

# **Terms and Conditions for use of BSUG Database**

This document to be submitted to each centre's Caldicott Guardian for their information before registering to submit data.

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## **Background**

The British Society of Urogynaecology (“**BSUG**”) is a national group of gynaecologists with a special interest and expertise in the treatment of incontinence and prolapse.

BSUG has developed a database (“**BSUG Database**”) of clinical and surgical data for the main purpose of allowing BSUG members (individual consultants) to audit their own practice and also the practice of their trusts / units with regards to management of incontinence and prolapse, to make sure that the service provided is safe and effective. Being a national database, it also enables publishing of *anonymous* statistical national information for clinical audit for these procedures. Subject to application, some of this *anonymous* data may also be shared with our members and used for research purposes.

Currently, there are more than 190000 patient episodes entered in the database with more than 400 users from more than 260 registered centres.

The database is stored within the NHS Health and Social Care Network (HSCN), which is hosted by ISO 27001, ISO 9001, Cyber Essentials certified suppliers and is only available to HSCN connected computers. The Database is accessed by web browser and runs on a 256 AES SSL connection.

Each user is a registered BSUG member and is verified by the BSUG administrator before been given a login.

Passwords need to change every 90 days and must be of a strong format (at least 8 characters, a combination of numbers, upper and lower case letters and at least one special character like ! or % e.g. Aa12345%).

Patient identifiable data (“**Patient Identifiable Data**”) is restricted to just three fields, none of which are compulsory, but a minimum amount of data must be inputted so that the episode of care can be retrieved to add follow-up data. The fields are: Date of Birth/ NHS number/ Hospital number. The link to Patient Identifiable Data is encrypted to NHS standards. Patient data can only be viewed by the consultant or their selected deputy who recorded it. Audit Reports generated by the database only contain statistical data without Patient Identifiable Data. The BSUG administrator can run National level reports which are limited to statistical outputs and contain no Patient Identifiable Data.

If a centre wishes to retrieve patient identifiable data for the purpose of clinical governance procedures, this can be facilitated by the BSUG. This data should be managed by the centre in accordance with the UK General Data Protection Regulation and Data Protection Act 2018.

## **Terms of Use**

This document sets out the terms under which BSUG allows its members to add clinical and surgical information to its database (**BSUG Database**), and the terms governing the use of the database.

### **1. Interpretation**

In these Terms of Use, the following definitions shall apply:

<b>BSUG</b>	The unincorporated association of Consultant Gynaecologists and Associate members known as the British Society of Urogynaecology;  The British Society of Urogynaecology is a charity registered in England (Number 1143157) and has its registered office at: BSUG c/o, Royal College of Obstetricians & Gynaecologists 10-18, Union Street, London SE1 1SZ.
<b>BSUG Database</b>	The database of clinical and surgical data relating to gynaecological procedures which is owned and operated by BSUG and is powered by BSUG's proprietary software;
<b>Consultant</b>	A Consultant who subscribes as a user of the BSUG Database;
<b>UK GDPR</b>	UK General Data Protection Regulation;
<b>DPA 2018</b>	Data Protection Act 2018;
<b>Patient Identifiable Data</b>	Any personal data from which a patient could be identified e.g. hospital number, NHS number, date of birth, etc;
<b>Record</b>	A patient record on the BSUG Database, containing clinical and surgical data, which may include Patient Identifiable Data or be in an anonymous form and 'Records' shall be interpreted accordingly.

### **2. Consultant Warranties**

- 2.1 If the Consultant is an NHS employee, he/she warrants that he/she has obtained consent from his/her NHS Trust (or Health Board) to add Patient Identifiable Data relating to his/her NHS patients to the BSUG Database.
- 2.2 When creating a Record on the BSUG Database, the Consultant shall be deemed to warrant that the Patient has consented to the disclosure into the BSUG Database of their Patient Identifiable Data and the processing to be carried out by BSUG on the terms of BSUG's current approved wording.

- 2.3 If a patient withdraws consent and informs the Consultant, it is the responsibility of the clinician to delete any Patient Identifiable Data from the Database, or liaise with the BSUG database administrative team to facilitate removal of the Data.

