

Access Committee for CLS Cohorts

Terms of Reference

Scope of the Committee:

The role of the Access Committee is to take decisions on applications requesting access to electronic data and biological samples from the CLS birth cohort studies¹. The aim is to allow important research to proceed while minimizing risks². The Committee is not concerned directly with the scientific merit of proposals but, rather, it addresses risks and benefits in determining whether access should be granted. However, in some instances, particularly when access is requested to a finite resource, judging the balance between risks and benefits may demand that appropriate consideration be taken of the scientific merit of the proposal. The Committee also provides a source of strategic advice and support to the funders.

As a distinct, though related, role, the ACCC is also the Committee of Final Appeal for any disputed decisions relating to access applications to the UK Twins study.

Terms of Reference:

- To establish policies and procedures for applications to access all types of data collected through the Birth Cohort Studies. This includes mechanisms by which responsibility for taking decisions on access to non-sensitive data could rest with the Data Custodians³ of the birth cohort studies and procedures whereby low risk data are available to researchers through designated archival services operating to approved standards of access and security.
- To consider and authorise individual applications requesting access to electronic data and/or biological samples from the birth cohort studies (where responsibility has not previously been designated to the Data Custodians). A framework of precedents will be established to ensure timely consideration of subsequent requests and, where appropriate, allowing Data Custodians to approve specific classes of applications.
- To address the following issues in determining whether access should be granted:
 - Medical ethics
 - Sensitivity of data
 - Statistical disclosure
 - Governance of the data – what consent has been given by cohort members and/or data owners
 - General risks – public perception, risk to continuation of cohort, sample depletion.
 - Confidentiality of data
- If appropriate, to take advantage of third party specialist knowledge, particularly where an application has not already been through established peer review mechanism.
- To provide strategic advice to funders to help them develop and maintain efficient and effective data, sample and tissue access mechanisms both nationally and internationally. This advice may include direct input as a multi-disciplinary group of experts as well as the identification of specific issues needing special consideration by funders. In particular, the Committee will advise the funders regarding the facilitation of stream-lined access of research users to data and samples while simultaneously respecting and securing the rights and well-being of study participants and of the cohort studies themselves. In providing such advice the

¹ Currently: NCDS (1958 Birth Cohort) – including data collected, and physical samples generated, through the biomedical sweep, BCS70 (1970 Birth Cohort) and Millennium Cohort Study (2000/01), Next Steps (formerly known as the Longitudinal Study of Young People in England, LSYPE)

² See for example Richard Thomas and Mark Walport “Data Sharing Review Report” July 2008 , page 70: <http://www.justice.gov.uk/docs/data-sharing-review-report.pdf>

³ Data Custodians are representatives of the PI team responsible for managing the birth cohort studies

Committee will give appropriate recognition to the extensive input of individual scientists and research groups to the development and maintenance of these important national studies.

- The Committee is not the final decision-making group for substantive issues of strategy or policy. The CLS Strategic Advisory Board (SAB) will provide strategic advice to CLS on policies for use of access to the resource. This advice will be given in light of funder policies and, in particular, guidance from the Expert Advisory Group on Data Access (EAGDA). The CLS director will be responsible for acting on this advice. The Access Committee may bring key issues to the notice of the SAB, via its chair who will sit *ex officio* on the SAB. It may also submit operational or strategic documents for consideration by the SAB, but the latter will maintain ultimate decisional power.
- To provide a Committee of Final Appeal for any disputed decisions relating to access applications to the UK Twins study
- The CLS SAB will ratify the Terms of Reference for the ACCC and will act as the appeals body for disputed decisions relating to the CLS cohorts (but not for decisions relating to UK Twins).

Audit Procedures:

The Committee will maintain an effective audit mechanism. All applications will be reviewed, and progress recorded and evaluated. The audit mechanism will include oversight of returned data.

Membership:

- Independent Chair – who will sit on the CLS Strategic Advisory Board
- Independent Deputy Chair – Voting member of the Committee appointed by the Chair
- Up to five (5) additional independent members (representing a range of medical/genetic and social science experts that are all capable of enacting the roles identified above)
- A representative from CLS will form part of the Committee as a voting member
- Tenure of membership – 3 years, with option to extend for a further 3 years after the first term only. Appointment to the Committee will be staggered in order to ensure continuity of membership.

Quoracy arrangements:

The full Committee involves three groups at its meetings: independent full members; technical review team members; and invited observers including representatives from each of the three funders (MRC, WT and ESRC) and the Principal Investigator of the main 1958BC grant. Specialist technical staff (members of the technical review team) includes Senior Officers from: (1) the Institute of Education (CLS); (2) Cambridge Institute for Medical Research; (3) ALSPAC laboratories; and (4) UK Twins Study

- Members of the technical review team are strongly encouraged to attend all meetings.
- Quoracy formally requires: “the attendance of three full independent members (with at least one independent member with genetic expertise and one with social science expertise) and that either the Chairman or the Deputy Chair must be present for continuity”.
- For face to face meetings, where it is unavoidable, attendance of a member by teleconference, will count as being present.

