Welcome to the Integrated Research Application System

IRAS Project Filter

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

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

Please enter a short title for this project (maximum 70 characters)
BTS ILD Registry

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

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

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

( ) Clinical investigation or other study of a medical device

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

( ) Basic science study involving procedures with human participants

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

( ) Study involving qualitative methods only

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

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

( ) Research tissue bank

(●) Research database

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

( ) Other study

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

(●) England

( ) Scotland

( ) Wales

( ) Northern Ireland

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

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

4. Which applications do you require?

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

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

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

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

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

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

RESEARCH DATABASE

NHS Health Research Authority

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

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

REC Name:
North West - Haydock Research Ethics Committee

REC Reference Number:
22/NW/0319

Submission date:
31/08/2022

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

Part A: Core Information

Administrative information

1. Title of the Database

British Thoracic Society Interstitial Lung Disease Registry Project

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

Organisation	British Thoracic Society
Address	17 Doughty Street
	London
Postcode	WC1N 2PL
Telephone	02078318778
Fax	02078318766

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

Title	Forename/Initials	Surname
Prof	Andrew	Wilson

Address	Norwich Medical School
	University of East Anglia
	Norwich
Postcode	NR4 7TJ
E-mail	a.m.wilson@uea.ac.uk
Telephone	01603 591257

Mobile	
Fax	01603 593752

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

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

Title	Forename/Initials	Surname
Ms	Sally	Welham

Address	The British Thoracic Society
	17 Doughty Street
	London
Postcode	WC1N 2PL
E-mail	sally.welham@brit-thoracic.org.uk
Telephone	02078318778
Mobile	
Fax	02078318766

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

○ Yes ◉ No

Purpose of the Database

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

When the BTS Lung Disease Registry Programme was established in 2013 two groups of data subjects were included in the proposal: those with idiopathic pulmonary fibrosis (IPF) and those with sarcoidosis. This programme will now be expanded to include data subjects with interstitial lung disease (ILD) with any evidence of fibrosis and also non-fibrosing sarcoidosis. This will include people with idiopathic pulmonary fibrosis (IPF), sarcoidosis, exposure related interstitial lung disease including asbestosis, drug related and hypersensitivity pneumonitis; connective tissue disease related ILD including rheumatoid related and scleroderma related ILD as well as unclassifiable ILD and rare forms of ILD. Inclusion for the database will be determined following a physician diagnosis most often following a multidisciplinary meeting decision which is based on international guidelines were available.
Data collection began in January 2013, after ethical approval was granted by the Cambridge Central REC in October 2012 (ID: 12-EE-0381) and renewed in October 2017 (reference 17-EE-0346). Patient identifiable data (name, date of birth, NHS/HSC number and postcode) together demographic details, lung function, reports of imaging, comorbidities, medications and other treatments including oxygen and pulmonary rehabilitation. Additional data for sarcoidosis participants include occupational status and sarcoidosis related extra-pulmonary complications. We wish to expand the information to capture the diagnostic classification of fibrotic ILD, any relevant environmental or drug exposure, presence or absence of serological tests and side effects of anti-fibrotic therapy.
Participating centres are asked to provide additional data for participants (clinical results, medication, changes in clinical status) on an annual basis. All subjects are asked for informed written consent for storage of these data. Clear written guidelines are in place to minimise access to individuals' personal information. In the vast majority of cases, researchers accessing the database are provided access to anonymised, coded data only.
Data collection is primarily prospective, although centres will be able to enter data retrospectively from January 2013 onwards. Participation is open to all secondary and tertiary care respiratory clinics in the UK, although at this time centres with a specialist interest in these diseases are more represented in the database than other sites.
Particularly sensitive data will not be held.