### **3. Acceptable Use by Consultants**

- 3.1 The Consultant's access to the BSUG Database is limited to the Records which he/she and/or his/her deputy have added. The Consultant must not attempt to gain access to any other Records stored in the BSUG Database, save that access to Records which have been created by other consultants (with Patient Identifiable Data removed) is permitted within the same centre by arrangement with BSUG and with the agreement of all of the consultant's concerned.
- 3.2 The Consultant may only use the data in the BSUG Database for the purpose of auditing operation demographics, indications, outcomes, and complications. Records must never be used for the purpose of making decisions about the treatment of the patient.
- 3.3 The Consultant will be subject to the same legal and professional duties to keep Patient Identifiable Data in the BSUG Database or which he/she has extracted from the BSUG Database confidential as he/she is under in relation to clinical records. In particular, the Consultant shall:
- 3.3.1 Always log-out of any computer system or application when work on the BSUG Database has finished;
  - 3.3.2 Not leave a terminal unattended and logged in from which a third-party could access the BSUG Database;
  - 3.3.3 Not share his/her username and password with any other person;
  - 3.3.4 Change his/her password at regular intervals. It is suggested that this is done at intervals of not greater than 90 days;
  - 3.3.5 Avoid using short passwords, or using names or words that are known to be associated with him/her.
- 3.4 The Consultant shall not knowingly enter information which is inaccurate into the BSUG Database. The Consultant will use reasonable endeavours to ensure that Records which are created are from consecutive cases and completed and updated as necessary. Records should not be created in anonymous form, as Patient Identifiable Data will be required to enable updating to take place.
- 3.5 The consultant agrees to delete any Record or remove Patient Identifiable Data from that Record (whichever is requested) where the patient requests this locally. (A delete function is built into the BSUG database).

- 3.6 If a consultant moves to a different centre, he/she will have read only access to the records of their NHS patients from previous centre. They will not be able to make any changes to those records. However, they will continue to have full access to the records of all of their private patients.

#### **4. Acceptable Use by Deputy to Consultant**

- 4.1 A Consultant may assign a deputy for their records on the database. The deputy should be working in the same centre as the Consultant and may not be a BSUG member. BSUG will provide access to the named deputy as requested by the Consultant, to enable them to log in to the database. The deputy assigned could deputise for multiple consultants from the same centre. Also, multiple deputies can be assigned for the same consultant.
- 4.2 Once the deputy selects the consultant that they are acting for, he / she will be able to see patient identifiable information of the records under the respective consultant, when acting as deputy to them. The deputy will be able to create records, change or update records and delete records on behalf of the consultant.
- 4.3 The Deputy will be subject to the same legal and professional duties to keep Patient Identifiable Data in the BSUG Database or which he/she has extracted from the BSUG Database confidential as he/she is under in relation to clinical records. In particular, the Deputy shall:
- 4.3.1 Always log-out of any computer system or application when work on the BSUG Database has finished;
  - 4.3.2 Not leave a terminal unattended and logged in from which a third-party could access the BSUG Database;
  - 4.3.3 Not share his/her username and password with any other person;
  - 4.3.4 Change his/her password at regular intervals. It is suggested that this is done at intervals of not greater than 90 days;
  - 4.3.5 Avoid using short passwords, or using names or words that are known to be associated with him/her;
  - 4.3.6 The Deputy shall not knowingly enter information which is inaccurate into the BSUG Database. It is, however, the responsibility of the Consultant to ensure accuracy of the records under their name.
  - 4.3.7 If a consultant wants to no longer take the service of a deputy, he / she can inform the BSUG to remove the deputy. Once the deputy is taken off from this role, he/she will no longer be able to access the data of the consultant they previously deputised for.