Modus operandi:

The committee will judge applications using the criteria and protocols outlined in a document entitled “*Policy for use and oversight of samples and data arising from the 1958 Birth Cohort*” (Annex A). This document may change from time to time. The current version is dated 9th August 2010 and the designated assessment criteria are as follows:

Assessment criteria

- Has the application been submitted by *bona fide* researchers?
- Does the application violate (or potentially violate) any of the ethical permissions granted to the study or any of the consent forms signed by the participants or their guardians?
- Does the application run a significant risk of upsetting or alienating cohort members or of reducing their willingness to remain as active participants of the particular CLS cohort of which they are a participant?
- Does the application address topics that fall within the acknowledged remit of the cohort in which they are a member, as understood by participants?
- Does the application request access to an infinite resource (data or cell line DNA) or a finite resource ?
- If the request is for a finite resource, then the application is seen as being in competition with other potential applicants (both current and future) and the quality of the science is reviewed formally (if necessary using independent external reviewers). Successful peer review by a major funder will usually be taken as evidence of appropriate quality.

Decision making:

Decisions of the Committee, including whether to grant access to a particular application, will generally be by consensus. In the unusual event of the Committee being unable to reach a clear consensus (as judged by one or more independent members) the decision will be put to a vote by the Chair, Deputy-Chair and independent members of the committee. If the votes are split evenly, the chairman will have a casting vote.

Frequency of Meetings:

The Committee will meet quarterly face to face, and on a monthly basis by teleconference.

UK Twins:

UK twins has its own primary access committee and generates very little work for ACCC. In the three years since ACCC was invited - via Wellcome Trust - to take on the role of Committee of Final Appeal for UK Twins, no appeals have been referred up to us. Critically, if and when an appeal is submitted, the ACCC will be decisional. Because UK Twins is not a CLS cohort, ACCC will not refer issues generated by UK Twins up to CLS SAB.

Membership of the Committee

Access Committee for CLS Cohorts

Members	Term of office
<p>Professor Paul Burton (Chair) School of Social and Community Medicine Faculty of Medicine and Dentistry University of Bristol Bristol BS8 2BN</p>	2009
<p>Professor Blair Smith (Deputy Chair) Division of Population Health Science Mackenzie Building Kirsty Semple Way Ninewells Hospital and Medical School Dundee DD2 4RB</p>	2009
<p>Professor Barbara Maughan King's College Institute of Psychiatry Denmark Hill London SE5 8AF</p>	2009
<p>Mr Paul Bradshaw ScotCen Social Research 73 Lothian Road Edinburgh EH3 9AW</p>	2012
<p>Professor Alissa Goodman Centre for Longitudinal Studies Institute of Education 20 Bedford Way London WC1H 0AL</p>	2014
<p>Professor Meena Kumari Institute for Social and Economic Research, University of Essex, Colchester, CO4 3SQ</p>	2014
<p>Professor Melinda Mills Department of Sociology University of Oxford, Manor Road, Oxford OX1 3UQ Nuffield College, New Road, Oxford OX1 1NF</p>	2014
<p>Dr Cathie Sudlow Division of Clinical Neurosciences, University of Edinburgh, Western General Hospital, Edinburgh EH4 2XU</p>	2014

Technical Advice Group	
<p>Dr Susan Ring School of Social and Community Medicine University of Bristol Bristol BS8 2BN</p>	2009 -
<p>Mr Jon Johnson Centre for Longitudinal Studies Institute of Education 20 Bedford Way London WC1H 0AL</p>	2009 -
<p>Mr Neil Walker Cambridge Institute of Medical Research WT/MRC Building, University of Cambridge Addenbrookes Hospital Cambridge CB2 0XY</p>	2009 -
<p>Dr Massimo Mangino (UK Twins Study) Department of Twins Research & Epidemiology St Thomas's Hospital Campus Westminster Bridge Road London SE1 7EH</p>	2011 -
Observers	
<p>Dr Katie Finch MRC Headquarters 1 Kemble Street London WC2B 4AN</p>	
<p>Dr Nidhee Jadeja Wellcome Trust HQ 215 Euston Road London NW1 2BE</p>	
<p>Ms Rachel Hall Economic and Social Research Council Polaris House North Star Avenue Swindon SN2 1UJ</p>	
Secretariat	
<p>Mrs Janet Jones Department of Health Sciences University of Leicester 22-28 Princess Road West Leicester LE1 6TP</p>	