
The Society for Endocrinology Research Projects – Data Access

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November 2025

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The Society for Endocrinology Research Projects ('SfE Research Projects')

SfE Research Projects are all built using the same database platform, and each one has its own information website, containing Research Project -specific information, located at <https://www.endocrinology.org/clinical-practice/data-registries/>

This Data Access Policy (DAP) for SfE Research Projects covers the following:

- The procedure that should be followed for requesting access to data from any specific project;
- The processes for reviewing and approving / rejecting any such request;
- The terms and conditions that data access is subject to;
- Terms relating to publication of outcomes based upon SfE Research Project data ('Publication Policy').

The DAP also includes information regarding the governance and oversight of SfE Research Projects.

1. Governance & Committees

The Clinical Committee

The Clinical Committee has direct oversight of the SfE Research Projects program, and will coordinate Research Project operations under the general stewardship of Council. Details of the composition and role of the Clinical Committee can be found here <https://www.endocrinology.org/about-us/governance/clinical-committee/>

Each SfE Research Project has a dedicated Research Project Steering Committee. Details of the Research Project Steering Committee for a specific SfE Research Project can be found here <https://www.endocrinology.org/clinical-practice/data-registries>.

Data Access Committee

Each Research Project Steering Committee and the Society's Research Working Group will act as the Data Access Committee for that particular Research Project's data. The Research Project Steering Committee may wish to bring in additional input from Clinical Committee, or elsewhere, if there is a request for access to data that requires particular expertise to assess. The Research Working Group will deem whether the data access request is eligible for project specific review from the Project Steering Committee. It is recognised that the project steering committee may have a conflict of interest on a data access request which is why the Society's research working group is additionally requested to view the data access request forms and all will be asked to declare a conflict of interest prior to the assessment of the data access request form

Project Management

Day-to-day project management of SfE Research Projects falls with the Society office.

Ethics Committee

Each of the projects will undergo ethics application and approval for the project's protocol.

2. The Utility of the Research Projects

It is expected that the SfE Research Projects will mainly facilitate academic and/or commercial Secondary Research of the data collected during routine clinical care, supplemented by the patients themselves. This form of research will be authorised through ethics approval for each Research Project at that initiation of the project, amendments may be used to add data outcomes to facilitate the data access requests, additionally data access requests may need their own ethics applications to use the data; and will also be sanctioned by acceptance of intended data uses described in the participant information sheet. It is anticipated that the data may be used by a wide range of stakeholders (“Investigators”), to provide:

- a. A source population for the conduct of Clinical Trials;
- b. Information on specific interventions related to defined patient groups;
- c. Follow-up of rare condition patient populations;
- d. Life-cycle assessment of the effectiveness and safety of interventions and medicinal products development and approvals;
- e. Robust data on disease epidemiology, patients’ characteristics and current standard of care;
- f. Source population data that can be linked to other datasets on specific outcomes;
- g. Data to industry, regulators and other trial lists to facilitate the design of pragmatic trials for rare conditions as well as for conducting post-authorisation studies;
- h. Linkages to other endocrine research projects and databases approved by the Steering Committees.

3. Data Access Requirements

SfE encourages the wide use of the data contained in the SfE Research Projects across academia, public health and the pharmaceutical industry.

All Investigators requesting access to Research Project data must complete a Data Request Form – a template for which is shown in Appendix 1 and 2 below, and available for completion at <https://www.endocrinology.org/clinical-practice/data-registries>.

The minimum requirements for data access to be approved by the Research Project Steering Committee are:

1. Intended use must be for the furtherance of scientific knowledge or improved clinical outcomes for patients (including future pharmaceutical solutions);
2. The investigator must demonstrate that they have sufficient funding in place to complete their research objectives;
3. Investigators must agree to, and observe, the terms and conditions pertaining to Research Project data access.

Note that any third parties or individuals that are not contributing to the advancement of clinical research or treatments will not be considered for a data access request.

To discuss the criteria for access to Research Project data, or pre-clinical trial access, prior to completing a Data Request Form Investigators should contact research@endocrinology.org.

4. Role-Based Access Rules

Investigators from a variety of backgrounds can request access to Research Project data. This includes academic and healthcare institutions, government and public health organisations, patient organisations and the pharmaceutical industry. It is anticipated that the following broad groups of investigators may want to access Research Project data:

Patient participants	Study participants will only have access to their own data which they input to the third-party themselves, supplied by PeopleWith, which is being used to collect real world patient information. They will have ability to add in data at any point in time (using a mobile App). They may have questionnaires ‘pushed’ onto their app when appropriate per the protocol of the specific Research Project in which they are participating.
Clinical contributors	This group will have access to all of the data, both clinical and patient-entered, for those participants connected to their centre. A ‘Centre Lead’ will be responsible for the data access governance at each local centre, as per ICH Principal Investigator responsibilities – Good Clinical Practice Training and Certification. The Society will keep a Trial Master File on each project, which will require scanned copies of delegation logs, GCP certificates and CVs.
Society office	Will have access to all Society Research Project pseudo-anonymised data and provide role-based access. If there are data points not explored in the original dataset which a Data Access Request has requested, it will be at the discretion of the Steering Committee to ask the sites or patients for further information. These data points would be added following an amendment to ethics with any changes to the protocol additionally. The Society Office have access to the data in order to mine the data, do statistical analysis, and provide reports to those requesting data access.
Investigators Researchers & Investigators	Clinicians, Scientists, and Researchers, will be provided with pseudo-anonymised, mined datasets or reports (unless they request that all data is fully anonymised) following approval of their requests by the Steering Committee of the relevant Research Project and following any necessary ethics approvals.
Investigators Industry	Industry will be provided with pseudo-anonymised, data analysis reports (unless they request that all data is fully anonymised) following approval of their

	<p>requests by the Steering Committee of the relevant Research Project and any necessary ethics approvals.</p> <p>Note for compliance: Industry project sponsors will be able to request research questions on their own brand/product but not with regard to specific competitor brands. All generic and modified-release formulations that are used for treatment data points are made available.</p>
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Where a pharmaceutical or medical equipment company is providing funding to the development and ongoing maintenance of a particular Research Project, under an agreement that anticipates future access to the data collected, the company will be assessed for suitability under the Data Access Policy prior to any funding being accepted. Companies will complete a self-declaration of compliance with the Society’s ‘Working with Commercial Companies’ policy which is reviewed by the Society’s Corporate Liaison Committee.