#### **5. Responsibility of the NHS Trust**

- 5.1 The NHS trust where the Consultant manages the patients and undertakes operations will be responsible for providing the facilities for creating records on the BSUG database. The facilities necessary for use of the database include a computer connected to the secure NHS HSCN network. The trust IT department should allow access to the database, and ensure it does not get blocked by their firewall / security software.
- 5.2 If Consultants of a centre agree to allow the trust/centre to use their BSUG data for the trust's clinical governance processes, this can be facilitated by BSUG on request by the consultant/s of the trust. The data should be handled by the trust in accordance with the UK General Data Protection Regulation and Data Protection Act 2018, as this data may contain patient identifiable information.
- 5.3 If a consultant moves to a different centre, the old centre will have access to the records of NHS cases undertaken by the consultant to be counted / viewed only in reports. None of the records will be available to the previous deputies at old centre for making any changes.

## **6. Acceptable Use by BSUG**

- 6.1 BSUG is the Data Controller as defined by the UK General Data Protection Regulation, in relation to the Patient Identifiable Data stored within the BSUG Database. BSUG will only process Patient Identifiable Data for the purpose of publishing *anonymous* statistical information for research, to establish a national dataset and to enable individual NHS Trusts (or Health Boards) and consultants to audit operation demographics, indications, outcomes and complications.
- 6.2 BSUG acknowledges that Patient Identifiable Data disclosed by the Consultant will be confidential information of the patients. Accordingly, BSUG will not disclose this data to any third parties, except in the following circumstances:
  - 6.2.1 The disclosure is to an information technology service provider of BSUG, with whom BSUG has a written contract pursuant to which the supplier has undertaken not to process the Patient Identifiable Data except in accordance with BSUG's instructions and to take appropriate technical and organisational measures to safeguard the security and integrity of the Patient Identifiable Data;
  - 6.2.2 The disclosure is to the Consultant or the Patient. If a solicitor requests data entered on the BSUG database, they need to present written consent from the patient to access this and the BSUG will obtain clinician consent to share this data. Both must be obtained before this can be shared;
  - 6.2.3 The disclosure is of Patient Identifiable Data in relation to an NHS Patient and the disclosure is made to the NHS Trust (or Health Board) through which the patient received any of the treatment to which the data relate;

- 6.2.4 The disclosure is to BSUG or any legal entity which is wholly owned by BSUG for processing strictly in accordance with these Terms of Use (in the form that they were in when the Consultant subscribed as a user of the BSUG Database); or
- 6.2.5 The disclosure is required by law or is otherwise in accordance with the UK General Data Protection Regulation and/or Data Protection Act 2018.
- 6.3 The information comprised in records added to the database may be published to the public or a section of the public by BSUG once it has been appropriately de-identified, such that it is no longer possible to identify a patient from the data.
- 6.4 BSUG currently protects the security of Patient Identifiable Data by storing it within the NHS Health and Social Care Network (HSCN), which is hosted by ISO 27001, ISO 9001 and Cyber Essentials certified suppliers.
- 7. Intellectual Property Rights**
- 7.1 BSUG shall own all copyright and database right (if any) in the records added to the BSUG Database by the Consultant.
- 8. Termination of Service/Removal of Data**
- 8.1 BSUG reserves the right to withdraw the Consultant's access to the BSUG Database at any time.
- 8.2 Notwithstanding any other provision of this agreement, the Consultant shall be entitled to either delete whole episodes from a patient record, or delete a patient record completely, which he/she enters into the Database during the period of his/her subscription. For the period of 5 years after the Consultant's subscription has ended, the Consultant shall be entitled to request (by written notice to BSUG at its registered office address) that BSUG delete or procure the deletion of Patient Identifiable Data which the Consultant has added to the BSUG Database. All such data shall be deleted within 60 days of receipt of the Consultant's notice.
- 8.3 BSUG will also delete Patient Identifiable Data entered by the Consultant where:
- 8.3.1 The patient has requested this or has withdrawn his/her consent to the processing being undertaken by BSUG; or
- 8.3.2 In the case of Patient Identifiable Data which relates to NHS Patients, the relevant NHS Trust (or Health Board) has requested its deletion; or
- 8.3.3 If the deletion of the Patient Identifiable Data is deemed by BSUG (at its sole discretion) to be appropriate.
- 8.4 Subject to the foregoing, Patient Identifiable Data directly relating to recurrence shall be retained by BSUG for 5 years after the period of clinical audit (10 years) has been



completed, or for 5 years after the expiration of a Consultant's membership. At the end of the retention period, Patient Identifiable Data will be securely deleted or anonymised, for example by aggregation with other data, so that it can be used in a non-identifiable way for statistical analysis.