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

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

This data is required for an understanding of the epidemiology and disease burden for people with ILD as at present the incidence, prevalence and natural history of these conditions is relatively poorly understood in the UK. The prognosis for these individuals is poor with median survival similar to many cancers and there is considerable unmet need. It will also be used for benchmarking between different hospitals to ensure best practice is shared and improve patient care. It will also permit identification of people eligible for clinical trials given the paucity of treatments available for these individuals and the importance of clinical trials in this area. At the time consent is taken patients are asked if they are happy to be contacted by their own hospital team about relevant clinical trials, so the BTS Lung Disease Registry Programme provides a clear pathway by which trial managers may have their details passed on to clinicians who have a pool of patients with a clearly expressed wish to be considered/contacted for relevant trials

Anonymous data will be made available, following a robust review process, to academics and industrial partners who wish to analyse the data contained within the database. Record linkage will be possible, where consent is obtained for this, with other databases, and potentially biobanks, which require informed consent.

Other similar databases occur in different countries throughout the world but this is the only such database in the UK. It will therefore provide UK data on the burden of disease and provide insights into the outcomes of therapeutics and other treatments.

Governance of the database is overseen by the British Thoracic Society (BTS). BTS has convened a BTS ILD Registry Steering Group that meets a minimum of twice yearly to oversee the project. All applications for research access to the database are considered by the main BTS standing committee with responsibility for information governance (currently the BTS Information Governance Committee, but this will be incorporated into the work of the BTS Quality Improvement Committee from 2023). A copy of the terms of reference of the steering group and both committees are included with this application. From 2023 the Quality Improvement Committee will be responsible for overseeing all BTS projects which include substantial information governance elements, and the terms of reference will be updated to reflect this.

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

The British Thoracic Society has embedded public and patient involvement in all of its activities and has a Lay Trustee who contributes to the Society's activities. The former BTS Public Liaison Committee was involved in the development of the Lung Disease Registry Programme and in the initial application for funding. The steering group includes a lay representative and representatives from relevant patient charities (Action for Pulmonary Fibrosis and SarcoidosisUK), ensuring the patient perspective is central to the programme’s governance structure

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

The results of research arising from the database will be presented at national and international meetings and will be published in peer reviewed journals. Results will be disseminated to local participating centres. Results will also be summarised on the British Thoracic Society's publicly accessible website (www.brit-thoracic.org.uk). Annual reports for the Registry have been published for the majority of the years the programme has been active, and the previous three annual reports have been accompanied by lay summaries.

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

The database is managed by BTS via the BTS ILD Registry Steering Group according to the submitted terms of reference. There is also oversight from the BTS Information Governance Committee (due to cease in December 2022, at which point this role will be held by the BTS Quality Improvement Committee) and the BTS Board of Trustees.

Development of the database was originally supported by a grant from the Health Quality Improvement Partnership (HQIP). This funding was matched, in kind, by BTS. Additionally, a grant was provided from Boehringer Ingelheim and InterMune for the enhancement of the data collection software in 2014 (this was a one-off grant and there is no ongoing relationship with BTS and either Boehringer Ingelheim or InterMune). It is possible that similar grants may be sought in the future, and any grants from pharmaceutical companies would need to be in line with BTS policies on pharmaceutical involvement (and approved by the BTS Board of Trustees).

The database is hosted by BTS using the Society's existing servers. The launch of the BTS Data Access Request Process in 2018 meant that some specific research projects would be able to apply for access to Registry data. A nominal fee is charged for this service. The BTS Data Access Policy is attached to this application. Applications are scrutinised and are only approved if BTS governance has fully reviewed the details and believes the methods of data storage and analysis to be sufficient and appropriate. BTS also confirms that the requested data items are minimised, with justification required for each item requested by the applicant.

Information governance

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

- [ ] Initials
- [x] Full name
- [x] Address
- [x] NHS or CHI number
- [x] Hospital ID no.
- [ ] GP registration
- [x] Date of birth
- [ ] Year of birth
- [x] Date of death
- [x] Postcode
  - ( ) District level
  - ( ) Sector level
  - ( ) Sub-sector level
  - (•) Unit level
- [ ] Other geographical identifiers

Purpose for which postcode/geographical identifiers required:

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

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

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

Management and oversight of the database is undertaken in accordance with the BTS Information Governance Policy (Current Version 5.1, July 2022 is enclosed with this application as supporting document 8). This policy enforces the Caldicott principles and is compliant with the Data Protection Act 2018.