5. Protocol Wording

The process for data access is clearly explained in each of the projects protocol and the initial ethics (MREC) submission via the IRAS application form. Data Access Requests should try to align to the outcomes of the study where possible.

6. Pseudo-Anonymisation of data

Patient-collected data are inputted directly by the patient into the bespoke Research Project App. These data are visible to the patient themselves through the App, and the health care professionals who manage that patient. Patients will be encouraged to add additional, day-to-day information regarding their condition into the App, to help build a broader picture of the impact of clinical interventions. However, they will not be able to see the clinical details entered by their healthcare professional to avoid the patient self-diagnosing, changing behaviours etc.

Clinically collected data are inputted by the Health Care Professional at the participating Trust into the bespoke Research Project electronic data capture system. The healthcare professional can then see their patients’ clinical and patient collected data in the same place.

The Society office has access to the data collected from all centres and the patient directly, but only at a pseudo-anonymised level. Only pseudo-anonymised data, or fully-anonymised data if specified, will be available for access by any other party under the Society Data Access Policy. To reiterate, no-one outside of the patient, the healthcare practitioner assigned to them and the relevant Principal Investigator (centre lead) is able to see non-pseudo-anonymised data for the patients who have consented to participate in the Research Project.

Patients will be made aware of the data protection policy for the App upon signing up to the research project. PeopleWith, the providers of the App platform, are verified by the Organisation for the Review of Care and Health Apps (ORCHA) and fully General Data Protection Regulation (GDPR) compliant. A copy of the data security credentials of PeopleWith are available to patients or participating NHS centres on request.

7. Data Analysis Tools

Non-industry research for the enhancement of science: Access to unembellished Research Project data will be provided via 2 factor authentication password-managed, bespoke Investigator access rights. Such access will be time controlled, and also locked to a certain IP address(s). It is envisaged that one or more statistical programmes will be embedded within the Research Project platform for statistical analysis to be performed. A detailed immutable history of individual Investigator data enquiries / downloaded results, which must only be used for the purposes specified in the Data Access Request Form, will be accessible to the Society office for audit purposes. Extracting raw data from the Research Project platform, including any form of screen scraping, will be prohibited.

Categories of Data

1. A question where the answer is provided by availability of raw data only;
2. A question where the answer is provided by joining two or more raw data points (aggregated data);
3. A question that requires some form of enhanced statistical analysis in order to be the answered.

An extra charge will be levied for any enhanced statistical analysis required to answer a data access request. For example confidence intervals or p value significance. Enhanced statistical analysis will be presented in a numerical format only. No commentary on the results of any statistical analysis will be provided.

Industry research: Research questions should be detailed in a Data Access Request Form and the Society will extract the data or, where appropriate, perform the enhanced statistical analysis required to answer such questions on the requestees behalf. Any such statistical analysis must only be used for the purpose specified in the Data Access Request Form. The results of the statistical analysis will be shared with industry in a report format with no raw data available. Non-Industry researchers may also opt for this option.

8. Process for Seeking Access to Data

- 8.1. Having read and understood the data access requirements set out in this Data Access Policy, the Investigator should complete a Data Request Form (template shown in Appendix 1 and 2) – found at <https://www.endocrinology.org/clinical-practice/data-registries>.
- 8.2. The Society office will check that the Data Request Form has been completed satisfactorily alongside the Research Working Group and forward the document to the nominated Research Project Steering Committee for consideration.
- 8.3. All data access requests will be assessed by the Research Working Group and Research Project Steering Committee for compliance with the anticipated use of that Research Project data as submitted to, and approved by, the relevant ethics authority.
- 8.4. If the Investigator is in the medical industry (eg pharmaceuticals, medical equipment etc) the application will also be referred to the SfE Corporate Liaison Committee for review.
- 8.5. In cases where the contents of a new data access application overlap with an existing active application, the Investigators of the two applications will be advised by the Society Office and Research Project Steering Committee.

- 8.6. There will be three approval rounds per year (across all Research Projects) in April, September, and December, unless there are extenuating circumstances, which suggest that a data access request requires more urgent consideration. The relevant Research Project Steering Committee will have discretion over the decision to undertake a more urgent data access review.
- 8.7. The Research Project Steering Committee members will consider the data access request individually and return completed feedback forms to the Society office.
- 8.8. The Society office collate the feedback, including that from the Corporate Liaison Committee where appropriate, and return the collated forms to the Chair of the Research Project Steering Committee.
- 8.9. If additional information in support of the data access request is requested by the Research Project Steering Committee they will inform the Society office, who will request the information from the Investigator. When the additional details are received, the Society office will pass this information to the Project Steering Committee.
- 8.10. Once the Research Project Steering Committee have made their decision regarding a data access request, feedback will be provided to the Investigator, within four weeks of the application being reviewed
- 8.11. If the application for access has been successful, the Investigator will be sent a Data Sharing Agreement (DSA) – a template for which is shown in Appendix 3 - to sign before any access is granted.
- 8.12. The Society office will be responsible for mining the data covered by the data request and providing access to the data via a secure portal.
- 8.13. The Society office will maintain a log of activity for each user granted access to Research Project data.

9. Dissemination of Data Analysis Activity

Details of all approved requests for data access, including brief details of the intended use of the data, will be posted on the relevant Research Project website, including outputs where possible (Appendix 8)

Annual reports for all research activity using the Research Project data will be obtained from Investigators and a lay summary posted on the website. If the Investigator anticipates that this may not be appropriate, for commercial or scientific reasons, this should be detailed in the Data Request Form.

Acknowledgements and attribution of any publications should follow the conditions in Section 5 of the DAP.

10. Charge For Data Access

SfE operates a transparent, cost recovery model, aligned with UK practice (e.g., UK Biobank's tiered access fees; NHS England DARS component charging).

Any member of the Research Project Steering Committee or Principal Lead Investigator at a participating NHS Centre will be granted free of charge access to data for the duration of their tenure on the Steering Committee, or the duration of data collection at the NHS site respectively, and for 6 months afterwards, but such access will still be expected to comply with the Data Access Policy, Request Forms and Data Sharing Agreement.

Any Member of the Society (for no less than 9 months prior to a data access request), conducting non industry research, will incur a £3,000 - £9,000 processing fee per new, time-controlled, data access request. The price will be based on the complexity of the request and the number of data points. 'No cost extensions' will be considered upon application, but if rejected may incur a fee of £1000 per 6 months at the discretion of the Research Project Steering Committee.