## **9. Consultant Personal Information**

9.1 BSUG will not disclose the Consultant's personal information provided during the registration process (including your name, email address and hospital), except in the following circumstances:

9.1.1 The disclosure is to BSUG or any legal entity which is wholly owned by BSUG (where the recipient agrees to comply with this clause 8.1 in relation to onward disclosure).

9.1.2 The disclosure is made to the IUGA/EUGA as part of the Consultant's BSUG membership/subscription.

9.1.3 The disclosure is required by law or is otherwise in accordance with the UK General Data Protection Regulation and/or Data Protection Act 2018.

## **10. Variation**

10.1 BSUG may vary these Terms of Use at any time. All variations will apply to the Consultant 14 days after the Consultant has received notice from BSUG (by email) of the revised Terms of Use, but will not alter the provisions relating to Data Protection and confidentiality applicable to data which has already been disclosed to BSUG. The sending of an email to the email address associated with the Consultant's account shall be sufficient service for this purpose and all other purposes under these Terms of Use.

## **11. Miscellaneous**

11.1 These Terms of Use does not include any licence of intellectual property rights not expressly and clearly granted.

11.2 These Terms of Use are subject to the laws of England and Wales and any disputes arising under or in connection with these Terms of Use shall be subject to the exclusive jurisdiction of the courts of England and Wales (save that this clause shall not prevent BSUG bringing proceedings against the Consultant in any other jurisdiction).

11.3 The benefit of the contract created on these Terms of Use shall not be assignable by the Consultant, but may be assigned (in whole or in part) by BSUG to an entity referred to in clause 8.1.

11.4 Access to the BSUG Database and application is provided on a without warranty basis and BSUG can accept no liability for any loss or corruption of information uploaded or any unavailability of the service.

## **Code of Conduct**

**(For users of the BSUG database)**

**DO NOT BREACH PATIENT CONFIDENTIALITY** – Safeguard confidential information by following the basic rules listed below.

**DO NOT DISCLOSE PATIENT INFORMATION TO ANYONE WHO IS NOT AUTHORISED TO RECEIVE IT** – this includes staff not directly involved in the care of the patient

**DO NOT DIVULGE YOUR COMPUTER OR SECURITY PASSWORDS TO ANY OTHER PERSON** – If you suspect someone knows your password then you must change it immediately

**DO NOT USE SOMEONE ELSE'S PASSWORD TO GAIN ACCESS TO INFORMATION**

**DO NOT LEAVE A COMPUTER TERMINAL OR PC LOGGED ONTO THE SYSTEM UNATTENDED**

**DO NOT LEAVE PATIENT'S BSUG RECORDS UNATTENDED**, especially in public areas.

**DO NOT DOWNLOAD PATIENT IDENTIFIABLE INFORMATION FROM THE SYSTEMS ONTO ANOTHER COMPUTER SYSTEM** without permission from the BSUG Committee

**DO NOT WILFULLY RECORD INACCURATE DATA** - All information must be, to the best of your knowledge, accurate and up to date.

**DO NOT ACCESS INFORMATION ABOUT YOURSELF, YOUR RELATIVES OR FRIENDS**  
– You do not have an automatic right to such information

**DO NOT GIVE CONFIDENTIAL INFORMATION OVER THE 'PHONE OR VIA FAX** without first checking the identity and authority of the caller/receiver.