All confidential, patient identifiable data are held in an encrypted, firewall protected database. Access to the database is password controlled and is limited to a maximum of ten named individuals at each participating site. Health data and identifiable data are held on the same servers but are separated by encryption and by differing user access requirements.

Individual participating sites only have access to the data of participants entered at their own site.

Researchers may request access to pseudonymised data from the Registry database. This is only permitted following approval by the relevant BTS committee responsible for information governance (currently the BTS Information Governance Committee, and due to change to the Quality Improvement Committee from 2023). Researchers intending to carry out analysis using geographical identifiers would only be able to apply for access to post codes at district level.

Prior to being provided access to the database researchers will be required to provide a signed agreement to confirm that they will adhere to the principles laid out in the BTS Information Governance Policy and relevant current legislation.

Where necessary it is anticipated that local training programs will be available to cover the important aspects of data protection.

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

Physical Security
The physical servers which hold the Registry data are held securely by Aptum (formerly known as Cogeco Peer 1) Managed Hosting Services, on behalf of Westcliff Solutions (Westcliff Solutions is the IT support provider for BTS). Direct access to the servers is severely restricted, and the Aptum Master Service Agreement provides full details of the physical security measures in place. These measures include: 24/7 security patrols, biometric scanners, fire protection and uninterruptable power supplies. Physical access to the database server room is security controlled with access for authorised persons. A log of entry is available whenever necessary.

The full database is held on the same physical servers, with access to patient identifiable data and access to pseudo-anonymised clinical data entirely separated. Clinicians who participate in the Registry are able to view data for patients from their site only, and therefore directly under their care – clinicians are never able to view data for patients registered under any other site. For management purposes, clinicians are able to view both clinical information and personal identifiable data for the patients directly under their site's care.

BTS staff are able to view pseudo-anonymised clinical data for the purpose of site management and data analysis. However, BTS staff are never able to view patient identifiable data.

As the database is accessed from clinics across the UK the physical security measures governing access at hospital level are detailed at site level. All participating sites are NHS institutions; therefore they must abide by NHS security measures.

Software Security
User access is controlled by username and password. The password is controlled by a policy that requires at least eight characters, including at least one numeral and at least one capital. When a new user is registered they are sent two separate emails, one containing their username and one containing their password. Every time a new page or section of the application is accessed the user credentials are checked to ensure that a user cannot access data that they do not have permissions for.

Anti-virus and intrusion prevention signatures are applied immediately, whilst operating system and server updates and patches are evaluated on our test servers before being applied to the live sites. This is done as soon as practically possible after a new update has been made available. SQL backups are run every four hours and disk image backups are run overnight. All backups are securely stored on the server and two off-site locations. Each backup is encrypted and transferred either via secure FTP or over our internal VPN; this secures them in transport as well.

All aspects of technical security, including user access, firewalls, encryption, intrusion prevention signatures, anti-virus measures, updates and backups are undertaken directly by Westcliff Solutions (the IT support provider for BTS) and are formally agreed in the annually reviewed Westcliff Hosting Terms & Conditions. The database is fully encrypted.

Encryption
User passwords and dataset fields containing sensitive information (e.g. patient identifiable data) are encrypted within the database using an internal key. This key is contained with the application source code and is only accessible to employees of Westcliff Solutions (the database provider for BTS). Overall this means that the data are encrypted three times, first at disk level, then at file level and finally the patient identifiable fields are encrypted within the database itself. This provides an extremely secure level of protection that is robust and well within recommended guidelines.

An audit trail of when and by whom the database is accessed is maintained and inspected periodically by BTS.

