Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
mASCARA

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

(●) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

3. In which country of the United Kingdom is the database established?

(●) England

( ) Scotland

( ) Wales

( ) Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying data to the database be located? *(tick all that apply)*

- [x] England
- [x] Wales
- [x] Scotland
- [x] Northern Ireland

4. Which applications do you require?

- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)

6. Do you plan to include any participants who are children?

- ○ Yes
- ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- ○ Yes
- ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- ○ Yes
- ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

- ○ Yes
- ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

- ○ Yes
- ◉ No

RESEARCH DATABASE

NHS Health Research Authority

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
mASCARA

Please complete these details after you have booked the REC application for review.

REC Name:
East Midlands - Derby Research Ethics Committee

REC Reference Number:
24/EM/0002

Submission date:
01/12/2023

A management protocol or similar document should be enclosed with this application. This should be a comprehensive outline of the purpose, operation, methods, policies and governance of the database.

Part A: Core Information

Administrative information

1. Title of the Database

Multinational Anal Squamous Cell Carcinoma: Registry and Audit

2. Name and address of the establishment *(i.e. the legal entity responsible for storage of the data)*

Organisation	Imperial College London
Address	154 Norfolk Place St Mary's Campus
Postcode	W2 1PG
Telephone	+44 (0)20 7594 3328
Fax	

3. Name of the Applicant *The applicant should be the person with overall responsibility for the management of the Database and will be regarded as the Data Controller.*

Title	Forename/Initials	Surname
Miss	Sarah	Mills

Address	Chelsea and Westminster Hospital 369 Fulham Road
Postcode	sw10 9nh
E-mail	sarah.mills58@nhs.net
Telephone	07939723118

Mobile	
Fax	

A copy of a current CV (maximum 2 pages) for the applicant should be enclosed.

4. Name of the Data Custodian *This should be a senior person at the establishment, other than the applicant, who is independent of the research database team and able to provide assurance that appropriate information governance is in place.*

	Title	Forename/Initials	Surname
	Professor	Paul	Elliott
Address	154 Norfolk place St Marys Campus		
	Imperial College London		
	London		
Postcode	W2 1PG		
E-mail	p.elliott@imperial.ac.uk		
Telephone	+44 (0)20 7594 3328		
Mobile			
Fax			

5. Has this database (or any part of the database) previously been the subject of an application for ethical review?

(●) Yes ( ) No

If Yes, was the application approved?

(●) Yes ( ) No

Name of Research Ethics Committee:	East Midlands - Derby Research Ethics Committee
Date of decision:	16/01/2019
REC reference number:	18/EM/0397

Purpose of the Database

6. Summarise the types of data to be stored. *Please state the population base and the selection criteria for inclusion of data in the Database. Indicate what data is already held and summarise the plans for further data collection from patients, service users or care records. Indicate whether any particularly sensitive data will be held.*

In 2019 we set up mASCARA which is an international database of anal squamous cell carcinoma (SCC) outcomes.

mASCARA is a secure web-based platform that has been available to use from May 2019. It has been designed to be GDPR compliant and had gained ethical approval from the Derby Research and Ethics Committee in the UK. This is an application to renew the REC opinion for another 5 years.

The inclusion criteria is any patient (male or female) over 18 years of age, with or without HIV, with a histologically confirmed diagnosis of anal high grade squamous intraepithelial lesion (HSIL) or Squamous Cell Carcinoma (SCC).

12 sites have completed the registration process with approval of their local Research and Development departments since the database was created. The database currently holds 275 pseudonymised patient records. As yet we have not used, analysed or released any data. We plan on continuing recruitment of more national and international centres and increasing the amount of data/information held in the database.

The database includes data on demographics, staging, treatment (surgical and oncological), prior screening attendances and outcome data such as survival and recurrence.

The Data is entered by a clinical site in a pseudonymised form without the pseudonymisation key or other means for

the database administrators to identify individuals from the Data. Once a new record is created, patients are allocated a randomized identification number, which is linked to a health services identifying number (for example hospital number in the UK or national insurance number equivalents in Europe) on the first page of the database interface, to ensure that there is no duplication of previous records. Records can also be found and updated but will be kept in a format that you cannot search for an individual patient.

Most centers will already have their cancer outcomes available and would need to input these into mASCARA once registered to the database, which requires approval of their local research and development departments; a GDPR compliant data access agreement between the site and Imperial College needs to be signed. Final end outcomes such as recurrence, 5 year survival or death would be inputed unto the database at a later stage if this information is not available.
We provide an example consent form and patient information leaflet within the study documents.

