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)
SDMregistries

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)
SDMregistries

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

REC Name:
West of Scotland REC 1

REC Reference Number:
24/WS/0059

Submission date:
01/05/2024

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

International Registries For Rare Conditions Affecting Sex Development & Maturation (formerly known as I-DSD/I-CAH)

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

Organisation	The University of Glasgow
Address	MVLS IT Services
	Sir James Black Building
Postcode	G12 8QQ
Telephone	01413302813
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
Professor	S. Faisal	Ahmed

Address	Royal Hospital for Children
	Office Block, RHC & QEUH campus
	Glasgow
Postcode	G51 4TF
E-mail	Faisal.Ahmed@glasgow.ac.uk
Telephone	0141 451 5841

Mobile	07362458988
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
	Mr	Paul	McLaughlin
Address	IT Manager, Room 203		
	James Black Building		
	University of Glasgow		
Postcode	G12 8QQ		
E-mail	paul.mclaughlin@glasgow.ac.uk		
Telephone	01413302813		
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:	WoSREC
Date of decision:	09/09/2019
REC reference number:	19/WS/0131

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.*

The population base is people with a health concern about their sex or sexual development. Most of these people are identified in childhood and may also present in early infancy with an abnormality of the development of the external and/or internal reproductive organs. There is a large amount of variation in how these patients are managed across the UK as well as across the world. In addition, there are enormous gaps in our knowledge about the aetiology of these conditions and the long-term outcome in adults with these conditions. The original I-DSD Registry was conceived following the Chicago Consensus meeting in 2005 when the need for pooling standardised information in cross border registries was identified as a priority. The prototype ESPE DSD Register became the EuroDSD Registry when it was supported by EUFP7 in 2008 and in 2011 it became the International DSD (I-DSD) Registry when it secured a grant from the UK MRC. By 2014, it was clear that the I-DSD Registry was collecting information on several broad groups of conditions that needed a dedicated condition specific module within the Registry. Therefore, I-DSD developed a module for congenital adrenal hyperplasia and called it I-CAH and in 2022, it launched another module for Turner Syndrome, I-TS. All these modules use the same registry platform within which they have a dedicated condition specific module for these three groups of conditions. Over the next year, it is anticipated that the registry platform will have a dedicated module for hypogonadotropic hypogonadism and for Klinefelter Syndrome. These are all conditions that are already collected in the existing registry but for detailed information they need a dedicated module. As many people do not identify with the term Disorder of Sex Development, (DSD), it was felt that a suitable replacement would be conditions affecting sex development and maturation, ie SDMregistries. This change in terminology also aligns with the terminology that has been adapted in the European Reference Network for Rare

Endocrine Conditions (https://endo-ern.eu/rare-sex-development-maturation-conditions/) . The registries are currently supported from funding from a wide range of sources that includes fees incurred by investigators for obtaining data for research, project grants, income from the biennial symposium and unrestricted education grants from the pharmaceutical industry. In 2023, I-DSD/I-CAH/I-TS has a network that reaches 260 centres in 63 countries on all the continents. Of these, 135 active centres from 45 countries use the registries and have entered over 7,500 cases where information can be shared for a range of purposes that have the ultimate aim of improving the health of people with these rare conditions.

The Registry is used in all the continents and is highly research active. It has a steering committee and a scientific panel and has a stand-alone international biennial meeting. It has been scrutinised by previous ethics advisers of the EuroDSD and I-DSD programmes. Patient and parent input has been provided through representation within the steering committee as well as through a dedicated workshop held for user groups in Bologna in 2016. The registry, is currently open to approved eligible users with clinical and/or research interests in conditions affecting SDM. The inclusion criteria include any patient with a condition affecting sexual development and maturation. The registry consists of brief diagnostic details but no patient identification details except gender and date of birth and date of death. Each case dataset is provided with a unique registry identifier. The clinician entering the data is asked to make a local record of this unique registry identifier and keep a local link to the actual case. Each centre has one lead clinician (the centre lead) who is clinically responsible for all cases in their centre. Other members of the team may apply for access to upload cases in the same centre on behalf of the centre lead. In those cases where patients are seen by more than one registered centre, the named clinician for the Registry will be from the first centre. This reduces the chances of entering duplicate data. Clinicians entering/editing/modifying data shall receive notification immediately after completing the activity with the edit history and unique Registry identifier number which they can keep for their records locally.