Location of data access
Users at participating hospitals: Users may access the Registry through a secure online portal – all data remain on

BTS servers and may only be accessed while the user is logged in. Users are encouraged to log in from NHS/HSC systems only. Secure passwords are used, alongside other features such as logins timing out after inactivity, and accounts being locked after a number of failed login attempts.

When administrative staff at BTS work remotely, remote access technology is used. This means secure BTS-owned devices directly access BTS servers. The devices are encrypted and use biometrics for access. Access to BTS technology may be immediately revoked in the event of theft or loss.

Additional mechanisms
Westcliff Solutions Ltd routinely monitor the Registry site for suspicious activity (e.g. unusually high activity, or if a user attempts to enter a suspicious character – such as < or > - into a free text field). Any suspicious activity would be immediately reported to BTS. Some members of BTS Head Office Staff also have access to error reports generated through the site and are able to contact Westcliff Solutions if they notice unusual error report traffic.

BTS also maintains compliance with the NHS Digital Data Security and Protection Toolkit and with Cyber Essentials.

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

Responsibility for monitoring the database's systems and procedures lies with BTS. Monitoring of the physical and software integrity of the database is overseen by the BTS's database provider, Westcliff Solutions. The Society will be immediately alerted should there be any intrusion attempts made on the database or the hosting server. Compliance with database procedures and relevant legislation is overseen by the BTS Board of Trustees in direct accordance with the BTS Information Governance policy (Version 5.1, July 2022)

Use of data by the Research Database team or other researchers

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

(●) Yes ( ) No

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

Research will include epidemiological and cohort studies looking at disease behaviour and outcome in individuals with fibrotic ILD and sarcoidosis. The database will also be used to identify individuals who fulfill the recruitment criteria for active clinical trials. Record linkage will also be possible with other databases requiring informed consent.

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

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

( ) Yes (●) No

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

Applications for research will be considered by the BTS committee responsible for information governance (currently the BTS Information Governance Committee, but this will be the BTS Quality Improvement Committee from 2023) which in turn will be overseen by the BTS Board of Trustees. Both groups consist of members with considerable ongoing expertise in research and which also engage the involvement of patients and public. Where necessary the option will exist for proposals to be sent out for external peer review prior to acceptance.
See attached BTS Data Access Policy

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

Clinicians at individual sites only have access to subjects entered at their site.
All study subjects are assigned a unique study number (patient ID) on entry to the database. BTS staff are only able to identify patients by this numerical patient ID. Researchers will not have access to the numerical patient ID, instead the identifiers will be 'salted'. This means before any pseudo-anonymised data are transferred to researchers, all unique, anonymised patient IDs will be removed and replaced with random numbers (using the Excel random number generator function). This process will take place each time a data access request is approved, therefore no two sets of pseudo-anonymised data will be released with common identifiers.

Researchers intending to carry out analysis using geographical identifiers would only be able to apply for access to post codes at district level; in such circumstances researchers will be mandated to adhere to the codes of confidentiality laid out by Caldicott, the BTS Information Governance Policy and the Data Protection Act 2018.

Patient identifiable data will not be released to researchers, with one potential exception: should another project where patients have given specific written consent seek to link to Registry data, BTS may approve that request. Should such a request be approved then data linkage would need to take place, and this would require identifiers to be cross-referenced in a secure technical environment. Such a request has only been made once in the ten years the Registry has been active (seeking to link genetic markers to outcome data) and that request was rejected because the REC approval and patient consent obtained did not allow for such linkage. Should the REC approve the linkage of data to another project (where the patient had given specific consent to both projects) then data would be linked in this way for records entered from January 2023 onwards. Records entered prior to January 2023 would only be linked in this way if the clinician has specifically confirmed – through a question in the dataset – that renewed consent has been obtained using the new consent form.

Subjects are made aware of the potential uses to which their data might be put when they are asked for their informed consent to be included in the database.