Academic/Clinician/Scientist Investigators who are Non-Members of the Society will incur a £6,000-£18,000 processing fee per new, time-controlled, data access request. The price will be based on the complexity of the request and the number of data points. 'No cost extensions' will be considered upon application, but if rejected may incur a fee of £1000 per 6 months at the discretion of the Research Project Steering Committee.

The required duration of access to Research Project data for non-industry Investigators must be stipulated in the initial Data Access request, otherwise this will be set for 3 months. Approval of the requested duration is at the Steering Committee's discretion. If the request is more than 12 months the Steering Committee will request additional reasoning for this extended time period.

If the Researcher access request requires enhanced statistical analysis (and related reporting) this will incur an additional charge of £700 per day. Statistical analysis may be outsourced. If the statistical analysis is undertaken by the Society, no time-based access will be provided to the applicant.

Industry investigators and/or industry agents will be charged a fee for data queries commensurate with the cost of development and ongoing maintenance of the Research Project. The fee level will recognise any relevant terms contained within an agreement with the industry Investigator to provide development funding for the Research Project, and the wider relationship between the Investigator and the Society. The fee will start at £75,000 and be determinant on the complexity of the request and the number of patients available.

Changes to any data request may, at the discretion of the Project Steering Committee, incur a fee dependent on the nature and timing of the change to the request.

Appendix 1 – Research Project Data Request Form – Researchers

Before completing this form, please check you have read and considered the Society for Endocrinology (SfE) Research Project Data Access Policy.

1.	Which SfE Research Project are you applying for access to data from?	
2.	Details of Principal Investigator (name institution name & address & Institutional e-mail address) & SfE membership number (if applicable)	
3.	Details of Coinvestigator(s) (name, institution & Institutional e-mail address)	
4.	Full Name of Project/Research Question	
5.	Short Name of Project for Communication purposes, if appropriate	
6.	This application has been discussed with all the co-investigators (notification of approval of this application will be sent to all coinvestigators)	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	What are the main reasons for requesting data access from the SfE Research Projects?	<input type="checkbox"/> To assist with designing a new project <input type="checkbox"/> To perform a survey to participating centres <input type="checkbox"/> To obtain de-identified existing patient data from the Research Project <input type="checkbox"/> Any other project – please provide details below
8.	Has the project been funded?	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to question 12) <input type="checkbox"/> Not applicable
9.	Source of project funding	
10.	Start date of funding (can be approximate)	
11.	End date of funding (can be approximate)	
12.	Is there a plan to apply for funding?	
13.	How will the data access costs be covered?	

14.	Has this project been peer reviewed and approved by any organisation? (e.g. funding body, ethics body, regulatory agency, other formal organization)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
15.	Please provide details of these organisation(s) and the date and duration of approval (A copy to be provided)	
16.	If not approved, is there a date for submission	<input type="checkbox"/> Yes; provide date: <input type="checkbox"/> No
17.	Background and rationale for support required (max 500 words)	
18.	What is the primary aim or hypothesis of the project?	
19.	What are the primary outcomes that will be measured?	
20.	What are the secondary outcomes that will be measured?	
21.	Describe the methodology including project design (max 500 words)	
22.	State the inclusion criteria of the cases that will be recruited	
23.	State the exclusion criteria of the cases that will be recruited	
24.	Specify the data points that is required from the Research Project using the Data Request justification section of the Data Dictionary	
25.	Specify any data fields that are not currently collected in the Research Project but will be necessary for your project	
26.	Summary of project for the website, if appropriate (max 200 words)	
28.	How will this project improve the health of the people with the condition that is being studied?	
29.	Will the project require collection of patient reported outcomes/surveys?	
30.	List the expected outputs and how they will be disseminated	

31.	State publication plan for authorship of abstracts and full papers and how it compares to our recommendations	
32.	Timeline from start of project to above outputs	
33.	Planned start date of the project?	
34.	Planned end date of the project? Expected Publication Timeline	
35.	Have you received data from the Society for Endocrinology Research Projects previously? (provide dates and outputs references)	
36.	Please add any additional/relevant information. The team may contact you for further clarification.	
37	Please indicate that you agree to comply by your organisation's policy on Data Breaches and inform the Society for Endocrinology if there is any breach of data protection whilst the access to the data has been granted.	Yes <input type="checkbox"/> No <input type="checkbox"/>
38	Confirmation of attachment of ICH GCP Certification of those requiring access	Yes <input type="checkbox"/> No <input type="checkbox"/>
39	Do you require the Society Office to perform any statistical analysis? If yes please provide what analysis is required. OR Do you require a timed access into the platform and are performing your own statistical analysis? If yes to B, then state how long you require access to perform this analysis.	

Form Completed by:

Date of Completion:

Date of Submission:

Please submit this form to research@endocrinology.org. Your request will be considered by the relevant SfE Research Project Steering Committee April, September and December each year.

TERMS AND CONDITIONS: If your request is successful, you will be required to sign a Data Sharing Agreement (based upon Appendix 3 of the Data Access Policy), with no raw data being transferred from the platform. Upon completion of your work, you will be required to sign a termination as well (based on Appendix 4 of the Data Access Policy). All research outputs must be approved by the relevant Research Project Steering Committee before dissemination, submission or publication. Your outputs must cite your source of data as per the Publication Policy (appendix 5 and 6 of the Data Access policy). Before transferring any data outputs from the platform, please notify the Society Office. The nature of the data access request will be made available on the Society website within 1 month of approval. If your output is delayed, please keep the Society informed, if the output is delayed significantly a request for the same research question may be granted to another researcher.

Appendix 2 Research Project Data Request Form – Commercial Companies

Before completing this form, please check you have read and considered the Society for Endocrinology (SfE) Research Project Data Access Policy.