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?*

The demand for the SDMregistries platform has remained strong and continues to get stronger. This is clear from its activities which are summarised in its Annual Activity Report (https://sdmregistries.org/activity-report/). The Registry has now become the standard international portal through which clinicians and researchers exchange information in a standardised and secure fashion. At each centre, more than one clinician can be provided with rights to enter new data, but only the centre lead can delete records.

In addition to great research value, the data that are stored on the Registry have also increasingly been used for care quality improvement projects (https://sdmregistries.org/quality-improvement/). The Registry acts as a resource which facilitates the collection of data which researchers can use to contact lead clinicians through the Project Management Group. Clinicians need to comply with their local country's rules on ethics and information governance. Individual clinicians shall only be able to search the Registry for their own patients.

The Project Management Group (https://sdmregistries.org/project-management-group/) oversees access to the Registry and the long-term use of the data. They are advised by a Data Access Committee (https://sdmregistries.org/data-access-committee/) which examines all requests for data. Researchers with potential studies approach the Project Management Group and this Group ensures that studies have all the appropriate approvals for being granted access rights. The Steering Committee that oversees all the activities of SDMregistries abd the Data Access Committee consist of patient representatives as well as representatives of international professional societies.

In summary, named clinicians approved by the Project Management Group enter data on patients regularly on the electronic registry. In the UK, clinicians shall provide patients and their parents if the patient is less than 16 with an information sheet and an opt-in consent form. Following approval by the Data Access Committee, the Project Management Group, will provide researchers with information on patients suitable for their study for a limited period and subject to a data sharing agreement.

The potential benefits include:-

1. The collection of these data will allow researchers internationally to design new studies and have the ability to recruit large enough groups of carefully ascertained patients.
2. The registry will promote the use of standardised methods of collecting data and describing clinical conditions. It will, therefore, also drive up standards of clinical care.

3. Such a registry would be the only means of conducting long-term outcome studies.
4. By developing a uniform process for collecting data, the registry will promote standards of information governance.

To date over 30 full publications have been produced using data from SDMregistries (https://sdmregistries.org/research-output/).

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?

The SDMregistries project seeks advice from its panel of experts on ethics issues. For the UK development of the electronic web-based registry, service user representatives from groups such as CLIMB CAH Support Group and the AIS Support Group and dsdFamilies.org provided input into the Registry. The I-DSD Steering Committee and the Data Access Committee include members who are patients or parents of patients. Based on their input we only include patients after informed consent (Opt-in system), have developed user-friendly information leaflets and support studies that have a patient focus. The biennial International DSD meetings have strong representation from patients and parents and their input was enhanced further through the COST action, DSDnet which organised a dedicated workshop for patients and parents to provide input on registries. The Registry also allows patients to access the Registry and request deletion or revision of the data. In the next version of the Registry, patients and parents will also have the ability to complete Patient Reported Outcomes.

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

The Registry can be used for secondary research on anonymised data which may result in publication in a journal or dissemination at a conference or meeting, thereby falling into the public domain. In these cases, patients will not be informed of the specific use of their data. The use of data will already be consented through the Opt In consent process where patients are given information leaflets. Patients can find out more from the website https://sdmregistries.org/. SDMregistries also holds a regular drop-in session that is open to everybody and it also has a contact page https://sdmregistries.org/contact/ which can be used to contact the Project Management Group.