In the case of identifying candidates for clinical trials, researchers would approach BTS with a request that participating sites be contacted with information about the trial. This could include BTS reviewing the database to ensure that the appropriate hospitals were contacted. For example, for a clinical trial seeking patients with a specific ILD (or meeting other specific criteria BTS would be able to contact hospitals which have patients who meet those specific criteria. The registry leads at participating centres would then be in a position to contact suitable patients regarding clinical trial participation.

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

Data will only be shared with researchers following acceptance of study proposals by the BTS committee responsible for information governance (currently the BTS Information Governance Committee, but this will be the BTS Quality Improvement Committee from 2023). In advance of receiving data, individual researchers and study Sponsors will be expected to demonstrate in writing that they have in place appropriate policies regarding the handling and security of patient identifiable data. Researchers will be provided with pseudonymised data.

In addition, data will only be transferred when it is safe and lawful to do so. Two-factor authentication will be used to ensure usernames and passwords are provided separately, and data files will only be transferred using one of the following methods; 1) saving in a restricted access area of the project folder, 2) emailing in an encrypted format, 3) using an encrypted and password secured laptop, or 4) uploading on a secure website in an area that is accessible only using usernames and passwords.

Concordance with the BTS Information Governance Policy will be monitored by the ILD Registry Steering Group. It will be expected that individual Study Sponsors will monitor and confirm researchers' compliance with the Data Protection Act and local data handling policies.

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

It is not anticipated that the research will produce findings of significance for individuals. However, in the event that these were to occur the information would be fed back to the participating clinician at the centre caring for the individual concerned so that findings might be acted on appropriately.

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

individuals concerned?

◉ Yes ○ No

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.
In the case of research findings being of direct clinical significance to individuals, these data will be passed to local participating clinicians who will be expected to communicate the findings with individuals and to provide appropriate clinical support and intervention. Subjects will have access to the counselling support provided at local centres by the Patient Advisory Liaison Service (PALS).

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

◉ Yes ○ No

If Yes, please give details and describe any additional safeguards you will put in place:
It is anticipated that some applications for access to anonymised data for research may come from overseas.

Applications for data access from overseas researchers would be considered by the appropriate BTS committee (currently the BTS Information Governance Committee, but this will be the BTS Quality Improvement Committee from January 2023). The committee would ensure applications were only approved where sharing anonymised patient details overseas met with the conditions of the Data Protection Act 2018.

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

Researchers will be expected to apply to BTS for each individual study for which they require access to data. Therefore, once studies are complete, researchers will not be permitted to reuse data for new studies except following a subsequent accepted application to BTS. Approval for subsequent studies will follow the process in place for all studies.

Regarding retention of data, Study Sponsors will be expected to archive data from completed studies in accordance with appropriate national and locally agreed standards. Evidence of compliance with the BTS Information Governance Policy and the 2018 Data Protection act will be sought in advance of releasing data to individual sites.

Data collection and informed consent arrangements

Question 26 applies to existing collections of data only.

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

◉ Yes ○ No ○ Not applicable

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

If No, or if existing consent does not cover the purposes now proposed, say whether consent will now be sought. Please include details of the arrangements for seeking consent in your answer to questions 28 - 30. If consent will not be sought, please justify.
The British Thoracic Society Lung Disease Registry Programme had previously received REC approval in October, 2012 (reference 12-EE-0381) and renewal in October 2017 (reference 17-EE-0346). All arrangements (i.e. processes and paperwork) which were used were approved by the REC either at the original approval/renewal or specifically approved by the REC separately to that process (e.g. the data access paperwork was approved by the REC in 2018)

The attached patient information/consent forms (attached) have been updated to reflect the expansion of the Registry to include interstitial lung disease with any evidence of fibrosis, and non-fibrosing sarcoidosis. In order to reflect changing practice nationally, patient consent may be obtained using either a printed or emailed form and returned to the hospital team in the following ways:

- The form may be completed with a physical signature and returned to the hospital by hand or by post

- The form may be completed with a physical signature and emailed to the hospital as a scanned or photographed copy
- The form may be completed electronically (e.g. with a typed signature) and returned to the hospital by email (the form would only be accepted in this instance if it was returned using an email address known to belong to the patient and therefore the hospital was confident the response was directly from the patient).