1.	Which SfE Research Project are you applying for access to data from?	
2.	Details of Company name & address & e-mail address)	
3.	Full Name of Project/Research Question/Interest in the Data	
4.	This application has been discussed with any other departments of your company? (which departments if yes)	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	What are the main reasons for requesting data access from the SfE Research Projects?	<input type="checkbox"/> To assist with designing a new product/existing product <input type="checkbox"/> To perform a survey to participating centres <input type="checkbox"/> To obtain de-identified existing patient data reports from the Research Project <input type="checkbox"/> Any other project/reason – please provide details below
6.	Confirmation the Company is able to fund the data access request (prices found with the Data Access Policy or from discussion with the Head of Partnerships and Corporate Support)	<input type="checkbox"/> Yes
7.	Has this request been peer reviewed by any clinical or medical colleagues?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
8.	Background and rationale for support required	
9.	Describe the questions of the data you wish to ask and the rationale behind them	

10.	Specify the data points that is required from the Research Project using the data dictionary for the project	
11.	Specify any data fields that are not currently collected in the Research Project but will be necessary for your project	
12.	Summary of project for the website, if appropriate (max 200 words)	
13.	How will this project improve the health of the people with the condition that is being studied?	
14.	Will the project require collection of patient reported outcomes/surveys?	
15.	List the expected outputs and how they will be disseminated	
16.	State publication plan for authorship of abstracts and full papers and how it compares to our recommendations	
17.	Timeline from start of project to above outputs	
18.	Planned start date of the project?	
19.	Planned end date of the project? Expected Publication Timeline	
20.	Have you received data from the Society for Endocrinology Research Projects previously? (provide dates and outputs references)	
21.	Please add any additional/relevant information. The team may contact you for further clarification.	
22.	Please indicate that you agree to comply by your organisation's policy on Data Breaches and inform the Society for Endocrinology if there is any breach of data protection whilst the access to the data has been granted.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Form Completed by:

Date of Completion:

Date of Submission:

Please submit this form to research@endocrinology.org. Your request will be considered by the relevant SfE Research Project Steering Committee April, September and December each year.

TERMS AND CONDITIONS: If your request is successful, you will be required to sign a Data Sharing Agreement (based upon Appendix 3 of the Data Access Policy), with no raw data being transferred from the platform. All research outputs must be approved by the relevant Research Project Steering Committee before dissemination, submission or publication. Your outputs must cite your source of data as per the Publication Policy (appendix 5 and 6 of the Data Access Policy). Before transferring any data outputs from the platform, please notify the Society Office. The nature of the data access request will be made available on the Society website within 1 month of approval. If your output is delayed, please keep the Society informed.

Appendix 3 – Research Project Data Sharing Agreement (DSA)

THIS AGREEMENT is made the ____ day of _____ 20[]

BETWEEN:

(1) **SOCIETY FOR ENDOCRINOLOGY ('SfE')** of Starling House, 1600 Parkway North, Bristol, BS34 8YU;

(2) **[PARTY 2] ('Applicant')** of [ADDRESS];

(each a "Party" and together the "Parties")

BACKGROUND:

(A) The Applicant wishes to access data contained within a specified SfE Research Project for the purposes of medical research.

(B) This Agreement sets out the terms and conditions that shall apply to the sharing of Research Project data between SfE and the Applicant.

NOW IT IS HEREBY AGREED as follows:

Project data

1.1. The Research Project collects only minimal patient identifiable information in addition to patient date of birth. Any further patient data required should be detailed in the Data Request Form but is not guaranteed, and can only be obtained via the Society for Endocrinology engaging with the reporting clinician and patients (if appropriate) via the App, and will be subject to the information governance framework at the clinician's medical centre.

1.2. Information exchanged as part of research is covered by Society for Endocrinology and local research governance.

Principles

1.3. Information sharing between the parties shall adhere to the principles of the UK Data Protection Act (2018), the EU GDPR (2018), the UK GDPR (2021) and the 'Conditions of Ethical Approval' as stipulated by the Medical Research Ethics Committee (MREC) or international equivalent.

1.4. SfE warrants and undertakes that all Personal Data has been collected, processed and transferred in accordance with the regulations in 2.1 and that it has obtained all the necessary approvals to collect and transfer the data to the Applicant.

Conditions of Release of Data

- 1.5. The information that will be shared with the Applicant will be access to the data collection platform by SfE, according to current regulations at the Society for Endocrinology.
- 1.6. Data user access codes will only be provided to named individual users who are stipulated in the Data Request Form, and for the time period specified.
- 1.7. It is the responsibility of the Applicant to ensure that access to data provided by SfE is only permitted to the named individual to whom access has been granted, and that there is no sharing of data access codes with any individuals not named on the Data Request Form completed by the Applicant.
- 1.8. The Applicant shall notify SfE as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the data, and to co-operate with any investigation conducted by SfE in connection with the unauthorised or accidental access, use or disclosure of the data (which, may also be reported to the relevant Ethics committee by SfE).
- 1.9. The Applicant should inform SfE on a timely basis if any named individual leaves the project, and no longer requires access to the data for the project detailed in the Data Request Form.
- 1.10. Data is given access to for specific projects to specific people. Data cannot be used for other research projects by the same researchers or used by other researchers for any purpose. The use of Research Project data by other people, or for research projects not specified on the Data Request Form, is not permitted, will require a separate Data Request Form application, and may incur an additional administration fee.
- 1.11. The information to be shared shall be the same as the description of the data requirements specified in the Data Request Form that was approved by the relevant SfE Research Project Steering Committee.
- 1.12. The Applicant will be required to confirm in writing that they have appropriate technical and organisational measures in place to protect any data provided under this Agreement against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.
- 1.13. The Applicant and institution confirm that they have confidentiality policies (which may be separate policies) and that their employees are trained in confidentiality, including citation of the relevant policies as appropriate.
- 1.14. The Applicant must treat any personal data received from the Research Project with a level of confidentiality that is at least equivalent to the following principles. All personal patient data will be treated as strictly confidential and the Applicant shall have in place procedures so that any third party it authorises to have access to any personal patient data, including employees and (sub)Processors, will respect and maintain the confidentiality and security of the personal data. Any person or organisation acting under the authority of the Applicant, including a (sub)Processor, shall be obligated to process the personal data only on instructions from the

Applicant and in accordance with the permitted use under this Agreement. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data.

