**Terms of Reference and Implementation Guide for the Oxford Primary Care Hosted Research Datasets Independent Scientific Committee (PrimDISC)**

**Background to this document**

The Nuffield Department of Primary Care Health Sciences (NDPCHS) is developing a unified approvals process for accessing departmental data resources. This includes applications to use primary care research datasets, and for the re-use and re-analysis of existing Departmental Trials, Cohorts or other studies. There will be an independent committee to review applications. This Committee, PrimDISC, will work to provide access only to NDPCHS assets listed in: XXX, as some resources require a particular (different) mode of access. This list/site will be reviewed at least on a yearly basis and ideally monthly to ensure it is maintained up-to-date. PrimDISC acts on behalf of the NDPCHS Research Committee.

**Examples of the type of data (non-exhaustive list) that this document covers are:**

* Observational research within hosted primary care research databases where appropriate
* Completed Trials data from the CTU
* Completed cohort data (including early waves of follow-up)
* Special consideration will be necessary for on-going studies where data is still being collected

This includes access to raw data, summary tables and analyses which have not been previously published where the Nuffield Department of Primary Care Health Sciences are the Information Asset Owners regardless of the original study location or the source of funding.

This document sets out how the Terms of Reference for a unified approvals process may be operationalised.

***Terms of Reference***

* To follow the criteria and principles set out by the NDPCHS Research Committee in assessing and advising on research applications to access NDPCHS databases
* To provide timely and high-quality peer review of the scientific (medical, epidemiological, methodological) merit of research protocols proposing access and use of the patient data within its remit
* To provide timely and high-quality peer review of the feasibility, quality and public health value of applications proposing the use of the patient data within its remit
* To assess and advise on ethical or confidentiality issues that may arise during access and/or use of the patient data within its remit in research studies, taking into consideration input from the research ethics committees or other groups, as relevant
* To follow the criteria and principles set out by the relevant oversight boards in assessing and advising on applications to access the databases
* To review internal workings of the Committee to ensure consistency, efficiency and high standards of peer-review are maintained
* To advise the research teams on technical issues that may arise.
* To advise on other specific issues within its remit, as requested.
* To assess if the proposed project requires ethical approval and to make any positive evaluation contingent to confirmation that this has been obtained.

**Operationalising the formation of the committee**

***Initially PrimDISC will consist of:***

* Independent Chair appointed by the Department’s Research Lead and/or Head of Department: Professor Rafael Perera
* Deputy Chair will be appointed in competition and judged by the HoD, Chair and Department Research Lead
* 3 academic members from NDPCHS Oxford as nominated by the Research Lead and/or Head of Department: Professor Stavros Petrou, Professor Clare Bankhead, and Dr James Sheppard)
* 3 external academic members from Oxford and elsewhere (advertised positions)
* 2 Patient and Participant Involvement representative

Members may stand for a maximum of five years. Existing members will sit on the committee for 2 or 3 years, whilst other members are appointed, so that the membership is gradually replaced throughout the years.

We expect representation of the different assets discussed in PrimDISC (e.g. ORCHID) although they might not be members of PrimDISC and clear guidelines regarding Conflict of Interests will be followed.

The committee will be committed to equality, and will value and strive for diversity in the membership.

Meetings will be considered as quorate when attendance is 50% +1.

**Secretariat and resourcing**

Secretariat formed by combining the existing staff and secretariat from ORCHID and other Department Professional Service staff. (Lucy Curtin has agreed, others to be considered include Ivelina Yonova, Sneha Anand, Jolanta Parkinson).

* Applications will be submitted to the Secretariat.
* Feasibility or appropriateness of a proposed analysis will be screened by the secretariat to ensure that the proposed projects (and applicants) are suitable. If this is unclear they will liaise with the PIs on the appropriate data resources before review by the committee. In case of re-use of primary research studies (departmental trials, cohorts), advice from the PI/IAO is likely.
* At the time of application the Secretariat will ensure that the applicant must be a bona fide researcher employed or studying at an appropriate institution
* This will also apply to the situation where researchers are developing grant applications. Committee review will be necessary once funding has been secured, or the project is likely to go ahead.
* Secretariat will assign each validated project to two members of the committee to review before the next meeting.
* Expansion is likely needed to share workload of project review – particularly for ORCHID
* Resources will be needed for this process

**Committee meetings**

* Monthly meetings will be convened (may need to be longer than 2 hours)
* A detailed proposal must be provided, and must be demonstrably in the public interest; - to be determined by the committee
* Fast track/urgent applications may be expedited if there is an urgent scientific need to do so.
* If many applications are deemed fast track then the frequency of committee meetings may be increased to adapt to the demand.
* Two members of the committee to review each application before the next meeting.
* These members will present their review to the whole committee with a recommendation for approval, revise and resubmit, or reject.
* Applications will be circulated to all members for information and to inform discussion during the monthly meeting
* Where a committee member is an investigator on an application to be discussed, they must step out of the meeting for the relevant discussions.
* Where an application is to re-use or re-analyse a Departmental Trial or Cohort, the PI or Information Asset Owner will be notified in advance and asked to attend the meeting to present any particular considerations pertaining to that dataset.

**Particular considerations**

Some Data resources bases may need other external approvals e.g. ORCHID access will require approval from this committee, the Joint Research and Surveillance Centre Committee (JRSSCC), and currently, individual ethical approval for each project. Overarching ethical approval is underway.

* Trials and Cohort data from existing and historical projects are all conducted under individual ethical approval – ethical and other approvals for reanalysis of these data will be decided on a case-by-case basis – but it is likely that new analyses may require ethical amendment. The case for this will be informed by the PI/IAO for the data required.
* Research is often conducted over a prolonged period of time, necessitating an extensive amount of work prior to any output generation. It may therefore, be necessary to have a period of time whereby data from primary research projects are restricted to the PI and the research team. This will be considered on a case-by-case basis for permissions to re-use bespoke data.

**Requirements for accessing data**

* *Privacy considerations:* participant level data will only be released as pseudonymised, or fully anonymised data. Applicants must not attempt to identify participants; - to be ensured by the IAO
* *Data-transfer agreement:* data-transfer agreements must be signed between the applicant and the NDPCHS SIRO, or delegated signatory. – between the IAO, Applicant and SIRO
* *Return of derived data:* applicants must undertake to provide to the Department, within a specified period, any derived data not requiring linkage to other studies.

## Constraints on access to data resources

The Department has clear guidelines regarding the formal constraints on access to data sources. Members of PrimDISC are referred to the relevant documentation for clarification/explanation but the main aspects to consider in any proposal are:

* *Consent/legal:* the scope of the consent obtained
* *Ownership/control:* who owns thedata
* *Political sensitivities:* these could be specific to the place (e.g. country) where the research occurred

These issues are recognised in UKRI’s Common Principles on Data Policy (in particular, in Principle 5).

**Summary of Application Flow**

1. Applications for data access submitted to Secretariat
   1. Feasibility/design issues: Secretariat advise suitability of applicants, with guidance from PI if necessary Secretariat (not forwarded to Committee)
2. Full applications: Secretariat assign 2 lead reviewers
3. All applications circulated to committee ahead of meeting for information
4. At meeting: lead reviewers present each application
5. Committee decides: accept; revise and resubmit; reject
6. Secretariat notify applicants
7. Ethical approval sought (ORCHID and primary research studies)
8. Study abstract published on website
9. Data transfer forms completed prior to secure transfer of data

**Enquiries regarding data access and applications should be sent to** [orchid-reg@phc.ox.ac.uk](mailto:orchid-reg@phc.ox.ac.uk)