METADAC TERMS OF REFERENCE

Responsibilities

1. To consider requests for access to biological samples and data derived from the following studies:

    - 1958 National child Development Study (NCDS)
    - 1970 British Cohort Study (BCS70)
    - Millennium Cohort Study (MCS)
    - Understanding Society (UKHLS)
    - English Longitudinal Study of Ageing (ELSA)

2. To consider and authorise applications for use of the following data and samples:

    - Genotype data linked to phenotype and/or survey data
    - Genotype and other omics data not linked to survey data, when this carries a risk of disclosure or otherwise requires case-by-case review.
    - Biological samples intended for further analysis and linking to phenotype and/or survey data.

    METADAC will also consider new datatypes generated as these arise and decide if they meet the criterion of disclosure risk.

3. To judge applications using the criteria and protocols outlined in each Study's data access documentation and to apply METADAC policy. METADAC policy will be reviewed when necessary and made available to the public via its web-page.

4. To explore the potential for harmonisation between studies in the access procedures and the principles that underlie them, and to establish a framework of precedents to inform consideration of subsequent requests.

5. To undertake good practice in data governance, and review processes periodically as needed to respond to changes in the technical, legal and socio-ethical landscape of longitudinal research data and governance

6. To develop, pilot and adopt protocols for graduated decision making including, where appropriate, proportionate review of applications by a sub-group of the Access Committee.

7. To develop scalable processes for adding further studies to the governance arrangements under the METADAC.
   Other UK Longitudinal studies may be added depending on METADAC's anticipated workload. These will be studies that:
   - Need governance for managing researcher access to linked genetic data, biological samples, or omics data
   - Include 1000+ participants
   - Hold data in managed UK repositories (e.g. EGA, UK Data Archive)
   - Have an existing or agreed governance route for applying for unlinked survey data or genetic data
   - Hold data/samples under UK ethics agreements and laws on data protection and human tissue
   - Are longitudinal – include long-term participant follow-up

8. To contribute to discussion of national and international issues in data access policy and to consider policy issues arising from data applications or raised by Study Directors. As appropriate, to publish reports, position papers or comments to inform and facilitate other data access governance teams, funders and policy-makers, with emphasis on the application of policy in practice.

9. To disseminate policies to applicants and encourage adherence to all guidance and requirements.

10. To provide a Committee of Final Appeal for any disputed decisions relating to access applications to the Twins UK Study.

Membership

11. Membership of the Committee will comprise at least seven independent members as outlined below:

- An independent Chair (biomedical or social scientist)
- An independent deputy Chair (social or biomedical scientist, to complement the Chair)
- At least one academic member from the social sciences
- At least one academic member from the biomedical sciences
- At least one clinical member
- At least one academic member with legal expertise.
- Two study-facing members

The Chair and Deputy Chair will be one social scientist and one biomedical scientist.

To safeguard quoracy and improve continuity, an additional member from each category of expertise may be included as required.

12. A representative from among each Study's investigators will attend meetings in an advisory, ex-officio capacity.

13. A Funder representative, members of the Technical Review Team and a representative from the UK Data Service will be in attendance at Committee meetings as observers and to provide information to help inform decisions. Members of the METADAC research team may also attend to observe.

14. Members, including the Chair and deputy-Chair, will usually be appointed for three years, with the option to extend for a further three after the first term only. Appointment to the Committee will be staggered in order to ensure continuity of membership. The recruitment process will occur annually, when new appointments are necessary.

The Committee will co-opt members as and when there is a need for additional expertise. These members will have full voting rights and their term will end on appointment of new members through the annual recruitment process.

Mode of Operation

15. The Committee will meet face to face twice a year, usually in the first and third quarters of the year, to discuss emerging issues in relation to data access and provide information on these to the individual studies and funders. The Committee will also hold teleconferences, usually at six-weekly intervals. Study Directors will be copied into email correspondence regarding individual applications.

16. Applications will normally be considered by the full METADAC Access Committee. Quoracy formally requires the attendance of half the full independent members (with at least one independent member with biomedical science expertise and one with social science expertise) and that either the Chair or the Deputy Chair must be present for continuity. In addition at least one study-facing member must be present, or have provided comments in advance. For face to face meetings, where it is unavoidable, attendance of a member by teleconference, will count as being present.

17. Applications deemed suitable for Proportionate Review may be considered by a sub-set of the Data Access Committee as agreed by the DAC. Approval by Proportionate Review must be by unanimous agreement, and will be reported to the METADAC committee. Proportionate Review procedures will be subject to evaluation and adjustment by the METADAC access committee.

18. Comments from the Technical Review Team will be circulated to the Committee along with any applications requesting access to the data.

19. Decisions of the Committee on whether to grant access to applications will be based on a majority vote. In the event that either a) a majority decision amongst Committee members is not reached; or b) a Study Director has grave concerns that the Committee's decision creates unreasonable risk for the Study, the Chair of the Committee will refer the decision to the relevant appeals body (see *Dispute Resolution*).

20. Where appropriate, the Committee will take advantage of third party specialist knowledge, particularly where an applicant seeks to use depletable samples. Where necessary the specialist will be invited to sit on the Committee as a co-opted member.

21. The Committee is not the final decision-making group for substantive issues of strategy or policy. These will be raised and discussed with the Study advisory boards. For wider or generic policy issues, the Committee will raise and discuss issues with its three funders and the Study advisory boards as relevant.

Reporting

22. The Committee will report at least once a year on all study-specific issues to the respective Study Governing/Advisory Board and will support reporting as required for the Research Tissue Bank ethical approval. The work of the Committee will also be reported annually to funders through a single report submitted by the PI of the grant funding the work of the Committee. This may be shared with additional Boards/Committees within the wider governance arrangements of individual studies.

23. METADAC's activity will be publicly reported on its web-page for the interest of study participants, researchers and the general public.

Dispute Resolution

24. Study Governing/Advisory Boards will act as the appeals body for disputed decisions relating to individual studies (but not for decisions relating to UK Twins, for which METADAC is the Committee of final appeal). Should the Governing/Advisory Board fail to reach a decision or their decision is challenged, the request will be referred to the relevant funder(s) for a decision.