- 1.15. The Applicant shall not attempt to re-identify any individual from the data or communicate with any individual re-identified from the data, nor to link or attempt to link the data to other data or information except with specific prior written consent from SfE.
- 1.16. As a minimum, the Applicant will provide SfE with a progress report on a 12-monthly basis while the project is active and a final report at the end of the project.
- 1.17. After publication of the results of the study, SfE will terminate the Applicants access to the secure portal referred to in 3.1 above. The Applicant shall send a copy of the data that has been used for the publication to SfE through the secure systems in clause 3.1.
- 1.18. As a special precaution for people with rare conditions, the Parties acknowledge and agree that, other than date of birth, the data will be stripped of direct patient identifiers and will therefore be pseudo-anonymised before the Applicant is given access to it for research purposes. However, the Parties both further acknowledge and agree that circumstances may arise in which it may be or become possible to identify one or more living individuals from the data contained within the data set in which case such data shall be or become personal data for the purposes of data protection laws (“Personal Data”). If any such circumstance should arise, either the Party first becoming so aware shall notify the other Party and the Parties shall discuss how to proceed, or the Applicant may reject such data until it is pseudo-anonymised such that it is not possible to identify one or more living individuals.
- 1.19. In the event that a patient or participating centre withdraws its consent or objects to the use of the data, the Applicant will, at the instruction of SfE, immediately return or destroy the data from that particular data source.
- 1.20. If either Party becomes aware of a personal or institutional/company data breach, that Party shall promptly notify the other Party. In such a case, Parties will fully cooperate with each other to remedy the personal data breach, fulfil the (statutory) notification obligations timely and cure the damages. A personal data breach refers to: 1) a Personal data breach according to applicable law in the territory where the Data is treated, and 2) a Personal data breach as meant in articles 33 and 34 of the European General Data Protection Regulation.
- 1.21. If the Applicant is based in a country that is not within the United Kingdom and does not have United Kingdom “adequacy regulation” as listed on: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/international-transfers-after-uk-exit/#adequacy>

The international data transfer addendum set out in Annex 1 is hereby incorporated into this Agreement. <https://ico.org.uk/media/for-organisations/documents/4019536/idta.docx>

- 1.22. At the end of the specified data sharing period the Applicant will be required to complete a Data Sharing Agreement Termination form – see Appendix 4 (also available at <https://www.endocrinology.org/clinical-practice/data-registries>).

Acknowledgement and attribution of publications

- 1.23. If data from an SfE Research Project is used for a report or publication without any statistical or clinical input from the Society Office, the Society requires the user of the data to acknowledge the data source along with a disclaimer. 'The Society for Endocrinology has not reviewed this document and therefore this document may not reflect the views and opinions of the Society for Endocrinology'
- 1.24. In any publication or report where statistical or analytical support, or clinical input, has been required from SfE the relevant contributors at SfE must be included as co-authors.
- 1.25. The current recommended text for use in publications is available in Appendix 5 and 6 (Data Publications Policy) of the Society Data Access Policy.
- 1.26. Any document to be distributed or published must be sent to the Society Office for review well in advance, (at least 4 weeks) of the distribution, publication date, or submission date. A copy of published research based on data from the Research Project, must also be sent to the Society Office.
- 1.27. The source and data handling methods should be made clear in the 'Methods' section of any published work. The abstract should also include reference to the relevant SfE Research Project, which will allow for searching publications based upon these key words.

Liability

Except to the extent prohibited by law, the Applicant assumes all direct liability for damages which may arise from its receipt, use, storage or destruction of SfE Research Project data. SfE will not be liable to the Applicant for any use made of the data, including any loss, claim or demand made by the Applicant or made against the Applicant by a third party, due to or arising from the use, storage or disposal of the data by the Applicant, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of SfE.

The Applicant accepts that SfE does not routinely check the accuracy or validity of data in SfE Research Projects and, therefore, does not warrant that the information in the directory is accurate or reflect true patient data. To the extent permitted by law, therefore, SfE will not be liable, in any way whatsoever, for any loss or damage suffered by the Applicant through the use of inaccurate or erroneous data.

Agreement formalities

This Agreement shall be signed by the Chair of the relevant SfE Research Project Steering Committee and a suitably authorised office holder of the Applicant organisation.

Period of agreement:

- Data shared and available for analysis: [dd/mm/yyyy] to [dd/mm/yyyy]
- Data shared for storage only: [dd/mm/yyyy] to [dd/mm/yyyy]

Review date: [dd/mm/yyyy]

Signed on behalf of Society for Endocrinology by:

Name:
(please print)

Role: Chair of Society for Endocrinology Research Project Steering Committee

Signature:

Date:

Signed on behalf of the Applicant by:

Name:
(please print)

Role:

Signature:

Date:

A copy of this Agreement will be posted by the Society for Endocrinology on the information sharing register (Appendix 8).

Signed on behalf of the Institution or Company

Name:
(please print)

Role:

Signature:

Date:

Annex 1 – International Data Transfer Addendum

International Data Transfer Addendum to the EU Commission Standard Contractual Clauses

VERSION B1.0, in force 21 March 2022

This Addendum has been issued by the Information Commissioner for Parties making Restricted Transfers. The Information Commissioner considers that it provides Appropriate Safeguards for Restricted Transfers when it is entered into as a legally binding contract.

Part 1: Tables

Start date		
The Parties	Exporter (who sends the Restricted Transfer) Party A	Importer (who receives the Restricted Transfer) Party B
Parties' details	<p>Full legal name: Society for Endocrinology</p> <p>Trading name (if different): N/A</p> <p>Main address (if a company registered address): Starling House, 1600 Bristol Parkway North, Bristol, BS34 8YU</p> <p>Official registration number (if any) (company number or similar identifier): Registered in England no. 349408 Registered charity no. 266813</p>	<p>Full legal name: [REDACTED]</p> <p>Trading name (if different): [REDACTED]</p> <p>Main address (if a company registered address): [REDACTED]</p> <p>Official registration number (if any) (company number or similar identifier): [REDACTED]</p>
Key Contact	<p>Full Name (optional):</p> <p>Job Title:</p> <p>Contact details including email:</p>	<p>Full Name (optional): [REDACTED]</p> <p>Job Title: [REDACTED]</p> <p>Contact details including email: [REDACTED]</p>

Table 1: Parties

Addendum EU SCCs	<input type="checkbox"/> The version of the Approved EU SCCs which this Addendum is appended to, detailed below, including the Appendix information: Date: Reference (if any): Other identifier (if any): Or <input checked="" type="checkbox"/> The Approved EU SCCs, including the Appendix Information and with only the following modules, clauses or optional provisions of the Approved EU SCCs brought into effect for the purposes of this addendum:
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Module	Module in operation	Clause 7 (Docking Clause)	Clause 11 (Option)	Clause 9a (Prior Authorisation or General Authorisation)	Clause 9a (Time period)	Is personal data received from the Importer combined with personal data collected by the Exporter?
1	Yes	No	No			
2	No	N/A	N/A	N/A	N/A	
3	No	N/A	N/A	N/A	N/A	
4	No	N/A	N/A			N/A

