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 enter a short title for this project (maximum 70 characters)
The ESPE DSD Registry

1. Is your project an audit or service evaluation?

○ Yes ◉ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial or clinical investigation
○ 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, other human biological samples and/or 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)*

☑ England
☑ Wales
☑ Scotland
☑ Northern Ireland

4. Which review bodies are you applying to?

- [x] Research Ethics Committee
- [x] National Information Governance Board for Health and Social Care (NIGB)

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

- ○ Yes
- ◉ No

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

- ◉ Yes
- ○ No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

10. Is this project financially supported by the United States Department for Health and Human Services?

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

RESEARCH DATABASE

National Patient Safety Agency
National Research Ethics Service

Short title and version number: (maximum 70 characters – this will be inserted as header on all forms)
The ESPE DSD Registry

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

REC Name:
West of Scotland Research Ethics Committee 1

REC Reference Number:
To Complete

Submission date:
05/05/2009

Part A: Core Information

Administrative information

1. Title of the Database

The ESPE DSD Registry

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

Organisation	The University of Glasgow
Address	National E–Science Centre,Room 243B
	Kelvin Building
	University of Glasgow
Postcode	G12 8QQ
Telephone	0141 330 8606
Fax	0141 330 8625

3. Name of the Data Controller *(i.e. the person with overall responsibility for the management of the Database)*

Title	Forename/Initials	Surname
Prof	Richard	Sinnott

Address	The National e–Science Centre (NeSC
	Kelvin Building
	University of Glasgow
Postcode	G12 8QQ
E–mail	r.sinnott@nesc.gla.ac.uk
Telephone	01413308606
Mobile	
Fax	01413308625

4. Contact point within this organisation for purposes of the application *(if different to A3)*

	Title	Forename/Initials	Surname
	Dr	S. Faisal	Ahmed
Address	Dept of Child Health		
	Royal Hospital For Sick Children		
Postcode	G3 8SJ		
E−mail	s.f.ahmed@clinmed.gla.ac.uk		
Telephone	01412010571		
Mobile	07765422533		
Fax	01412012837		

Purpose of the Database

5. 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 ESPE DSD Group is a group of clinicians and academics who deal primarily with patients with abnormalities of gonadal or adrenal function that lead to a disorder of sex development. Most of these patients are identified in childhood and often 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.

In Scotland, a core dataset on children and young adults is currently stored on an electronic register held by the Scottish Genital Anomaly Network (SGAN) (sgan.nhsscotland.com) which is a national clinical managed care network supported by the National Services Division of NHS Scotland. The contents of this core dataset have been scrutinised by clinician members of SGAN, the executive group of SGAN which consists of service users and the Caldicott guardian for NHS Greater Glasgow & Clyde.

Until quite recently, there has been little consensus about data collection in patients with a disorder of sex development. In 2006, a group of international experts attempted to reach a consensus on terminology. The SGAN dataset adopted this terminology and the dataset has also been scrutinised by a working group within the European Society of Paediatric Endocrinology, ESPE (www.eurospe.org/about/ workinggroups/DSD) and the current version (attached) has now been adopted by this special interest group of ESPE and is currently being used as the core dataset within the EuroDSD project − a programme of research which started in 2008 and is funded by the EU Framework Project 7 grant (www.eurodsd.eu). As part of the EuroDSD programme, the core dataset has been transformed into an electronic web−based registry by experts at the National E−Science centre and who are led by Prof R Sinnott (www.nesc.ac.uk/nesc/staff/rsinnott.html). The web−based EuroDSD registry has been scrutinised by the ethics advisers of the EuroDSD programme (www.eurodsd.eu/en/wp−01−virtual−research−environment−vre.php). This registry, funded by the EuroDSD programme is currently only open to programme partners.

As the core dataset has achieved a very high level of consensus between professionals within Europe and there is current funding and support for the web−based registry, the next logical step is to extend the web−based registry to other clinicians in the UK. A similar level of enthusiasm exists in other partner states in Europe and some countries outside the EEA have also expressed an interest in this collaborative work. The inclusion criteria would include any patient with a suspected disorder of sex development. The registry will consist of brief diagnostic details but no patient identification details except gender. Each case dataset shall be provided with a unique registry identifier. The clinician entering the data shall be asked to make a local record of this unique registry identifier and keep a local link to the actual case. Each centre will only have one named clinician. 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 will reduce the chances of entering duplicate data. Clinicians entering/editing/modifying data shall receive an email immediately after completing the activity with the edit history and unique Registry identifier number which they can keep for their records locally.