At each centre a data guardian such a local MDT coordinator (a member of the direct care team locally) would be in charge of ensuring any relevant outcome information is updated.

Please enclose a list of all data items to be stored. Enclose a copy of any questionnaire to collect data from donors which is additional to data collected in the course of normal healthcare provision.

7. Justify the collection of this data and describe how it will be used for research. *Summarise the overall policy of the establishment for use of the data, including release to other researchers or research organisations. Say what other research databases already exist in this field. What will this database add to existing resources and what will be the potential benefits?*

Anal Squamous Cell Carcinoma (SCC) is an uncommon cancer with an incidence rate between 1 and 2 per 100,000 per year. The incidence of anal SCC is increasing rapidly, with an overall 63% increase in incidence rate of anal SCC in the UK since the 1990's. However, there is much discrepancy in best surgical practice for the treatment and prevention of anal SCC.

As anal SCC is a rare cancer it is difficult to gain sufficient patient numbers with enough statistical power to be able to provide evidence-based conclusions on best practice. Regional guidelines differ considerably and there is widespread variance in practice between different clinical centres.
Although generic cancer databases such as Cancer Outcomes and Services Dataset (COSD) in the UK and the National Cancer Database (NCDB) in the USA exist they are limited to the data streams that are available to them. Both cannot link, for example, to HIV status or outcomes related anal high-grade squamous intraepithelial lesion (HSIL) (the precursor to SCC). Neither can they report treatment regimes and recurrence rates.
It is likely that the increasing incidence is related to, at least in part, the increasing prevalence of HIV therefore not including this data is a significant confounding factor.
In order to provide a suitable platform to allow further dedicated study into anal SCC, we have developed an international Anal Squamous Cell Carcinoma registry; mASCARA.

mASCARA is to our knowledge is still the only international anal cancer registry which allows for the collection of data on demographics, relevant risk factors (HIV status, previous genital HPV infection, smoking), screening, previous anal HSIL treatment, SCC diagnosis, anal SCC end outcomes and core outcome research measures in anal cancer. Moreover, it allows us to compare best practice between different countries and in turn will be integral to the development of standardised best management guidelines for the treatment and prevention of anal cancer on an international level.

We have an established research base at Chelsea and Westminster Hospitals NHS Trust and at the Royal Marsden NHS Foundation Trust for research into the best treatment of anal squamous cell carcinoma as well as its prevention. This expertise is due to the Royal Marsden and Chelsea and Westminster being a tertiary referral centre for anal SCC as well as Chelsea and Westminster being the National Center for HIV related malignancy. Moreover Chelsea Westminster NHS Foundation Trust has recently been awarded funding by RM Partners cancer alliance to develop the Chelsea Anogenital Neoplasia Service (CANS), a service which aims to improve the early detection of anal cancer as well as treatment of anogenital HSIL for all high-risk patients; with a special focus on women who have so far been excluded from such strategies despite being the patient group most affected by anal SCC. We are therefore in a strong position to be leading on the development of evidence based guidelines, which will arise from the analysis of data from mASCARA.

The database is held centrally and only anonymous data will be analysed. The current REC approves the use of anonymised datasets from mASCARA for any relevant research project. Data will be anonymous on release as it will be released without any allocation numbers.

We do not intend to release any data to other research organisations. We have however previously received REC approval to provide NHS England with 10 anonymised outcomes annually for their audit purposes and to also create a

dashboard to improve the quality of care for anal SCC patients.
The ten outcomes are: number with Anal SCC, patient discussed in a specialist anal SCC MDT (yes/no), performance status (0-5), staging documented (yes/no), proportion with early staging (number), number of patients who had chemo-radiotherapy, number of patients with a permanent stoma after treatment, number of patients that undergo local excision of their tumour, number of patients who have an abdomino-perineal resection, 30-day readmission (yes/no), 5 year survival (yes/no).
NHS England have agreed, to maintain patient anonymity and they will not have any access to the dataset. The Data Controller will download from mASCARA an annual anonymised (no allocation numbers) secure excel spreadsheet of just these outcomes in hospitals in England.
Data is presented to healthcare professionals in a password protected dashboard for NHS use only. There is no geographical identifiers or any data that could lead back to a patient being identified from the dashboard.

We would like to keep the approval to provide NHSE with data with this REC renewal.