Table 2: Selected SCCs, Modules and Selected Clauses

<p>“Appendix Information” means the information which must be provided for the selected modules as set out in the Appendix of the Approved EU SCCs (other than the Parties), and which for this Addendum is set out in:</p>	
Annex 1A:	List of Parties: See ‘Table 1: Parties’ above
Annex 1B:	Description of Transfer: See the Society for Endocrinology Data Sharing Agreement (DSA) to which this Addendum is attached
Annex II:	Technical and organisational measures including technical and organisational measures to ensure the security of the data: See the Society for Endocrinology Data Sharing Agreement (DSA) to which this Addendum is attached
Annex III:	List of Sub processors (Modules 2 and 3 only): N/A

Table 3: Appendix Information

Ending this Addendum when the Approved Addendum changes	Which Parties may end this Addendum as set out in Section 19: <input type="checkbox"/> Importer <input type="checkbox"/> Exporter <input checked="" type="checkbox"/> Neither Party
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Table 4: Ending this Addendum when the Approved Addendum Changes

Part 2: Mandatory Clauses

Entering into this Addendum

- Each Party agrees to be bound by the terms and conditions set out in this Addendum, in exchange for the other Party also agreeing to be bound by this Addendum.
- Although Annex 1A and Clause 7 of the Approved EU SCCs require signature by the Parties, for the purpose of making Restricted Transfers, the Parties may enter into this Addendum in any way that makes them legally binding on the Parties and allows data subjects to enforce their rights as set out in this Addendum. Entering into this Addendum will have the same effect as signing the Approved EU SCCs and any part of the Approved EU SCCs.

Interpretation of this Addendum

- Where this Addendum uses terms that are defined in the Approved EU SCCs those terms shall have the same meaning as in the Approved EU SCCs. In addition, the following terms have the following meanings:

Addendum	This International Data Transfer Addendum which is made up of this Addendum incorporating the Addendum EU SCCs.
Addendum EU SCCs	The version(s) of the Approved EU SCCs which this Addendum is appended to, as set out in Table 2, including the Appendix Information.
Appendix Information	As set out in Table 3.
Appropriate Safeguards	The standard of protection over the personal data and of data subjects' rights, which is required by UK Data Protection Laws when you are making a Restricted Transfer relying on standard data protection clauses under Article 46(2)(d) UK GDPR.
Approved Addendum	The template Addendum issued by the ICO and laid before Parliament in accordance with s119A of the Data Protection Act 2018 on 2 February 2022, as it is revised under Section 18.
Approved EU SCCs	The Standard Contractual Clauses set out in the Annex of Commission Implementing Decision (EU) 2021/914 of 4 June 2021.

ICO	The Information Commissioner.
Restricted Transfer	A transfer which is covered by Chapter V of the UK GDPR.
UK	The United Kingdom of Great Britain and Northern Ireland.
UK Data Protection Laws	All laws relating to data protection, the processing of personal data, privacy and/or electronic communications in force from time to time in the UK, including the UK GDPR and the Data Protection Act 2018.
UK GDPR	As defined in section 3 of the Data Protection Act 2018.

4. This Addendum must always be interpreted in a manner that is consistent with UK Data Protection Laws and so that it fulfils the Parties' obligation to provide the Appropriate Safeguards.
5. If the provisions included in the Addendum EU SCCs amend the Approved SCCs in any way which is not permitted under the Approved EU SCCs or the Approved Addendum, such amendment(s) will not be incorporated in this Addendum, and the equivalent provision of the Approved EU SCCs will take their place.
6. If there is any inconsistency or conflict between UK Data Protection Laws and this Addendum, UK Data Protection Laws applies.
7. If the meaning of this Addendum is unclear or there is more than one meaning, the meaning which most closely aligns with UK Data Protection Laws applies.
8. Any references to legislation (or specific provisions of legislation) means that legislation (or specific provision) as it may change over time. This includes where that legislation (or specific provision) has been consolidated, re-enacted and/or replaced after this Addendum has been entered into.

Hierarchy

9. Although Clause 5 of the Approved EU SCCs sets out that the Approved EU SCCs prevail over all related agreements between the parties, the parties agree that, for Restricted Transfers, the hierarchy in Section 10 will prevail.
10. Where there is any inconsistency or conflict between the Approved Addendum and the Addendum EU SCCs (as applicable), the Approved Addendum overrides the Addendum EU SCCs, except where (and in so far as) the inconsistent or conflicting terms of the Addendum EU SCCs provides greater protection for data subjects, in which case those terms will override the Approved Addendum.
11. Where this Addendum incorporates Addendum EU SCCs which have been entered into to protect transfers subject to the General Data Protection Regulation (EU) 2016/679 then the Parties acknowledge that nothing in this Addendum impacts those Addendum EU SCCs.

Incorporation of and changes to the EU SCCs

12. This Addendum incorporates the Addendum EU SCCs which are amended to the extent necessary so that:
 - a. together they operate for data transfers made by the data exporter to the data importer, to the extent that UK Data Protection Laws apply to the data exporter's processing when making that data transfer, and they provide Appropriate Safeguards for those data transfers;
 - b. Sections 9 to 11 override Clause 5 (Hierarchy) of the Addendum EU SCCs; and
 - c. this Addendum (including the Addendum EU SCCs incorporated into it) is (1) governed by the laws of England and Wales and (2) any dispute arising from it is resolved by the courts of England and Wales, in each case unless the laws and/or courts of Scotland or Northern Ireland have been expressly selected by the Parties.
13. Unless the Parties have agreed alternative amendments which meet the requirements of Section 12, the provisions of Section 15 will apply.
14. No amendments to the Approved EU SCCs other than to meet the requirements of Section 12 may be made.
15. The following amendments to the Addendum EU SCCs (for the purpose of Section 12) are made:
 - a. References to the "Clauses" means this Addendum, incorporating the Addendum EU SCCs;
 - b. In Clause 2, delete the words:

"and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679";
 - c. Clause 6 (Description of the transfer(s)) is replaced with:

"The details of the transfers(s) and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred) are those specified in Annex I.B where UK Data Protection Laws apply to the data exporter's processing when making that transfer.";
 - d. Clause 8.7(i) of Module 1 is replaced with:

"it is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer";
 - e. Clause 8.8(i) of Modules 2 and 3 is replaced with:

"the onward transfer is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer;"
 - f. References to "Regulation (EU) 2016/679", "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with

- regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)” and “that Regulation” are all replaced by “UK Data Protection Laws”. References to specific Article(s) of “Regulation (EU) 2016/679” are replaced with the equivalent Article or Section of UK Data Protection Laws;
- g. References to Regulation (EU) 2018/1725 are removed;
 - h. References to the “European Union”, “Union”, “EU”, “EU Member State”, “Member State” and “EU or Member State” are all replaced with the “UK”;
 - i. The reference to “Clause 12(c)(i)” at Clause 10(b)(i) of Module one, is replaced with “Clause 11(c)(i)”;
 - j. Clause 13(a) and Part C of Annex I are not used;
 - k. The “competent supervisory authority” and “supervisory authority” are both replaced with the “Information Commissioner”;
 - l. In Clause 16(e), subsection (i) is replaced with:

“the Secretary of State makes regulations pursuant to Section 17A of the Data Protection Act 2018 that cover the transfer of personal data to which these clauses apply;”;
 - m. Clause 17 is replaced with:

“These Clauses are governed by the laws of Scotland.”;
 - n. Clause 18 is replaced with:

“Any dispute arising from these Clauses shall be resolved by the courts of Scotland. A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of any country in the UK. The Parties agree to submit themselves to the jurisdiction of such courts.”; and
 - o. The footnotes to the Approved EU SCCs do not form part of the Addendum, except for footnotes 8, 9, 10 and 11.

Amendments to this Addendum

- 16. The Parties may agree to change Clauses 17 and/or 18 of the Addendum EU SCCs to refer to the laws and/or courts of Scotland or Northern Ireland.
- 17. If the Parties wish to change the format of the information included in Part 1: Tables of the Approved Addendum, they may do so by agreeing to the change in writing, provided that the change does not reduce the Appropriate Safeguards.
- 18. From time to time, the ICO may issue a revised Approved Addendum which:
 - a. makes reasonable and proportionate changes to the Approved Addendum, including correcting errors in the Approved Addendum; and/or
 - b. reflects changes to UK Data Protection Laws;

The revised Approved Addendum will specify the start date from which the changes to the Approved Addendum are effective and whether the Parties need to review this Addendum including the Appendix Information. This Addendum is automatically amended as set out in the revised Approved Addendum from the start date specified.

19. If the ICO issues a revised Approved Addendum under Section 18, if any Party selected in Table 4 “Ending the Addendum when the Approved Addendum changes”, will as a direct result of the changes in the Approved Addendum have a substantial, disproportionate and demonstrable increase in:

- a. its direct costs of performing its obligations under the Addendum; and/or
- b. its risk under the Addendum,

and in either case it has first taken reasonable steps to reduce those costs or risks so that it is not substantial and disproportionate, then that Party may end this Addendum at the end of a reasonable notice period, by providing written notice for that period to the other Party before the start date of the revised Approved Addendum.

20. The Parties do not need the consent of any third party to make changes to this Addendum, but any changes must be made in accordance with its terms.

Appendix 4 – Research Project Data Sharing Agreement Termination (DSAT)

Applicant name:	
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Confirms that:

1. Society for Endocrinology Research Project data has only been used for the purposes outlined in the signed Data Sharing Agreement.
2. The data has not been shared with other parties not specified in the signed Data Sharing Agreement.
3. Any data that was not used for analysis for the purpose of an output has been destroyed in accordance with the criteria set out in the signed Data Sharing Agreement, and was destroyed on [dd/mm/yyyy].
4. Data that was used for analysis for the purpose of an output has been stored and shall be destroyed by [dd/mm/yyyy].
5. Data that was used for analysis for the purpose of an output was also returned to Society for Endocrinology on [dd/mm/yyyy].
6. Any publications that utilised the data supplied under this Agreement followed the Society for Endocrinology Publication Policy.

Signed on behalf of:

Name:
(please print)

Role:

Signature:

Date:

Appendix 5 – Data Publication Policy - Researchers

Prior to publication of any research findings based upon Society Research Project data, the Investigator must comply with the following requirements (as set out in the Data Sharing Agreement):

1. All materials to be published must be submitted to the relevant Research Project Steering Committee for approval, no less than 4 weeks prior to any deadline for approval. The approval of the Research Project Steering Committee will be evidenced in writing.
2. Project Steering Committee members who respond to comments and proactively contribute to the publication should be credited with authorship, additionally, SfE [title of project] Research Project Steering Committee 20XX should be credited as an author.*
3. Where possible, the List of Principal Investigators will be referenced in the publication, the current list will be provided at the time of publication to the applicant.*
4. The Research Project itself should be credited with authorship and/or acknowledged under the format of SfE [title of Research Project] Research Project, the institution address of Starling House, 1600 Bristol Parkway North, Bristol, BS34 8YU, and contact details of research@endocrinology.org.
5. All publications that do not include author contributions from the Research Project Steering Committee must include a disclaimer confirming that any views and opinions expressed in the material may not reflect the position of the Society for Endocrinology. ‘The Society for Endocrinology has not reviewed this document and therefore this document may not reflect the views and opinions of the Society for Endocrinology’.

The Society for Endocrinology can be approached for endorsement for a project via the Clinical Committee under the endorsement policy.

Disclaimer if Publication does not include authors from The Society for Endocrinology

The views and opinions expressed in this article are those of the authors and do not reflect the views of the Society for Endocrinology.

Disclaimer regarding Data Availability

The datasets generated or analysed during the current study are not available publicly but are available to access through a Data Sharing Agreement with the Society for Endocrinology.

Text to use in Methods section of abstract

Refer to the data or the Research Project as ‘The SfE [name of Research Project] Research Project’

Text to use in Methods section of full text

The ‘SfE [name of Research Project] Research Project is an international database of pseudonymised information on patients with [name of condition] and is approved by the Medical Research Ethics Committee in the United Kingdom as a research database of information that is collected as part of routine clinical care (Ethics Reference given to the applicant by the Society Office). The data within this Research Project are deposited by clinicians following informed consent from patients or guardians and managed by the Society for Endocrinology.

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- Opening slide or last slide of reviews or updates
- At the top or bottom of physical or e-posters

Please contact the Society at research@endocrinology.org to make requests for logos or to check any references to the Research Project within the body of your publication.

