled appropriately in accordance with best ethical practice, following approval of the *BTB Management*.

All projects will be reviewed by the *BTB Management* to determine the standard of the proposed research project, the likelihood of successful outcomes and the quantity and types of samples requested. The *BTB Management* retains the right to prioritise and not support all projects to protect the longevity of this limited resource. This ruling applies irrespective of the types or numbers of specimens sought from the BTB.

3.3. Guidelines and Procedure for Applications for Tissue and Data Access

3.3.1. Timing

A *Letter of Intent* may be submitted at any time. *Full Applications* must be submitted one month prior to a *BTB Management* meeting. The schedule for these meetings can be obtained from Dr Helena Bonner, RCSI CSM Liaison Officer, and Ms. Patsy Connolly, RCSI Department of Physiology and Medical Physics.

3.3.2. Procedure:

a) A *Letter of Intent* (LOI) must first be provided to Dr Helena Bonner, RCSI CSM Liaison Officer, containing:

- Name of Principal Investigator, Institution, mailing and email addresses, and telephone number
- The types of cases required and approximate numbers for each type
- Statistical justification for the number and types of cases required
- A statement of the aims / hypotheses of the proposed research
- A brief description of the technical approach
- Evidence that the proposed measurement technique(s) can be used on the specimens requested, for example does the proposed antibody work for immunohistochemistry in paraffin-embedded specimens
- Clinical and outcome data required

b) This LOI will be reviewed on receipt, and if the BTB can meet the outlined needs, a Full Application will be requested.

c) *Pilot Projects* are subject to the same guidelines as Full Applications. In general, however, pilot projects will involve limited numbers of specimens and data, for example 5 specimens of frozen tissue or 5 sections from a specific pilot TMA containing brain tumour. 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.

d) *Full Applications - Procedure*:

d.1) Before making an application, researchers may wish to confer with the *BTB Management* to discuss the appropriateness of BTB specimens for the proposed study.

d.2.) A full application must include:

- Principal Investigator name, Institution, mailing and email addresses, and telephone number.
- A 2-page description of the project and scientific justification.
- The aims/hypotheses of the proposed research.
- The types of cases required and approximate numbers for each type including full justification both scientifically and statistically.
- Full details of the final statistical analysis that will be undertaken and support available.
- A 2-page description of the technical approach and evidence that the proposed measurement technique(s) can be used on the specimens requested.
- Details on financial support for the research project

e) Full applications that have not had prior peer review may be sent out by the *BTB Management* to appropriate referees. If a proposal is currently under peer review by a granting agency, the BTB can provide a letter stating that the samples requested are available, subject to approval by the *BTB Management* once funding is obtained.

f) Applications and referees reports will be reviewed by the *BTB Management* within 30 days, 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 with a deadline of 30 days upon receiving the reviewers' comments. The group 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 *BTB Management* 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 grant proposal has approved funding. Conditions on, or restrictions of, use may be made.

g) The BTB Management will then work with the approved recipient to apply for ethical approval, prepare a Data Protection Impact Assessment and agree on the appropriate Material Transfer Agreement.

h) Any significant deviations from the agreed protocol must be sent by the applicants in writing for approval before proceeding.

i) 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 as the BTB collection grows if additional material is required for the same project.

j) The BTB may levy a fee to the researcher for the preparation and shipping of biological materials and operate a cost recovery which will be calculated based on the sample and clinical/follow up information requested.

k) The BTB reserves the right to withhold the supply of further material if the rate of progress is unacceptable.

l) Annual progress reports must be sent to the *BTB Management*.

m) At the conclusion of the project, residual materials will be returned, all requested research data will be transferred to the FreezerWorks database, and a final report prepared by the researchers.

4. ROLES and RESPONSIBILITIES

4.1. Responsibilities of the BTB Management Team

a) Attendance at Meetings
b) Adherence to this Governance process.
c) Raise any Conflicts of Interest.
d) Review and approve where appropriate applications for tissue and data access.
e) The BTB Management will work with the approved recipient to apply for ethical approval, prepare a Data Protection Impact Assessment and agree on the appropriate Material Transfer Agreement.
f) Provide regular updates to Brain Tumour Ireland as outlined in the Reporting section below.
g) Promote the Biobank as outlined in the Promotion section below.

4.2. Responsibilities of Investigators accessing BTB samples

The Principal Investigator(s) of the project agree:

a) To work with the BTB to get the appropriate ethical approval and sign the agreed Material Transfer Agreement and not to distribute the material to investigators or institutions who are not named in the approved application.

b) To list BTB and the Brain Tumour Ireland in the acknowledgement on any resulting publications and include any BTB members who fulfil authorship criteria for the study as it progresses. This is required as an outcome measure of BTB productivity.

c) To acknowledge the agencies that support the core activity of the BTB in any resulting publications.

d) To submit an annual report on this project.

e) To propose a timeline for project monitoring.

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

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

h) To lodge copies of relevant manuscripts utilising the brain tumour collection.

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

j) To return unused material to the BTB as appropriate. This will increase the longevity of the resource.

5. REPORTING AND PROMOTION

At a minimum, an annual report containing information such as how many samples were accessed, by whom and for what during the year – along with any summary updates from the researchers on their progress will be prepared by the BTB Management and provided to Brain Tumour Ireland (in time for their annual AGM) and other relevant stakeholders.

The BTB Management will be responsible for promoting the Biobank to attract interested researchers and raise awareness amongst the community about the Biobank's activities. A public version of the annual reports will be made available to be included on the relevant websites (Centre for Systems Medicine, Beaumont Hospital and Brain Tumour Ireland) as appropriate.

Appendix 1: Application Form to Brain Tumour Biobank

For Access to Biological Material and Data

Title of Project:

Name of Applicant(s):

Institution (s):

Principal Investigator:

Address: Phone Number: e-mail:

We/I hereby seek permission from Brain Tumour Biobank (BTB) to undertake the research work detailed in the attached proposal according to the conditions specified by the BTB. We/I will sign the BTB Material Transfer Agreement and will not distribute the material or data to third parties. We/I will list the "Brain Tumour Biobank" and "Brain Tumour Ireland" in the acknowledgements on any resulting publications and include any BTB member(s) who fulfil authorship criteria for the study as it progresses. We/I will meet the costs involved in preparing and shipping biological specimens and in extracting data from the central database. We/I realise that there is the potential that this human biological material may contain infectious agents, and therefore should be handled appropriately.

Signed: _____ Date: _____

Signed: _____ Date: _____

Signed: _____ Date: _____