In Scotland, there are current discussions which are ongoing with the Government to develop the dataset as it stands into a Scottish web−based clinical management toolkit which will be more than just a register of cases. Examples of this exist already in Scotland and include the cleft lip and palate network − www.cleftsis.scot.nhs.uk.

Please enclose a list of all data items to be stored.

6. 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. What will be the potential benefits?*

Within Europe as well as the UK, there is currently a strong demand for extending access to the EuroDSD Registry so that other clinicians can also enter data. In the future, it is also possible that others from outwith the EEA shall also be interested in participating in this project. It is envisaged that this Registry will then become the standard portal through which clinicians and investigators shall be able to exchange information in a standardised and secure fashion. At each centre, only one clinician shall be provided with rights to enter new data.

The data that will be stored on the Registry is by itself of very little research value. The Registry will simply act as a resource which facilitates the collection of meta−data which investigators can use to contact clinicians who are the sole contact point for patients. The investigators will have to secure ethics approval for their studies and the clinicians will need be responsible for securing local approval and obtain informed consent for specific studies. Investigators will only be available to perform studies for which they have ethics approval and their duration of access to the register shall be limited to the period of study. Clinicians shall need to comply with their local country's rules on information governance. Individual clinicians shall only be able to search the Registry for their own patients unless they have investigator level access for an approved study.

The special interest group of ESPE will act as the panel which will oversee access to the Registry and the long−term use of the data. Investigators with potential studies shall approach the ESPE DSD Group and this Group will ensure that studies have all the appropriate approvals for being granted access rights. Within the UK, the Society for Endocrinology and the British Society for Paediatric Endocrinology and Diabetes have also expressed an interest to be involved. Representatives of these two groups as well as other stakeholders including user support groups shall also be invited to provide their input into the UK limb of the registry.

In summary, named clinicians approved by the ESPE DSD Group shall enter core 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 ESPE DSD Group, investigators shall have access to search the Registry for patients suitable for their study for a limited period. They will then be able to contact the clinician responsible for the case of interest. Any subsequent studies performed with that case will require separate and specific ethics approval.

The potential benefits include:−

1. The collection of these data will allow researchers in the UK as well as in the EU 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.

7−1. How have you actively involved, or will you involve, patients, service users, or members of the public in establishing the database and its policies?

Service users have already been involved in the development of the SGAN Register. The EuroDSD project has already sought 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 have already been approached and provided input into the Registry. Based on their input we have decided to only include patients after informed consent rather than adopting an opt−out system.

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

The Registry itself will not be used for any research except for providing summary information of what the Registry consists of.

Patients shall be notified through the use of an information leaflet that will provide information about the Registry and information of the SGAN website where further details of what fields are included in the core dataset. This is the standard with which SGAN has adhered to.

In addition, Dr Ahmed has been invited by the CLIMB CAH Group to talk about the Registry at its annual meeting. It is envisaged that this may become a regular event at which the Group can be provided progress reports.

9. How will the Database be managed and financed?

The ESPE DSD Registry will be managed by the ESPE DSD Group. It is currently financed through the EuroDSD programme and a business case is being currently developed to seek funding from ESPE over the longer term. The NeSC has also been awarded a 5–year
platform grant (started August 2008) and is committed to maintaining the
Registry over the longer term.

Information governance

10. 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
- ☐ Date of death
- ☐ Postcode
- ☐ Other geographical identifiers
- ☐ Purpose for which postcode/geographical identifiers required
- ☑ Gender
- ☐ Occupation
- ☐ Ethnicity
- ☐ Other identifiers

11–1. 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 gender shall be stored on the Registry. This is achieved through fine grained security solutions based on role and identity based access control mechanisms developed by NeSC Glasgow.

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

The National e−Science Centre (NeSC) at the University of Glasgow have a body of projects and research 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 X509−based digitally signed roles (attribute certificates) are maintained in a secure attribute server maintained at NeSC. The assignment and revocation of roles and hence privileges to individuals involved in either entering clinical cases to the registry or accessing
clinical cases is through agreement with clinical investigators on the EuroDSD project. Authentication to the portal and delivery of attribute certificates for local authorisation at the portal level is made through the UK Access Management Federation and a dedicated Identity Provider at NeSC. This same standard will be maintained for the ESPE DSD Registry.

