



Requests for access should be made using the Application Form. A copy can be found on the UK-PBC website and can be requested from the UK-PBC Project Manager (uk-pbc@ncl.ac.uk).

Please refer to the rules below before submitting an application

Eligibility Criteria

Applications will be considered from qualified researchers. A qualified researcher refers to a scientist who is employed, or a student enrolled at, or legitimately affiliated with an academic, non-profit or government institution, or a commercial company. The institution must be able to provide institutional responsibility for appropriate research governance.

Assessment Criteria

Applications will be assessed to determine if:

- The applicant meets the eligibility criteria;
- The project described constitutes 'Biomedical research' in the context of the consent process, and is likely to be understood as such by the sample donors;
- It breaches any of the ethical permissions or restrictions in the consent forms for any component cohort or collection;
- It has the potential to produce information that will enable identification of individual participants;
- That PhD students include details of their research supervisors;
- The research breaches the Fort Lauderdale terms of data sharing for "Community Resource Projects", the PBC Genetics Study being considered to be such a project.

Proposals that are in direct conflict with existing approved studies will not be approved unless a formal collaboration can be established to the benefit of all investigators.

Conditions of Access

- Access will only be granted upon completion of a signed Data Access Agreement. Applications may include collaborators however each Institution involved must submit a signed Data Access Agreement.
- All individuals or organisations that agree to data sharing will take on the responsibility for maintaining confidentiality, only using data for approved purposes.
- All approved projects will be required to submit a report at pre-agreed intervals, or at completion of the project, to the UK-PBC Access Group.
- All individuals or organisations should pursue rapid and timely publication, acknowledging the data source as specified in the publication policy.

- Once study data has been published it will be made available via the same Data Access Agreement.
- No Intellectual property will be transferred with the data.

Assessment Process

Once contact is made with the UK-PBC Consortium, the consortium will identify a suitable UK-PBC Investigator to assist the applicant through the Access process.

Applicants are required to submit an outline application form once it has been developed in collaboration with the UK-PBC Investigator. The outline application is then reviewed by the UK-PBC Access Group who decide whether an application should be supported in principle or not.

Applicants will then be asked to respond to any questions raised by the access group or to provide additional information if necessary. This information will then be reviewed by the access group before a final decision is made. Where a unanimous decision cannot be reached, applications will be reviewed at an Access Group Meeting (usually held on a quarterly basis when necessary).

The panel consists of six individuals including independent experts in the area of PBC, representatives of the patient perspective and members of the UK-PBC consortium.

The panel will make recommendations to the UK-PBC Project Steering Committee who will have final decision on the outcome of requests.

Meeting dates are available upon request from the UK-PBC Project Manager.