In addition:-
- there is a twitter feed https://twitter.com/sdmregistries
- all outputs will be open access
- there are links to the websites of partner societies who are also present in the Steering Committee
- dissemination occurs through several scientific meetings where data are presented
- dissemination occurs at education and consultation meetings for patients
- lastly, there is also a 6-monthly newsletter (https://sdmregistries.org/news-events/)

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

SDMregistries is managed by a Steering Committee & its Project Management Group. It is funded through a range of activities including its biennial meeting (https://sdmregistries.org/11th-i-dsd-symposium-2024/), a postgraduate course (https://sdmregistries.org/2nd-postgraduate-course-in-dsd/), data access fees for researchers (https://sdmregistries.org/procedure-for-obtaining-registry-data- for-research/) and industry sponsors who support any of these activities. The University of Glasgow is committed to maintaining the Registry over the longer term. Developments in the registry, such as developing a specific condition specific module requires additional funding and this funding is provided by the expert groups who seek the condition specific module.

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

- [x] Year of birth
- [x] Date of death
- [ ] Postcode
- [x] Other geographical identifiers

please specify

- The hospital and health care provider where the patient receives clinical care.
- Access to 'the patient space' will require the email of the patient or the patient's carer. This will be an optional exercise which the patient will need to choose on the consent form and they will need to provide their email to their local clinical team.
- The date of birth is necessary to calculate several time dependent outcome indicator

Purpose for which postcode/geographical identifiers required:

- [ ] Deprivation scoring
- [ ] Lifestyle analysis
- [x] Geographical analysis

- [x] Gender
- [ ] Occupation
- [ ] 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.*

No personally identifiable data except those mentioned above shall be stored on the Registry. All those involved in the running and development of the Registry will have to be up to date with the General Data Protection Regulations and and will complete the University of Glasgow online course (http://www.gla.ac.uk/services/dpfoioffice/dataprotection onlinetr ainingmodule/) and familarise themselves with the University's policies on data protection and management at https://www.gla.ac.uk/myglasgow/openresearch/researchdatamanageme nt/. The registry platform has also undergone a satisfactory cybersecurity review and a University of Glasgow Data Protection Impact Assessment Review in 2023 (further information can be supplied)

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

IT Services at the University of Glasgow have a body of projects associated with fine-grained security. In restricting access to the registry and its contents, roles based access control (RBAC) and identity based access control (IBAC) mechanisms are applied. The assignment and revocation of roles and hence privileges to individuals involved in either entering cases to the registry or accessing cases will be through agreement with the SDMregistries project office. Authentication to the portal and delivery of attribute certificates for local authorisation at the portal level is made through a dedicated Identity Provider. This same standard will be maintained for the SDMRegistries project. The platform is currently undergoing a rebuild and the revised version will also have multifactor authentication built into it.

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

Access to the SDMregistries will be perpetually monitored and information logged on its usage. Basic internet-based monitoring tools shall be used for recording patterns of interactions (including ensuring that only recognised client IP addresses are used when accessing the registry). Finer grained auditing and logging of access and usage of the registry contents will be maintained through portal-based solutions which leverage the RBAC and IBAC mechanisms. Feedback on access and usage of the registry will be regularly discussed at project meetings. This is the system we have used for the other successful registries that we have run from Glasgow. In addition to internal governance systems and procedures, SDMregistries will also be governed by its Steering Committee.

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?

The data on the Registry has been used for several purposes including Searching for suitable cases, Designing a study, Preparing case for funding, Performing a prospective study that may require additional local ethical approval. The data on the Registry has been analyzed to provide a summary update on the contents of the Registry to funding bodies as well as to groups interested in using the Registry for their research. This research will also report on the use of the Registry and its development. Secondary research can be performed on the extended dataset by approved researchers subject to adherence to the conditions of ownership and publications described in the data sharing agreement and subject to the approval of the Data Access Committee. Further details of the process for obtaining data is provided at https://sdmregistries.org/procedure-for-obtaining-registry-data-f or-research/.