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

For the current EuroDSD project, the access to the registry is perpetually monitored and information logged on its usage. Basic internet−based monitoring tools such as GoogleAnalytics are 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 is maintained through portal−based solutions which leverage the RBAC and IBAC mechanisms. Feedback on access and usage of the registry is regularly discussed at EuroDSD meetings and via email between the EuroDSD collaborators. This same system shall be maintained for the ESPE DSD Registry.

Use of data by the Research Database team

Questions 14 – 19 apply where researchers within the Research Database team will have access to data for research. Answer in relation to this research programme.

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

◉ Yes ○ No

If Yes, questions 15 – 19 will be enabled.
If No, questions 15 – 19 will be disabled. Researchers will be required to apply individually using the project−based application form if they require ethical approval.
Go to question 20.

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

The data on the Registry shall be 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.

16. 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?

The above research will only be conducted by the members of the ESPE DSD Group and the National E−Science Centre who are involved in managing and developing the Registry. The main function of the Registry is not to perform research but to act as a conduit for specific ethics approved studies.

17. What conditions will apply to the sharing of data with researchers? *Please say how this will be monitored and enforced.*

As above researchers will be provided with a summary of what the Registry contains. They will not be allowed access to the Registry until they have ethics approval and access has been granted by the ESPE DSD Group.

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

Research performed on the Registry to provide summary data will not be of any direct clinical significance to patients or their relatives.

19. 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.
Summary reports of contents and activity within the Registry will not be of any clinical significance.

Use of data by external researchers

Questions 20 – 28 apply where the Research Database team will be releasing anonymised or pseudonymised data to researchers outside this team, whether in the same establishment or in other organisations in the UK or overseas.

20. Do you wish to seek generic ethical approval on behalf of external researchers who will be using data supplied by the Research Database team, under conditions agreed with the REC, without requirement for researchers to apply individually to the REC?

○ Yes ◉ No

If Yes, questions 21 – 28 will be enabled
If No, questions 21 – 28 will be disabled. Researchers receiving data will be required to apply individually to the REC using the project–based application form if they require ethical approval. Go to question 29.

Data collection and informed consent arrangements

Question 29 applies to existing collections of data only.

29. 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 31 – 33 If consent will not be sought, please justify.
To enter and share data across the UK, the EEA and beyond, the attached information sheet shall be used to obtain opt–in informed consent.

Question 30 relates to identification of the data cohort. It applies to all new data collection from patients, service users or health records.

30–1. How and by whom will records be identified?

The records will only be identifiable by the clinician entering the data.

30–2. Will this involve reviewing or screening identifiable personal information of potential data subjects?

(●) Yes ( ) No

30–3. 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.

30–4. Will individuals other than the direct healthcare team have access to identifiable personal information of potential data subjects for this purpose?

( ) Yes (●) No

Questions 31 – 33 apply in all cases except where the application relates to an existing data collection and consent has already been obtained.

31. 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.*

To obtain consent and for providing information about the Registry, hospital doctors shall approach the patients and their legal guardians, if applicable at the routine hospital visit.
In the case of additional procedures, what burdens could arise for participants?

32–1. 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 32–3.
Informed consent shall only be obtained with the help of an information sheet and consent form attached.

For children under the age of 14 yrs, approval is sought from their parents or legal guardians. When they turn 16 years, they shall be sent the information sheet to inform them of their inclusion on the Registry and their option to remove the data.

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

32–2. Will you record informed consent in writing?

(●) Yes ( ) No ( ) Not applicable

33–1. 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)*

Interpreters shall be used when necessary.

33–2. 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 beomes 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 will be an important consideration.

Questions 34 – 35 apply to all applications:

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

No

35. 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 clearly states that the data can be removed by the data subjects or their legal guardians.

Part B Section 2: 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 are eligible to be included on the Registry. Given that most patients with this group of conditions present in childhood, the focus of this research is primarily 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, this group of conditions is such 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. In SGAN, we have, therefore, opted for a blanket approach of covering every young person at a standard age of 16. The reading age of the information sheet is 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 a system shall be developed for sending a reminder 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 B Section 3: Additional information for applications to National Information Governance Board for Health and Social Care

1. Do you plan to extract data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

○ Yes ◉ No

2. Give a brief description of the confidential/sensitive patient information to be used.

The core dataset shall contain information on a number of key sensitive but objective features about disorders of sex development. Full dataset is attached.