8-1. How have you actively involved, or will you involve, patients, service users, or members of the public in establishing the database and its policies?

Once we obtained the original ethics and funding in 2019, we created a prototype database that patients and service users had an opportunity to review and comment on prior to finalization of the database, which is now live.

9. How will you inform data subjects and other patients, service users and members of the public of the results of research?

As data is anonymised, we are unable to contact individual patients. We will publish any results obtained in a peer reviewed journal.

10. How will the Database be managed, financed and sustained to ensure the potential benefits are realised?

The database is financed by a grant. The grant will incorporate, as well as its development costs, database maintenance costs for 10 years.
It will be managed centrally by our anal SCC management team at Chelsea and Westminster Hospitals NHS Foundation Trust.

Information governance

11. What personal identifiers will be held with the data records? *Please tick all that apply.*

- ☐ Initials
- ☐ Full name
- ☐ Address
- ☑ NHS or CHI number
- ☐ Hospital ID no.
- ☐ GP registration
- ☑ Date of birth
- ☐ Year of birth
- ☑ Date of death
- ☐ Postcode
- ☑ Other geographical identifiers

please specify

Location of hospital patient is treated at (ie: Chelsea, Bristol, Brighton).

Purpose for which postcode/geographical identifiers required:

- ☐ Deprivation scoring
- ☐ Lifestyle analysis
- ☑ Geographical analysis

- [x] Gender
- [ ] Occupation
- [x] Ethnicity
- [ ] Other identifiers

12-1. What systems will be in place to ensure the confidentiality of personal data? *What will be your policy for limiting access to identifiable data within the establishment. Say who will have access and for what purposes, what training they will have and how the confidentiality policy will be monitored and enforced.*

A patient's data is inputted into the database by a member of the direct care team at the site where the patient's care is based.
Patients are allocated a randomized identification number. The allocation number is linked to the patient's hospital number or international equivalent to ensure no duplication takes place but once inputted all data will be anonymised for analysis.
Only members of the direct care team have access to the allocation numbers of their own patients and they individually do not have access to raw data of other patients. Anonymized data will only be released on request by the data controller for specific agreed projects with REC approval.

13. What security and audit measures will be in place to secure access to identifiable data held by the Database?

All data will be held on a secure password protected professional medical database created specifically for this purpose.

Imperial College London will audit research activity.

14. What arrangements will be in place for monitoring the Database's systems and procedures?

Imperial College London monitors research activity and maintenance of the database.

Use of data by the Research Database team or other researchers

15. Do you wish to seek generic ethical approval for research projects using the stored data, under conditions agreed with the REC, without requirement for researchers to apply individually to the REC for approval?

(●) Yes ( ) No

16. What types of research will be undertaken and in what field(s) of health or social care?

Colorectal Surgery, Oncology, Gyneacology, Sexual Health and HIV medicine.

We will undertake retrospective population based research looking at outcomes of both Oncological and Surgical treatments, prediction models of the development of anal SCC from its precursor anal HSIL and patient demographics.

17. Give summary details of the research team. *It is not necessary to name individuals, but please give an indication of the types of researchers who are likely to be involved and the expertise available within the team, including IT and other support staff. Include any external research organisations or units you plan to collaborate with, if known.*

There is a centralised research team based at Chelsea and Westminster NHS Hospitals Foundation Trust of colorectal surgeons, oncologists, pathologists and statisticians. Imperial College London will act as the Data Custodian and monitor use of the database and GDPR compliance. The database is designed and hosted by Netsolving Ltd a professional medical database company with experience in providing other medical database solutions.

18. Will any types of research or research organisation be excluded from receiving data?

○ Yes ◉ No

19. What arrangements will be made to consider applications from researchers for access to the data? How will decisions on access be made and who will be involved? *Include details of arrangements for ensuring adequate scientific critique of research proposals.*

If outside of the remit of our disclosed plans to REC on this application, we would first ensure the request on the database is ourselves appropriate and of interest. This could be discussed at a local research meeting or MDT then request that the researchers gain REC approval for their project. We would only release anonymous data.

20. Please give details of how the data will be effectively anonymised or pseudonymised to protect the confidentiality of subjects. What measures will you take to prevent possible re-identification by linking to other databases?

Data is pseudonymised as we need to randomly allocate an identifying number to data inputted and ensure that no duplication take place. Only members of the direct care team will have access to their own pseudonymisation list and will not have access to the raw data for other research teams patients. All analysis will take place on anonymised data only (released without the allocated identification number).
Where patients are consented, the consent forms will also be kept by the direct care team and not stored at the sponsor site to protect confidentiality.