Additionally, it may be that the Registry could develop or utilise fully remote consent in the future (i.e. some form of portal where patients may securely confirm consent online). Should such a development become feasible – either centrally from BTS or with participating sites using their own trust-approved systems – BTS may choose to adopt this technology. In this case consent would be accepted from these systems provided exactly the same wording was used (so the content of the consent form would be exactly the same, it would just be presented using different technology).

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

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

Cases are identified by clinical personnel at participating data collection centres (NHS/HSC Hospitals).

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

○ Yes ◉ No

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

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

Data subjects will be approached by a member of the clinical team and provided with a copy of the patient information sheet during the course of their attendance at a hospital appointment or inpatient hospital admission. Alternatively, potential participants will receive the information sheet and consent form by mail.

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

◉ Yes ○ No

If you will be obtaining consent from adult data subjects, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.
If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.
If you will not be obtaining informed consent, please complete question 29-3.
If you will not be obtaining informed consent, please complete question 29-3.
Consent is undertaken by an appropriately trained healthcare professional at participating sites. Potential participants are provided with a written information sheet and where necessary will be provided 24 hours or more to consider their participation prior to providing written informed consent. Vulnerable adults or those unable to provide informed, written consent will not be approached.

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

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

◉ Yes ○ No ○ Not applicable

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

Where necessary, a suitable translator will be sought.

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

Appropriate local arrangements will be made, where necessary, to translate the consent form in to Welsh.

Questions 31 - 32 apply to all applications:

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

No

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

IIf subjects subsequently withdraw their consent then all data pertaining to their entry on the database will be removed. If consent is withdrawn prior to use of their data in any research project, then their data will never be used in any research project. If data have been used in a completed research project then minimal fully anonymised data will be retained for the purposes of research governance, but these data will not be used in any subsequent research studies.

Summary of the application

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

Title of the database: British Thoracic Society Interstitial Lung Disease Registry Project

Establishment responsible for management of the database:

Organisation	British Thoracic Society
Address	17 Doughty Street
	London
Postcode	WC1N 2PL
Telephone	02078318778
Fax	02078318766

Data to be stored and data collection arrangements (maximum 200 words):
Research programme/community supported by the database (maximum 200 words):