Please enclose the full dataset with the application to NIGB.

3. Please list each of the identifiers required for validation or linkage and say why each data item is required (i.e. the justification for this combination of data items).

- ☐ Name
- ☐ NHS number
- ☐ Hospital ID no.
- ☐ GP registration
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
- ○ District level
- ○ Sector level
- ○ Sub−sector level
- ○ Unit level
- ☐ Other geographical identifiers (please specify)
- ☐ Other identifiers (please specify)

4. Which identifiers will be retained for analysis purposes?

- ☐ Name
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
- ○ District level
- ○ Sector level
- ○ Sub−sector level
- ○ Unit level
- ☐ Other geographical identifiers (please specify)

- [ ] Purpose for which postcode/geographical identifiers required
- ( ) Deprivation scoring
- ( ) Lifestyle analysis
- ( ) Geographical analysis
- [x] Gender
- [ ] Occupation
- [ ] Ethnicity
- [ ] Other identifiers (please specify)

5. If you need access to sensitive data items, please list them here and give a reason for requesting access to each item.

There is no need to access any other sensitive data for the Registry.

6. What is the justification for using patient identifiable data and/or HES restricted fields? *Say why anonymised data would not be fit for purpose.*

Clinicians who enter data will be the only people who have access to the hospital number on their own patients. Investigators will only be able to see the unique Registry number. The investigators will contact the clinician using the Registry identifier. The Clinician will link this Registry identifier with the local hospital number to obtain further details from locally held case records.

7. What are the sources of data?

The source of the data is from clinical activity in hospitals.

8. Please provide an overview of the data flows. *You may use or enclose a diagram to explain this if it is helpful. Stages of identifiability/de−identification should be specified and use of encryption for transfer or storage where applicable.*

The attached sheet details the data flow.

9. What is the frequency of the required extract?

- ( ) Monthly
- ( ) Quarterly
- ( ) Annual
- (•) Not applicable

10. Describe what other data are held by the organisation, which might interact with the data requested to allow person identification. Will you be linking this data with data obtained with NIGB approval or HES data? If so for what purpose?

Not applicable

11. Which class(es) of section 251 support are you applying for? *Tick all that apply:*

☐ Specific support required (requires Regulations to be laid before Parliament)

☐ Support required under the Health Service (Control of Patient Information) Regulations 2002 for public health or cancer registry purposes

☑ Class 1 support: the process of extracting and anonymising the information

☐ Class 2 support: to obtain and use information about past or present geographical location

☑ Class 3 support: to select and contact patients to seek their consent

☐ Class 4 support: to link patient identifiable information obtained from more than one source

☑ Class 5 support: for auditing, monitoring and analysing patient care and treatment

☑ Class 6 support: to allow access to an authorised user for one or more of the above purposes

☐ Not applicable – only using HES/SUS data extract which is not identifiable

12. Please provide details of how you comply with each of the eight principles outlined in the Data Protection Act 1998.

1	Fair processing	Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the conditions in Schedule 2 is met; and in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.
2	Used for specified purposes	
3	Minimum necessary for the purpose	The minimal amount of data that is necessary to facilitate research will be collected.
4	Accuracy	Data in the Registry shall be checked for accuracy annually.
5	Kept for minimum time necessary	The registry will only keep gender as identifiable data. To facilitate long−term outcome studies the data shall be held for a period of 30 years.
6	In accordance with rights of data subject	All data subjects and their parents (if applicable) shall be informed of the existence of the Registry and their inclusion in the Registry.
7	Security and confidentiality protection	The national E−science centre at the University of Glasgow is renowned for its secure systems. It has standing policies that ensure that appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
8	Not disclosed outside the EU	Personal data shall not be transferred to a country or territory outside the European Economic Area, without informed consent of the patient/parent.

13. Have you undertaken a self−assessment using the NHS Information Governance toolkit?

○ Yes ◉ No

If Yes, please provide details of your scoring and a summary of the actions to be taken as a result:

14. Who will act as Information Guardian for any health records or other personal information used by the research team during the study?