21. What conditions will apply to the sharing of data with researchers? *Please summarise the terms of any data access or data sharing agreement and say how these will be monitored and enforced.*

We will only share data with other researchers if it is within the agreed remit of this REC committee assessment or if it is an unforeseen project, if a proposal is submitted with scientific merit that successfully gains REC approval.
Access to pseudonymisation lists will be password protected and only be accessible to each direct care team.
Access to the raw anonymous data will be password protected and only researchers with administrator status would be allowed to download anonymous data for analysis and share as requested.

22. Is it possible that the research could produce findings of direct clinical significance for individuals? *(This may include relatives as well as data subjects.)*

As data will be anonymised for analysis we will not produce findings of direct clinical significance to individuals.

23. Where research data is of direct clinical significance for individuals, will arrangements be made to notify the individuals concerned?

○ Yes ◉ No

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.
All data will be anonymised for analysis.

24. Will data be released to individuals/organisations conducting research outside the UK?

◉ Yes ○ No

If Yes, please give details and describe any additional safeguards you will put in place:
We allow international access to submit patients to the database. If a collaborating center requests anonymised data for their own research this will be provided as long as it is either within the pre-agreed REC approved remit of the database or, if unforseen, of scientific merit and approved by a REC at a later date.
Anonymised data will be sent securely via an encrypted email.

25. What policies will apply to further storage and use of data by researchers when studies are complete? What mechanisms will be in place for approving further studies?

The database will be held and used for research purposes for another 10 years. After this point, if further use is required REC approval will be sort.

Data collection and informed consent arrangements

Question 26 applies to existing collections of data only.

26. Has informed consent already been given to use the data for research?

◯ Yes ◉ No ◯ Not applicable

If Yes, please describe what arrangements were made to seek informed consent and for what purposes. A copy of the information sheet and consent form should be enclosed. Confirm that the consent covers the uses of personal data now proposed by the Research Database team.

If No, or if existing consent does not cover the purposes now proposed, say whether consent will now be sought. Please include details of the arrangements for seeking consent in your answer to questions 28 - 30. If consent will not be sought, please justify.
Existing collections of data are retrospective and held by direct care teams at collaborating centers. As data is historic it would not be feasible to consent for inclusion and data used for analysis will be anonymised.
If a patient is diagnosed with anal SCC after REC approval date, they will be consented by their local direct care team to have their data included in the database. Up to now, we have been consenting everyone diagnosed with anal SCC or HSIL after 1st January 2019 (date of previous REC approval). We would follow the same methodology if REC approval is renewed this second time with the new REC approval date.

Question 27 relates to identification of the data cohort. It applies to all new data collection from patients, service users or health records.

27-1. How and by whom will records be identified?

Records will be identified by the local direct care team from previous local clinical databases, MDT data and clinical encounters.

27-2. Will this involve reviewing or screening identifiable personal information of potential data subjects?

◉ Yes ◯ No

27-3. Please give details of how identification will be carried out and what resources will be used?

The local direct care team at each center will screen the suitability of the inclusion of their patients in the database. No personally identifiable data will be accessible to anyone outside of the patient's direct care team.

27-4. Will individuals other than the direct healthcare team have access to identifiable personal information of potential data subjects for this purpose?

◯ Yes ◉ No

Questions 28 - 30 apply in all cases except where the application relates to an existing data collection and consent has already been obtained.

28. How and by whom will data subjects first be approached? *Indicate whether this will be in the course of healthcare provision or whether additional procedures will be involved. In the case of additional procedures, what burdens could arise for participants?*

If patients are diagnosed with anal SCC after the REC approval date, they are treated as prospective patients and their consent is sought for the inclusion of their data in the database.
Patients are identified on their diagnosis and discussion of management at local MDT meetings. Patients are approached by members of their local direct care team in the course of healthcare provision.

29-1. Will you obtain informed consent from or on behalf of data subjects?

◉ Yes ○ No

If you will be obtaining consent from adult data subjects, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.
If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.
If you will not be obtaining informed consent, please complete question 29-3.
We seek informed consent from all patients recruited after the REC approval date, this is taken by a member of the patient's local direct care team.
Only patients with capacity to give informed consent will be included.

Please enclose a copy of the information sheet(s) and consent form(s).

29-2. Will you record informed consent in writing?