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.*

The Project Management Group consists of the project lead (S.F. Ahmed), a clinician scientist, a data scientist, a senior project manager, project support assistant, a clinical lecturer (specialist trainee). There are close links with the University's IT services, legal and contracts team and the data protection team. In addition, there is a steering committee and a data access committee that oversees data access. More recently the project has also developed a care quality improvement committee and a learning and training committee. Names and details are available at https://sdmregistries.org/about/. Research on the data in the Registry is performed by a wide range of investigators from across the world.

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.*

Searching the Registry for data at centres other than the user's own centre is only possible by the Project Management Group. Depending on the amount of work involved data searches will incur a fee which is stated at the website. Researchers are advised to get in touch for further information. The Office for Rare Conditions in Glasgow can provide more extensive study support depending on the investigator's needs and may include:-
- Advice on study process and design
- Liaising with Registry users on behalf of the study investigators
- Developing study specific modules
- Prospective investigators should contact the office before embarking on, developing, or seeking funding for the study so that the costs of this proposed work can be clarified. They complete a Data Request Form and a Data Sharing Agreement. They can use the Data Dictionary to identify fields required for their study.
Once submitted all study documents are sent to the Scientific Panel for approval.

Further details are available at https://sdmregistries.org/data-access/

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?

The data held in the Registry will be pseudonymised. The clinician entering the case data shall hold the NHS, CHI or Hospital ID number separately at their local centre. On completing the core dataset within the Registry, the clinician shall be provided with a unique registry number. The clinician shall store this registry number and the link to local case details (NHS,CHI number) in their local institution physically separate from the Registry. The Project Management

Group will not be able re-identify the patient. The clinical user will have strict instructions not to enter personally identifiable data (except for Date of Birth, Date of Death, Gender and Health Care Provider) in any section of the Registry. Access to 'the patient space' in the Registry will require the email of the patient or the patient's carer. This will be an optional exercise which the patient will need to choose on the consent form.

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.*

All prospective researchers will be asked to provide details of the proposed project including the need for funding, dissemination, patient and public involvement, clinical impact, publication policy at outset with specific timelines. They will also be asked to complete a data sharing agreement. They will be informed of the conditions of ethics approval of the data and instructed that any information or biomaterials that the investigators intend to collected which is over and above the information that is routinely collected as part of normal clinical care will require further ethics review. Approved researchers will be provided the data that they are seeking by the Project Management Group and contact with clinicians will be initiated by the Project Management Group. The Project Management Group will meet with the researchers at the launch of the project, 3 months after the launch and then 6-monthly while the project is active. Progress reports will be required at 12 monthly intervals and these will be supplied to the Data Access Committee.

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.)*

It is possible that patient centred outcome measures collected on individual patients may have some direct clinical significance. These data will be deposited in the individual's own web space and can be accessed by the patient. There will be clear guidance in this section that these data need to be discussed by the individual with their clinician. This approach has been adopted in other registries and from personal experience in the clinical setting, these features have strengthened the patient-doctor relationship and increased the patient's interest in their own condition.

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.
As discussed above, the data that will be collected will reflect clinical care and will be discussed at the clinic that the individual attends. In addition, aggregate data shall be posted on the SDMregistries website. However, centre specific and patient specific data shall not be publicly available.

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:
The data will be provided to all researchers approved by the Data Access Committee. The information sheet will clarify this and explicitly state that the data can be shared with any approved researcher. We have used this approach over the last two decades and all participants have allowed for the data to be accessed by any approved researcher in the world. This is very important in the field of rare conditions where the research may be performed at a site very far away from the patient. In addition, meaningful data from aggregates may only be possible when data are shared across international geographical boundaries. The Data Sharing Agreement that has been developed with the help of the legal team at the the University of Glasgow can be adapted for the purpose of the Office for Rare Conditions acting as a data processor (when receiving data from a centre) or data controller (when providing data to a researcher). Standard contractual clauses can be incorporated if any researcher works in a country where the UK does not have existing data adequacy agreements.

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?