	Title	Forename/Initials	Surname
	Professor	Richard	Sinnott
Post	e−Science Technical Director		
Qualifications	BSc, PhD		
Employer	University of Glasgow		
Work Address	National E−Science Centre		
	Kelvin Building		
	University of Glasgow		
Post Code	G12 8QQ		
Work Email	r.sinnott@nesc.gla.ac.uk		
Work Telephone	0141−330−8606		
Fax	01413308625		

15. Will you be applying to a NHS Research Ethics Committee (REC) for ethical review of this database?

○ Yes – application submitted

Name of REC:

REC reference number:

○ Yes – application not yet submitted

◉ No

16. Do you have anything to add in support of the application, which is not included elsewhere on the form?

Part B Section 4: Information Security Measures

Note on the Freedom of Information Act

While the NIGB Ethics and Confidentiality Committee (ECC) has no plans to publish any of the information contained in this section, as a public body NIGB is required to comply with the Freedom of Information Act 2000 (FOIA). All information included in applications is therefore potentially disclosable. While the FOIA provides exemptions, which would in most instances cover the security information in this form, the presumption is in favour of disclosure and the NIGB Secretariat would be required to evaluate each request for disclosure on a case by case basis and provide justification why information had not been disclosed. One exemption is where information has been provided in confidence. If you want assurance, therefore, that this document will be treated in confidence, please tick the box below.

☐ **I request that the information contained in this form is treated in confidence by the NIGB and its security advisers within the Department of Health**

Corporate level security policy (CLSP)

Questions 1–7 should be answered in relation to each organisation receiving and processing identifiable data. Please open a separate set of the questions for each organisation.

Organisation 1

1. Please give the name of the organisation.

National e–Science Centre, University of Glasgow, Glasgow G12 8QQ Scotland, UK

2. What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within this organisation?

The National e–Science Centre (NeSC) at the University of Glasgow have a body of projects and research 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 X509–based digitally signed roles (attribute certificates) are maintained in a secure attribute server maintained at NeSC. The assignment and revocation of roles and hence privileges to individuals involved in either entering clinical cases to the registry or accessing
clinical cases is through agreement with clinical investigators on the EuroDSD project. Authentication to the portal and delivery of attribute certificates for local authorisation at the portal level is made through the UK Access Management Federation and a dedicated Identity Provider at NeSC.

3. Please provide an assessment of how the organisation's CLSP complies with the principles of the management and control guidelines contained in ISO 27002 (formerly ISO 17799:2005) and ISO 27001:2005 (both formerly parts 1 and 2 of BS7799 "Code of practice for information security management"). *Confirm that the policy or policies have been formally adopted by the organisation and are fully implemented.*

The NeSC Glasgow with its emphasis on security, is compliant with the guidelines contained in ISO 27002 and 27001 in terms of good practice and procedures for system and information security. We work closely with the Robertson Centre for Biostatistics at the University of Glasgow (www.rcb.gla.ac.uk) and the SOPs that they have developed for information security and practices more generally (as documented in www.glasgowctu.org and accredited through BSI Standards, UKAS Quality Management and TickIT certificate number FS 80326). However it is the case that NeSC Glasgow themselves are not yet fully certified according to ISO 27002/27001. We note that the University of Glasgow as a whole had a successful network and server security audit review conducted in 2007 by Deloittes.

Please provide an electronic reference copy of the CLSP.

4. Who is responsible for the implementation of the CLSP?

	Title	Forename/Initials	Surname
	Professor	Richard O	Sinnott
Post	Post ?		
Qualifications	?		
Employer	University of Glasgow		
Work Address	National E−Science Centre University of Glasgow		
Post Code	G12 8QQ		
Work Email	r.sinnott@nesc.gla.ac.uk		
Work Telephone			
Fax			

5. What is the Data Protection Registration Number for this organisation?

The University of Glasgow's current Notification Number is Z6723578.

6. Does the registration specify research as one of the purposes of processing and include confidential patient information in the classes of data processed?

○ Yes ○ No

Further details:

Please provide a copy of the Data Protection Registration(s).

7. Please describe the physical security arrangements for the location(s) where patient identifiable data is to be (a) processed and (b) stored (if these are different).

The EuroDSD registry is maintained on a separate subnetwork at the University of Glasgow. The machine is a Sun Fire 40z machine running Linux Fedora Core 10. The machine is physically located in a closed office with no windows and only swipe card/passkey access. Access to this room is restricted to NeSC staff only. These standards will also be applied to the ESPE DSD Registry

System−level security policy (SLSP)

Ordinarily there should be one over−arching SLSP for the study which covers the processing by all partner organisations. Occasionally there may be one or two variations where more than one organisation is involved in holding and processing data. Where this applies, questions 8−14 should be answered in relation to each organisation's computer system to be used for processing patient identifiable data. Please open a separate set of the questions for each system.

