**ClinicAl research using LInked Bespoke studies and Electronic health Records (CALIBER)**

**Data access & NON-DISCLOSURE agreement for researchers**

This agreement is between the **University College London (UCL) Institute of Health Informatics** and **<insert name>** **(“Researcher”)** for access to CALIBER resources1.

# 1 Access to data resources

1.1 Data will be prepared according to researcher requirements based on the specifications of the approved project-specific Independent Scientific Advisory Committee (ISAC).

1.2 Researchers must register to use the data safe haven and attend the safe haven and information governance training before access to data will be granted.

# 1.3 Non-UCL staff will be granted UCL associate staff or honorary status and must abide by terms as set out by UCL.

1.4 Approved projects will either be led by a Farr investigator or will involve a named Farr investigator on the research proposal.

# 2 Lawful use of data

2.1 Data will be processed in accordance with the Data Protection Act (1998).

2.2 Researchers will abide by the conditions for handling data as set out in the UCL information governance policy (https://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/ig-documentation/SLMS-IG03\_Research\_Information\_Governance\_Policy\_v5.0.pdf).

2.3 Researcher use of data is limited to the purpose specified in the project approved ISAC and researchers will use the data according to the terms specified by the Clinical Practice Research Datalink (CPRD).

2.4 Researchers will not try to identify individual patients, primary care practices, hospital or other identifiable entities or combination of entities within the data.

2.5 The provided data will not be linked, merged, compared or tabulated in combination with other health or non-health data.

# 3 Security of the data

3.1 Data will only be accessed via the UCL data safe haven.

3.2 Staff that has access to data will abide by the terms specified in the UCL information security and supporting policies (<https://www.ucl.ac.uk/informationsecurity/policy>). Breaches of confidentiality (e.g. disclosure of confidential information to a person not authorised to receive it) constitute grounds for disciplinary action.

3.3 Knowlingly disregarding the conditions relating to the security of data will be considered a serious offence and will result in action being taken against the researcher and the researcher’s organization. UCL reserves the right to audit for adherence to the terms as written here.

3.4 All security or confidentially incidents or suspected incidents must be reported to Dr Spiros Denaxas (s.denaxas@ucl.ac.uk) within 24 hours.

3.5 Researchers will not share project data with anyone who is not named on the project ISAC.

# 4 Products and publications

4.1 Researchers will share all phenotypes, analytic scripts, codes, methods and tools developed as part of the project on the CALIBER data portal in the interests of transparency and reproducibility.

4.2 Researchers will acknowledge CALIBER resources in all publications, grants, reports, conference proceedings, websites, books or book chapters, and other citable objects (e.g. software, toolkits and algorithms).

4.3 It is good practice to register the project with clinical trials.gov and researchers should endeavour to do so.

***Declaration of responsibility by the lead researcher (Principal Investigator)*** 2

I hereby accept the terms described within the CALIBER data access and non-disclosure agreement and agree to abide by the conditions as set out above.

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| --- | --- |
| Lead researcher signature: |  .  |
| Lead researcher name (block capitals): |  .  |
| Position in organisation: |  .  |
| Date (dd/mm/yyyy): |  .  |
| ***CALIBER Approval***The responsible data custodian for the CALIBER Data Lab authorises the provision of access to the data to the beneficiary organisation under the terms specified in this agreement. |
| Signature: |  .  |
| Name (block capitals): |  .  |
| Position in organisation: |  .  |
| Date (dd/mm/yyyy): |  .  |

1Resources include CALIBER project data (and other linked data source(s)) as specified by the researcher; contribution the institutional license fee; guidance on the approvals process; access to CALIBER methods, tools and eInfrastructure; training; and membership of the CALIBER research community.

2The lead researcher is responsible for the management, conduct and reporting of the research project and will be named in the full research proposal.