All active and completed studies are published on the SDMregistries website at https://sdmregistries.org/studies/. A new researcher who proposes a study which overlaps with an active study will be put into contact with the other researchers. Researchers will be encouraged to consider new studies on the data that are already stored in the Registry and as new studies are performed the data in the Registry become richer. As long-term outcome is a critical

aspect of this Registry, it is proposed that the data shall be stored for a period of 30 years but an approval will be sought every 5 years. This will allow data to be stored indefinitely subject to the 5yrly ethics approval.

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.
Informed consent will be obtained from each patient (or their legal carer) who is entered into the registry. See questions 28-30.

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?

Patient identifiable records will be kept separately in the local hospital records by the clinician and their team who is entering the data. The pseudonymized data will be accessible to the clinician and their team, the patient as well as the Project Management Group. When the data are shared with a researcher, a Confidential Study ID for each case for that specific study will be provided to the researcher. The researcher will not be provided with the Registry ID. This will allow a double-lock system which will make it even more difficult for researchers to identify a case at any specific centre.

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 clinician responsible for entering the data shall have access to the locally held NHS/CHI/Hospital number and shall be able to link these to the unique Registry ID. This clinician will identify cases locally, obtain consent and enter core data into the Registry.

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?*

Data subjects will first be approached as part of routine healthcare.

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.
To obtain consent and for providing information about the Registry, the clinician or their respective team shall approach the patients and their legal guardians, if applicable, at the routine hospital visit. Alternatively, the clinician or the team can also provide information and obtain consent remotely by means such as tele or video consultation. An electronic copy of the signed consent form will need to be sent to the clinician's centre for local records and for the purpose of any future auditing.

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)*

Information sheets have been created in several languages already and this continues to increase as the project matures. See https://sdmregistries.org/information-sheets-consent-forms/.

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?

As the Registry becomes more widely adopted throughout the UK including Wales, there will need to be an appraisal of its use across the UK and how its use can be further extended. The development of information sheets in Welsh and other minority languages in the UK as well as other parts of the world remains an important consideration for this international registry. To date, we have not been asked to create any information in Welsh although Welsh centres are now participating in the Registry.

Questions 31 - 32 apply to all applications:

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

No.

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 information sheet will clearly state that the data can be removed by the data subjects or their legal guardians. In addition, the Registry is developing a patient dashboard which patients will have access to and within which they can alter their settings and notify their clinician that they would like to delete their data.

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: International Registries For Rare Conditions Affecting Sex Development & Maturation (formerly known as I-DSD/I-CAH)

Establishment responsible for management of the database:

Organisation	The University of Glasgow
Address	MVLS IT Services
	Sir James Black Building
Postcode	G12 8QQ
Telephone	01413302813
Fax	

Data to be stored and data collection arrangements (maximum 200 words):All data shall be stored on secure servers in the University of Glasgow and will be kept strictly confidential and all information will be handled through very secure electronic systems. The Registry users will not be able to make contact with any patient because the name, address and hospital number will not be recorded. Only the hospital doctor and their team will be able to contact the patient as they can link the data in the Registry to the hospital records. To access the data from the Registry, investigators will need to apply to the Data Access Committee and once the application has been approved, the data shall be provided to the investigators with strict data sharing agreement. The provision of data will also occur through secure electronic systems rather than just by email. Again, the data that are provided will not contain any information that can allow the investigator to link the information to the actual patient. A progress report will be obtained every year to understand the research progress of the investigators.
Research programme/community supported by the database (maximum 200 words):SDMRegistries is a project which was initially launched in 2008 as the ESPE-DSD Registry and has been developed with the needs of people with a wide range of rare conditions that affect sex development and maturation. The project has been highly successful and generated several important results. With increasing maturity it is also focussing in improving the quality of care. There are currently no other international registries for these group of conditions and around 200 centres from around 50 countries on all six habitable continents are currently using the platform.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Children from the age of birth onwards will be eligible to be included in the Registry. Given that a large proportion of rare conditions present in childhood, there is a considerable focus on this research in children, their management and their long-term outcome.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Consent shall be obtained from the person with parental responsibility. Whilst it is appreciated that many children under the age of 16 yrs can provide consent for themselves, it is possible that a number of children are not under regular followup from late childhood. Leaving it to the clinicians to ensure whether a child is mentally ready to provide consent was considered to be logistically difficult, especially as this project will cover several centres across Europe and beyond. We have, therefore, opted for a blanket approach of covering every young person at a standard age of 16 yrs. This is consistent with the GDPR too. The reading age of the information sheet has been kept low enough for older children above 14 to be able to understand the document and it can therefore, be used for a child presenting for the first time around that age. Within the electronic registry we have used a system where a reminder is sent to the clinician to obtain consent from a young person over 16 whose information was entered before the age of 14.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