System 1

8. Please identify the type of computer system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc).

The registry is based upon the Java Apache Spring, the Apache Struts2 framework and the Hibernate 3.3 GA database. It also exploits LDAP servers for storage of X509 attribute certificates and the Internet2 Shibboleth technologies for authentication and delivery of attribute certificates.

9. Will the system be (a) entirely standalone, or (b) connected (either temporarily or permanently) to a LAN or WAN network or be otherwise accessible remotely by another means such as dial−up modem? *If connected, please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy.*

The registry is on a secure sub−network at NeSC. This network has restricted access enforced through the portal and its security infrastructure which itself is provided by Shibboleth and RBAC/IBAC mechansims. The machine is locked down with all non− essential services turned off and restrictive firewall settings.

10. Please provide details of access and/or firewall controls implemented on (a) this system and (b) any LAN or WAN to which it is connected. *State who is responsible for the management of these arrangements.*

Access to the registry is through the EuroDSD portal. This portal recognises only the NeSC Glasgow Identity Provider in the UK Access Management federation. The server on which the registry database is stored is on an isolated sub−network at Glasgow. The firewall for this server is maintained by the NeSC Glasgow EuroDSD staff. All non− essential services on this server are turned off (telnet etc). Secure communications between the portal and the server is achieved through X509 certificates which are used to support local trusted communications.

11. Is there a system level security policy (SLSP) for this system?

(●) Yes ( ) No

If Yes, please provide an electronic reference copy of the SLSP.

12. Who is responsible for the management of the SLSP?

	Title	Forename/Initials	Surname
	Prof	Richard	Sinnott
Post			
Qualifications	PhD		
Employer	University of Glasgow		
Work Address	234b Kelvin Building National e−Sci		
	National E−Science Centre		
	Glasgow		
Post Code	G12 8QQ		
Work Email	r.sinnott@nesc.gla.ac.uk		
Work Telephone	01413308606		
Fax	01413308625		

13. Has the system ever been the subject of a security risk review?

(●) Yes ( ) No

If Yes, please provide details and confirm whether all the necessary recommendations have been implemented:

As noted in section 3.3, the University of Glasgow network and servers were subject to a security review by Deloitte's in 2007. This review certified that the University was deemed secure. However, a security review of the current EuroDSD registry and infrastructure upon which it is built has not undergone an independent risk assessment. Having said this, we perpetually conduct in−house security risk assessments and threat analysis, and take all necessary measures to ensure system and information security. We also note that NeSC Glasgow researchers involved in the EuroDSD registry have undergone Disclosure Scotland assessment and been awarded Honorary NHS contracts for the clinical work in which they are involved with the NHS.

14. Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse.

The access to the registry is perpetually monitored and information logged on its usage. Basic internet−based monitoring tools such as GoogleAnalytics are 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 is maintained through portal−based solutions which leverage the RBAC and IBAC mechanisms. Feedback on access and usage of the registry is regularly discussed at EuroDSD meetings and via email between the EuroDSD collaborators. In addition, as described in section 13.13 numerous other physical/technical aspects of security are used to protect the registry and its contents.

15. Will encryption be used?

(●) Yes ( ) No

If Yes, please indicate which software package you propose to use and confirm that it is to industry standard (128 bit):

Data encryption is used throughout the system. Communications with the portal are over an encrypted channel (exploiting SSL/https). Communications between the portal and the attribute authority (for digitally signed roles) are encrypted for delivery of signed SAML attribute assertions. Communications between the portal and the back end registry are encrypted using X509 keys to encrypt the communications.

Data destruction

16. Please describe the method of data destruction you will employ when you have completed your work using patient identifiable data.

The deletion of data will be undertaken on a case by case basis as deemed appropriate. This will include deletion / wiping of data from the database and any associated information that has been included. We also emphasise that the registry itself has been deliberately designed to be non−identifying to anybody who is searching the data except the clinician who has originally entered the data and who will be able to link the data to locally stored data through a local identifier.

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
NESC	Richard Sinnott

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.

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.

Signature of the applicant: .....

Name: Dr S. Faisal Ahmed

Date: 28/03/2009

Part D: Declarations

D2. Declaration by Data Controller

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.

Signature of the Data Controller: .....

Name: Prof Richard O Sinnott

Date: 05/05/2009