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
Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust	Dr Christine Fiddler
Aintree University Hospital, Liverpool University Hospitals NHS Foundation Trust	Dr Lisa Spencer
Birmingham Heartlands Hospital, University Hospitals Birmingham NHS Foundation Trust	Professor Sherwood Burge and Dr Gareth Walters
Blackpool Victoria Hospital, Blackpool Teaching Hospitals NHS Foundation Trust	Ms Melanie Caswell
Burnley General Teaching Hospital, East Lancashire Hospitals NHS Trust	Dr Saumitra Baksi
Castle Hill Hospital, Hull University Teaching Hospitals NHS Trust	Drs Simon Hart and Mark Major
Central Middlesex Hospital, London North West University Healthcare NHS Trust	Dr David Adeboyeku
Charing Cross Hospital, Imperial College Healthcare NHS Trust	Dr Robina Coker
Cheltenham General Hospital, Gloucestershire Hospitals NHS Foundation Trust	Dr Ananthakrishnan Raghuram
Chorley and South Ribble Hospital, Lancashire Teaching Hospitals NHS Foundation Trust	Dr Yussef Haider
Churchill Hospital, Oxford University Hospitals NHS Foundation Trust	Dr Rachel Hoyles
City Hospital, Sandwell and West Birmingham NHS Trust	Dr Arvind Rajasekaran
Countess of Chester Hospital, Cheshire and Wirral Partnership NHS Foundation Trust	Dr Aravind Ponnuswamy
Croydon University Hospital, Croydon Health Services NHS Trust	Dr Yogini Raste
Darlington Memorial Hospital, County Durham and Darlington NHS Foundation Trust	Dr Stephen Cowie
Ealing Hospital, London North West University Healthcare NHS Trust	Dr Mamoun Ibrahim
George Eliot Hospital, George Eliot Hospital NHS Trust	Dr Christine O'Brien
Glenfield Hospital, University Hospitals of Leicester NHS Trust	Dr Charlotte Swales
Gloucestershire Royal Hospital, Gloucestershire Hospitals NHS Foundation Trust	Drs Andrew White and Henry Steer
Good Hope Hospital, University Hospitals Birmingham NHS Foundation Trust	Dr Dimitrina Petkova
Guy's Hospital, Guy's and St Thomas' NHS Foundation Trust	Drs Surinder Birring and Boris Lams
Hammersmith Hospital, Imperial College Healthcare NHS Trust	Dr Robina Coker
Harrogate District Hospital, Harrogate and District NHS Foundation Trust	Vacant – data collection on hold until new local collaborator identified
Hexham General Hospital, Northumbria Healthcare NHS Foundation Trust	Dr Laura MacKay
Hinchingbrooke Hospital, North West Anglia NHS Foundation Trust	Dr Robert Buttery

King's College Hospital, King's College Hospital NHS Foundation Trust	Ms Hannah Fletcher
King's Mill Hospital, Sherwood Forest Hospitals NHS Foundation Trust	Dr John Hutchinson
Liverpool Heart and Chest Hospital, Liverpool Heart and Chest Hospital NHS Foundation Trust	Mrs Angela McComish
Musgrove Park Hospital, Somerset NHS Foundation Trust	Dr Janet Fallon
New Cross Hospital, The Royal Wolverhampton NHS Trust	Dr Ahmed Fahim
Norfolk and Norwich University Hospital, Norfolk & Norwich University Hospitals NHS Foundation Trust	Professor Andrew Wilson
North Devon District Hospital, Northern Devon Healthcare NHS Trust	Drs Georgina Hands and Alison Moody
Northern General Hospital, Sheffield Teaching Hospitals NHS Foundation Trust	Dr Stephen Bianchi
North Middlesex University Hospital, North Middlesex University Hospital NHS Trust	Dr Bhagyashree Jayaraman
North Tyneside General Hospital, Northumbria Healthcare NHS Foundation Trust	Dr Laura MacKay
Northwick Park Hospital, London North West University Healthcare NHS Trust	Dr Arnab Datta
Nottingham City Hospital, Nottingham University Hospitals NHS Trust	Dr Sy Giin Chong
Royal Papworth Hospital, Royal Papworth Hospital NHS Foundation Trust	Dr Helen Parfrey
Peterborough City Hospital, North West Anglia NHS Foundation Trust	Wing Commander Jon Naylor
Queen Alexandra Hospital, Portsmouth University Hospitals NHS Trust	Dr K. Suresh Babu
Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust	Dr Anjali Crawshaw
Queen Elizabeth Hospital, Gateshead Health NHS Foundation Trust	Dr Robert Allcock
Royal Blackburn Teaching Hospital, East Lancashire Hospitals NHS Trust	Dr Saumitra Baksi
Royal Brompton Hospital, Royal Brompton and Harefield NHS Foundation Trust	Dr Philip Molyneaux
Royal Derby Hospital, University Hospitals of Derby & Burton NHS Foundation Trust	Dr Srividya Narayan
Royal Devon and Exeter Hospital, Royal Devon & Exeter Foundation NHS Trust	Dr Michael Gibbons
Royal Free Hospital, Royal Free London NHS Foundation Trust	Dr Katie Ward
Royal Lancaster Infirmary, University Hospitals of Morecambe Bay NHS Foundation Trust	Dr Timothy Gatheral and Ms Clare Squires
Royal Preston Hospital, Lancashire Teaching Hospitals NHS Foundation Trust	Dr Yussef Haider
Royal Victoria Infirmary, The Newcastle upon Tyne Hospitals NHS Foundation Trust	Dr Ian Forrest
Russells Hall Hospital, The Dudley Group NHS Foundation Trust	Dr Mazhar Chaudri
Solihull Hospital, University Hospitals Birmingham NHS Foundation Trust	Dr Salman Ghani