◉ Yes ○ No ○ Not applicable

30-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information in English, or who have special communication needs? *(e.g. translations, use of interpreters)*

All informed consent interactions are conducted by the direct care team in clinical settings where access to interpreters and other communications aids is readily available.

30-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to data subjects in Wales?

If Welsh centers wish to participate we will liaise directly with their local Research and Development offices to provide an alternative translated Welsh Patient Information Sheet and Consent form.

Questions 31 - 32 apply to all applications:

31. Will any financial or other incentives be offered to data subjects?

There will be no incentives to data subjects.

32. What steps will be taken where data subjects subsequently withdraw consent to the use of their data? What information will data subjects be given about this?

The direct care team will be informed and asked to identify the randomly allocated patient identification number from the pseudonymisation list. Their data can then be deleted by an administrator. However, as analysis will be randomised, it will be impossible to delete data from previous downloaded versions of the data and previous analyses. The patient information leaflet clearly explains that depending of the time of the request we will be able to delete the patients record from the database but may not be able to prevent their data being used in analysis.

Summary of the application

33. Please provide a brief summary of the application in a form suitable for publication, using language easily understood by patients and public. *The summary will be published on the website of the National Research Ethics Service following the ethical review. You may cut and paste from answers to other questions.*

Title of the database: Multinational Anal Squamous Cell Carcinoma: Registry and Audit

Establishment responsible for management of the database:

Organisation	Imperial College London
Address	154 Norfolk Place St Mary's Campus
Postcode	W2 1PG
Telephone	+44 (0)20 7594 3328
Fax	

Data to be stored and data collection arrangements (maximum 200 words):The database will hold information about patients with Anal Squamous cell Carcinoma and and Anal High-grade Squamous Intraepithelial Lesions, its precancerous precursor. It will include demographics and cancer outcomes before and after treatment.This information will be taken from patient notes, will be held in a pseudoanymised format, released in an anonymised format and used for many different research projects aimed at better treating patients with anal cancer.
Research programme/community supported by the database (maximum 200 words):This database will be used by colorectal surgeons, HIV physicians, Gynaecologists and oncologists internationally as a valuable source of anonymised data that can support multiple studies and guide further research into the treatment of anal cancer.

Part C: Data Collection Centres

Please enter details of the organisations (NHS or other) in the UK that will act as data collection centres for this research database.

Data collection centre	Local collaborator
Chelsea and Westminster NHS Hospitals Foundation Trust	Miss Sarah Mills
The Royal Marsden NHS Foundation Trust	Professor Paris Tekkis
Swansea Bay University Local Health Board	Rhiannon Harries
Royal Liverpool and Broadgreen NHS Foundation Trust	Javed Ahsan
West Middlesex University Hospital	Miss Sarah Mills

Part D: Declarations

D1. Declaration by the applicant:

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. If the application is approved I undertake to adhere to the terms of the application of which the REC has given a favourable opinion and any conditions set out by the REC in giving its opinion.
3. I undertake to seek an ethical opinion before implementing substantial amendments to the terms of the application of which the REC has given a favourable opinion.
4. I undertake to submit annual progress reports to the REC.
5. I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application:
    - Will be held by the main REC indefinitely (or until 3 years after the closure of the Database).
    - May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
6. I understand that a summary of this application will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication

NRES would like to include a contact point with the published summary of the application for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- (●) Applicant named at A3
- ( ) Other – please give details
- ( ) None

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to the establishment and other research units and collaborators would be removed.

This section was signed electronically by Ms Sarah Mills on 30/11/2023 08:51.

Job Title/Post:	Consultant Surgeon
Organisation:	Chelsea and Westminster NHS Foundation Trust
Email:	sarah.vonroon@gmail.com

Part D: Declarations

D2. Declaration by Data Custodian

1. I confirm that the information in this application is accurate to the best of my knowledge and belief and I approve the application.
2. I confirm that the establishment has Data Protection Registration appropriate to the purposes described in this application.
3. I confirm that the establishment has an appropriate System Level Security Policy in place for the systems used by the Database.
4. If the application is approved, I confirm that I will take responsibility for ensuring that the arrangements described in the application are adhered to and any agreed conditions of ethical approval are complied with.

This section was signed electronically by Paul Elliott on 30/11/2023 11:39.

Job Title/Post:	AHSC Director of Information Governance
Organisation:	Imperial College London
Email:	p.elliott@imperial.ac.uk