Sample and Data Access Committee - Application Review Process

The purpose of the application review process is to ensure that samples released by the VIVO Biobank are used in scientifically valid research that meets the highest ethical standards and is meaningful to patients, carers and families. The committee recognises that many research projects will have already undergone peer review by national funding agencies and these projects will be fast-tracked through the system. The biobank research coordinator will manage the application review process with oversight and input from the committee co-chairs.

Application submission

- *Prior to submission*, applicants must consult the website and contact the VIVO biobank (via the generic email address) to ascertain whether the CYP Cancer Biobank can meet their requirements. In some instances, a short zoom will be arranged to talk through the proposal and address any specific queries.
- Applications and supporting documents (including evidence of external peer review) will be submitted electronically to the VIVO research coordinator.
- The research coordinator will check and log each application before processing. Applications will be assigned a co-ordinating team comprising one research coordinator and one co-chair.
- The research coordinator will prepare an impact statement for each application. This statement will enumerate the number of eligible samples currently held by the biobank. The Sample and Data Access Committee will review this impact statement alongside the application to assess how much the project would deplete the biobank resources and hence whether or not it can be supported.

Types of application

To facilitate timely review of projects, applications will be categorised into one of three types:

- Type A: Studies already peer-reviewed[1] and requesting pre-existing samples.
- Type B: Studies without appropriate peer-review and requesting pre-existing samples.
- Type C: Studies, including trials, requiring prospective sample collections and rolling programmatic projects. All requests from commercial companies will automatically fall into this category.
- Applicants will suggest the review category via a specific question in the application form but the final decision of the review process will rest with the co-chairs.
- Applications from non-UK based researchers are welcome and will be reviewed by the same system.

[1] The Sample and Data Access Committee will accept peer-reviews from major funding agencies and other biobanks. For example, Medical Research Council (MRC), Cancer Research UK (CRUK), Blood Cancer UK (BCUK) and as well as major non-UK funding agencies. The co-chairs of the Sample and Data Access Committee will be the final arbiters of what constitutes an appropriate peer-review.

Fast-track review process

- *Type A & B studies*. The research coordinator will email the application to all members. Members will review the scientific excellence, deliverability, clinical impact, level of patient/public involvement and engagement, and biobank impact of the study. Each member will complete an assessment sheet.
    - Type A studies: Assessment sheets will be returned to the researcher coordinator **within one week**. A minimum of four assessments is required for approval (see below for scoring details). Applications not approved at this point will be reviewed at the next meeting.
    - Type B studies: Assessment sheets will be returned to the researcher coordinator **within two weeks**. A minimum of six assessments is required for approval (see below for scoring details). Applications not approved at this point will be reviewed at the next meeting.
- *Type C studies*: Not applicable

Standard review process

- All Type C studies along with Type A and B studies not approved by the fast-track system will be reviewed at the next scheduled committee meeting.
- Two weeks prior to the meeting, the applications and supporting documents will be circulated to members of the committee. In the case of studies that failed the fast-track review system the research coordinator will also circulate a summary of assessments already completed.
- Members will score each application using the assessment sheet. Members must submit their scores to the research coordinator three days prior to the meeting. The research coordinator will collate the scores prior to the meeting.
- It is expected that all members of the committee will read all applications prior to the meeting as applications will not be formally presented.
- If the initial review process identifies issues requiring clarification, the co-chairs will consider inviting the lead applicant to attend the online meeting to answer specific questions.
- For a meeting to be quorate, at least one of the co-chairs must be present at each meeting plus at least six ordinary members. If the committee cannot reach a unanimous decision then a two-thirds majority vote will suffice to reach a decision.
- Applications will only be approved if they fulfil the following criteria:
    1. They achieve an average score of 2 in each of the three categories - “quality of scientific proposal”, “potential clinical impact” and “deliverability”.
    2. There is evidence of PPIE and/or Public Engagement:
        a. Each project MUST have a high-quality lay summary written in plain English. Also, the applicants MUST agree to write a final (written in plain English) that can be published on the VIVO biobank website AND

   b. All projects MUST have had some review/input from by patients, parents or the general public. This could be direct input from a PPI group, review by the PPI members of a grant review committee, lab open days, etc. The review/input should be in line with the scope and nature of the project.
   c. If relevant - Any project that involves an additional procedure (i.e. not standard-of-care) MUST have had direct input from patients and/or parents.
3. The impact on the biobank in terms of future sample availability should match the quality of the project and the likely clinical impact. Briefly, any project the uses up the final vial or uses very rare samples or sample sets must have received the top score for all three categories.

- Applications not approved will be either rejected outright or referred back to the applicant for revision.
- The Sample and Data Access Committee reserves the right to request external review for any application. Applicants will be requested to supply the names and contact details of two referees in case this option is required. However, the final choice of the external reviewers will rest with the committee.
- For complex studies the Sample and Data Access Committee may request that the PI attend a meeting to discuss the study in detail.

Project review and closure

- All projects will be required to submit a short annual report outlining key achievements and providing information on sample usage and outputs; including outputs relevant to the PPI community. On occasion, the PI may be requested to attend a meeting of the Sample and Data Access Committee to discuss their project.
- The maximum duration for any project is 5 years. The use of any existing/leftover samples should be discussed with the tissue bank and will usually require the submission of a new project application. Project initially predicted to last less than 5 years can be extended/renewed up to a maximum of 5 years.