Southampton General Hospital, University Hospital Southampton NHS Foundation Trust	Dr Mark Jones
Southmead Hospital, North Bristol NHS Trust	Dr Huzaifa Adamali
St Bartholomew's Hospital, Barts Health NHS Trust	Miss Laura Haggarty
St James' University Hospital, The Leeds Teaching Hospitals NHS Trust	Dr Paul Beirne
St Mary's Hospital, Imperial College Healthcare NHS Trust	Dr Melissa Wickremasinghe
University College Hospital, University College London Hospitals NHS Foundation Trust	Dr Joanna Porter
University Hospital, University Hospitals Coventry & Warwickshire NHS Trust	Dr Beatriz Lara
University Hospital of North Midlands, University Hospitals of North Midlands NHS Trust	Dr Helen Stone
University Hospital of North Tees, North Tees & Hartlepool NHS Foundation Trust	Dr Graham Miller
Wansbeck Hospital, Northumbria Healthcare NHS Foundation Trust	Dr Laura MacKay
Whiston Hospital, St Helens and Knowsley Teaching Hospitals NHS Trust	Dr Louise Brockbank
Worcester Royal Hospital, Worcestershire Acute Hospitals NHS Trust	Professor Steve O'Hickey
Wythenshawe Hospital, Manchester University NHS Foundation Trust	Dr Nazia Chaudhuri
Aberdeen Royal Infirmary, NHS Grampian	Dr Own Dempsey
Forth Valley Royal Hospital, NHS Forth Valley	Dr Matthew Embley
Glasgow Royal Infirmary, NHS Greater Glasgow and Clyde	Dr George Chalmers
Lorn & Islands District General Hospital, NHS Highland	Vacant – data collection on hold until new local collaborator identified
Ninewells Hospital, NHS Tayside	Dr Mark Spears
Perth Royal Infirmary, NHS Tayside	Dr Mark Spears
Royal Alexandra Hospital, NHS Greater Glasgow and Clyde	Vacant – data collection on hold until new local collaborator identified
Vale of Leven District General Hospital, NHS Greater Glasgow and Clyde	Vacant – data collection on hold until new local collaborator identified
Glan Clwyd Hospital, Betsi Cadwaladr University Health Board	Dr Sarah Davies
University Hospital Llandough, Cardiff and Vale University Health Board	Dr Ben Hope-Gill
Wrexham Maelor Hospital, Betsi Cadwaladr University Health Board	Dr Neil McAndrew
Antrim Area Hospital, Northern Health and Social Care Trust	Dr Paul Minnis
South West Acute Hospital, Western Health and Social Care Trust	Dr Terence McManus
The Ulster Hospital, South Eastern Health and Social Care Trust	Dr Karol Henry

Part D: Declarations

D1. Declaration by the applicant:

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

Contact point for publication

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

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

Optional – please tick as appropriate:

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

This section was signed electronically by Dr Andrew Wilson on 31/08/2022 16:59.

Job Title/Post:	Prof of Respiratory Medicine
Organisation:	UEA
Email:	a.m.wilson@uea.ac.uk

Part D: Declarations

D2. Declaration by Data Custodian

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

This section was signed electronically by Miss Sally Welham on 31/08/2022 17:05.

Job Title/Post:	Chief Executive
Organisation:	British Thoracic Society
Email:	sally.welham@brit-thoracic.org.uk