*The lists of Steering Committees and Principal Investigator Lists will be kept on an annual basis, ie, the 'THYROID Study Steering Committee 2025' or the 'THYROID Study PI Consortium 2025'

Appendix 6 – Data Publication Policy – Commercial Companies

Prior to publication of any research findings based upon Society Research Project data, the Company must comply with the following requirements (as set out in the Data Sharing Agreement):

1. All materials to be published (internal and external use) must be submitted to the relevant Research Project Steering Committee for approval, no less than 4 weeks prior to any deadline for approval. The approval of the Research Project Steering Committee will be evidenced in writing.
2. Project Steering Committee members who respond to comments and proactively contribute to the publication should be credited with authorship, additionally SfE [title of project] Research Project Steering Committee 20XX should be credited as an author.*
3. The Research Project itself should be credited with authorship and/or acknowledged under the format of SfE [title of Research Project] Research Project, the institution address of Starling House, 1600 Bristol Parkway North, Bristol, BS34 8YU, and contact details of research@endocrinology.org.
4. All publications that do not include author contributions from the Research Project Steering Committee must include a disclaimer confirming that any views and opinions expressed in the material may not reflect the position of the Society for Endocrinology. ‘The Society for Endocrinology has not reviewed this document and therefore this document may not reflect the views and opinions of the Society for Endocrinology’.

The Society for Endocrinology can be approached for endorsement for a project via the Clinical Committee under the endorsement policy.

Disclaimer if Publication does not include authors from The Society for Endocrinology

The views and opinions expressed in this article are those of the authors and do not reflect the views of the Society for Endocrinology.

Disclaimer regarding Data Availability

The datasets generated or analysed during the current study are not available publicly but are available to access through a Data Sharing Agreement with the Society for Endocrinology.

Text to use in Methods section of abstract

Refer to the data or the Research Project as ‘The SfE [name of Research Project] Research Project’

Text to use in Methods section of full text

The ‘SfE [name of Research Project] Research Project is an international database of pseudonymised information on patients with [name of condition] and is approved by the Medical Research Ethics Committee in the United Kingdom as a research study of information that is collected as part of routine clinical care (Ethics Reference given to the applicant by the Society Office). The data within this Research Project are deposited by clinicians following informed consent from patients or guardians and managed by the Society for Endocrinology.

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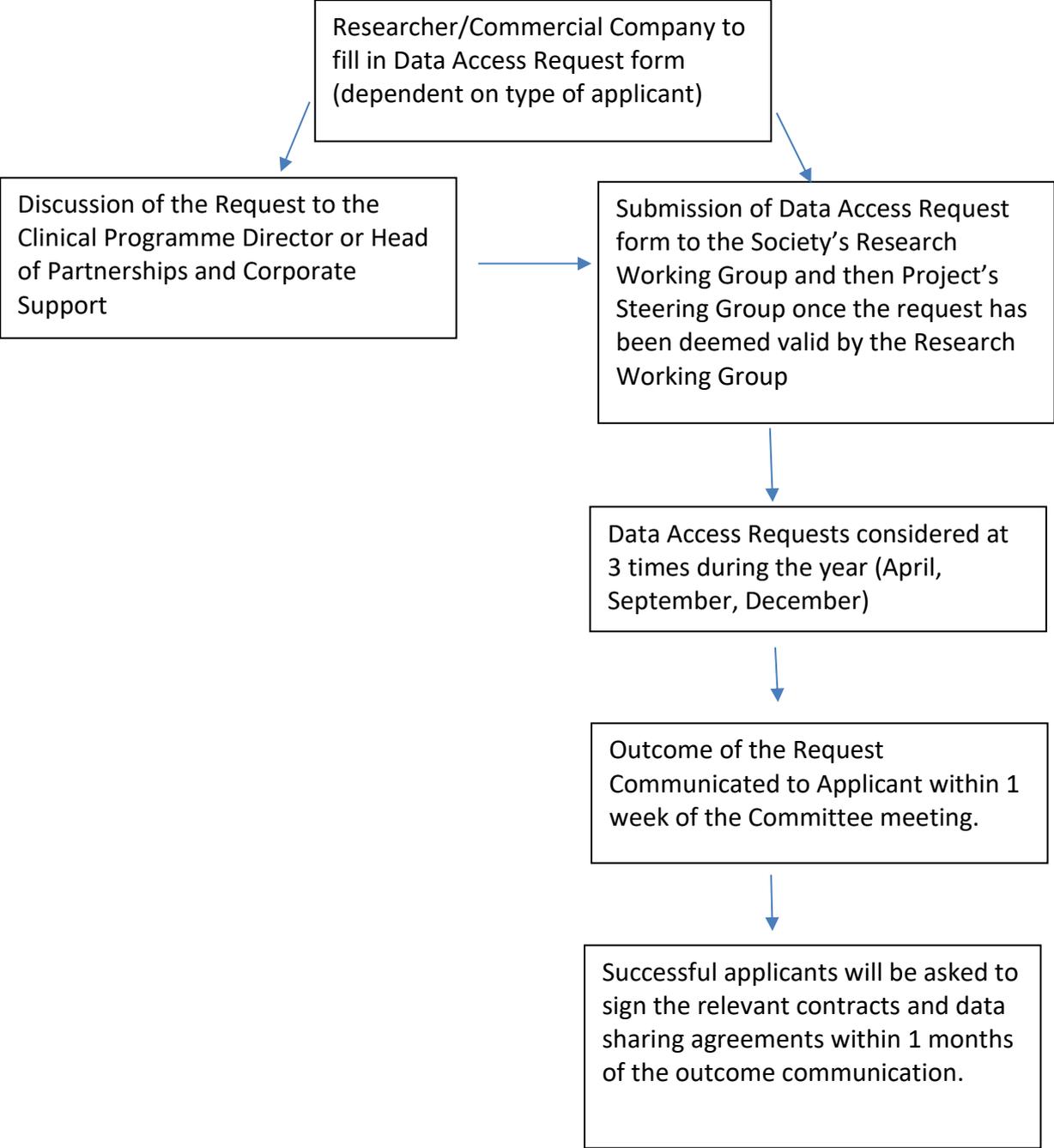
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- At the top or bottom of physical or e-posters

Please contact the Society at research@endocrinology.org to make requests for logos or to check any references to the Research Project within the body of your publication.

*The lists of Steering Committees will be kept on an annual basis, ie, the 'THYROID Study Steering Committee 2025'

Appendix 7 - Flow of Data Access Diagram



Appendix 8 – Data Access Register

This will be available of the Society for Endocrinology website. This will be updated following each round of Data Access request applications.

SfE Project Title	Applicant Name(s) (Company Name)	Title of Project	Start and End Date	Publications