Children under the age of 16 years and their parents shall be provided with the single information sheet. An additional sheet has been developed for the child between the ages of 8 and 14 years, as attached.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

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
Greater Glasgow & Clyde NHS Board	Faisal Ahmed
Aberdeen Royal Infirmary	Susan McGeoch
Addenbrooke's Hospital	Ajay Thankamony
Alder Hey Children's Hospital	Joanne Blair
Barts Health NHS Trust	Evelien Gevers
Birmingham Children's Hospital	Ruth Krone
Brighton & Sussex University Hospitals NHS Trust	Shankar Kanumakala
Bristol Royal Hospital for Children	Elizabeth Crowne
Bristol Royal Infirmary	Natasha Thorogood
Cardiff & Vale University LHB	Aled Rees
Churchill Hospital, Oxford	Jeremy Tomlinson
Doncaster and Bassetlaw Teaching Hospital	Anuja Natarajan
East Surrey Hospital	Ben Field
Great Ormond Street Hospital for Children	Peter Hindmarsh
Guy's & St Thomas' NHS Foundation Trust	Michal Ajzensztejn
James Cook University Hospital	Mark Burns
King's College Hospital (London)	Ved Bhushan Arya
Kingston Hospital NHS Foundation Trust	Eswari Chinnasamy
Leeds Children's Hospital	Nadia Amin
Leicester Royal Infirmary	Savitha Shenoy
Manchester Royal Infirmary	Alex Lewis
Ninewells Hospital	Nicholas Conway
Norfolk and Norwich University Hospital	Emma Webb
Nottingham University Hospitals NHS Trust	Tabitha Randell
Oxford Children's Hospital	Fiona Ryan
Princess Anne Hospital, Southampton	Gabriella Gazdagh
Royal Devon & Exeter NHS Foundation Trust	Bijay Vaidya
Royal Hallamshire Hospital (Sheffield)	Miguel Debono
Royal Hospital for Children and Young Peple	Harriet Miles
Royal Infirmary of Edinburgh at Little France	Roland Stimson
Royal Manchester Children's Hospital	Mars Skae
Sheffield Children's Hospital	Nils Krone
St Bartholomews Hospital, London	Marta Korbonits
St Georges Hospital, London	Zacharoula Karabouta

St Peter's Hospital	Thang S. Han
St Thomas' Hospital	Paul Carroll
The Christie Hospital NHS Foundation Trust	Safwaan Adam
The Royal Belfast Hospital for SickChildren	Noina Abid
The Royal Victoria Hospital (Belfast)	Steven Hunter
The Royal Victoria Infirmary (Newcastle)	Tim Cheetham
University Hospital Birmingham	Helena Gleeson
University Hospital of Wales, Cardiff	Hima Bindu Avatapalle
Chealsea & Westminster Hospital	Rebecca Scott

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 Professor SF Ahmed on 19/04/2024 16:36.

Job Title/Post:

Organisation:

Email: faisal.ahmed@glasgow.ac.uk

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 Mr Paul McLaughlin on 22/04/2024 11:26.

Job Title/Post:	IT Manager
Organisation:	University of Glasgow
Email:	paul.mclaughlin@glasgow.ac.uk