**DO NOT PUT CONFIDENTIAL WASTE INTO ANYTHING OTHER THAN A FACILITY APPROVED CONFIDENTIAL WASTE BAG.**

**TRY TO MINIMISE ANY PRINTING OR RECORDS AND REPORTS AND IF YOU DO NEED TO PRINT OUT DATA ENSURE THAT IT IS USED AND DISPOSED SECURELY.**

**FINALLY, DO NOT HESITATE TO SEEK ADVICE ON SECURITY IF YOU ARE NOT SURE.**

## **PATIENT INFORMATION SHEET**

Last Updated: 25th July 2024

### **The British Society for Urogynaecology (“BSUG”) Database**

The British Society of Urogynaecology (“BSUG”) is a national group of gynaecologists with a special interest and expertise in the treatment of incontinence and prolapse. We would like to seek your permission to include your personal data and important information about your operation in the audit database developed by BSUG and support the ongoing national audit. We have invited you to take part in our database as you are due to have, or have recently undergone a surgical procedure, and we believe that the information about this procedure could help us to improve patient care in the future. We are intending to involve as many individuals that have undergone surgical treatment for prolapse, incontinence and mesh procedures (all pelvic floor surgeries) in our database as possible.

Before you decide, it is important that you understand why this project is being undertaken and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

#### **What is the purpose of the Database?**

BSUG has developed a database of clinical and surgical information which we hope will make future procedures as safe and effective as possible. Hospital Trusts and individual Consultants can use this information to look at their practice and make any necessary changes for the improvement of patient care.

#### **Do I have to take part?**

- No. Taking part is entirely voluntary.
- You can withdraw from the database at any point and you will not be required to give a reason for doing so. Your withdrawal will not affect your clinical care in any way.

#### **What will happen to me if I decide to take part?**

- You will not need to do anything from your end and will receive clinical care as usual.
- Your consultant and their team will include some of your personal information like date of birth, NHS number and hospital number, and clinical information about your condition and operation into the database.
- Your consultant team may also collect information about the outcome of your operation so that it is possible to look at success rates and potential complications associated with individual procedures.

#### **Will my information within the Database be kept confidential?**

- BSUG has made the necessary arrangements to ensure that all information collected is de-identified and kept safe and secure.
- No-one apart from your consultant and/or their team will have access to any identifying information about you.
- Patients will be identified within the database by episode number only, with all direct identifiers removed.

- Responsible members of The British Society for Urogynaecology and/or NHS Foundation Trust may also be given access to the data to assist them in maintaining the compliance with applicable statutory obligations and/or regulations.

### **How will BSUG use my data?**

- We will only be using the information provided by your clinician (from your medical records) for clinical audit purposes.
- The British Society for Urogynaecology is the data controller which means that we are responsible for looking after your information and using it properly. When collecting your personal data, we will use the minimum amount of personally identifiable information possible.
- An online copy of the main database is also available to BSUG members on the public network (<https://www.bsug.net/>). However, this database is available for reporting purposes only, with all information being de-identified, and patient data remaining anonymous. Although this website is on a public network, the data is not available to the general public, and is only available to your consultant team and the BSUG administrator.
- Any personal data processed for audit purposes shall be retained for 5 years after the period of clinical audit (10 years) has been completed, or for 5 years after the expiration of your clinician's BSUG membership (whichever is earlier).
- Any personal data collected and processed within our database will be managed in line with the Records Management Code of Practice for Health and Social Care 2021 (Updated October 2023). More details of which can be found by visiting the link below:  
<https://transform.england.nhs.uk/information-governance/guidance/records-management-code/>
- You can find out more about how we use your information by contacting [bsug@rcog.org.uk](mailto:bsug@rcog.org.uk).
- All personal data is processed and stored within the UK and therefore, BSUG does not transfer personal data internationally.

### **What will happen to the data collected as part of the Database?**

- The data collected will be used by BSUG members to audit their own practice, their centre's practice, and to compare it to national practice and outcomes. It will also be used by BSUG to produce national reports on a regular basis to audit national practice, and the outcomes of urogynaecological operations.
- There may be occasions where a BSUG member would like to use the database for research purposes. In such cases, the BSUG member will need to obtain permission from the BSUG Research Committee. If permission is granted, the data shall be provided to the researcher in an anonymous form, so that patients cannot be identified. The research being undertaken may also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).
- Patients will not be identified from any report or publication placed in the public domain. This would also apply to any information used when presenting our findings at a conference for example.
- Special category data and any documents containing personal information, such as consent forms, will be stored securely by your consultant within the NHS Health and Social Care Network (HSCN), which is hosted by ISO 27001, ISO 9001 and Cyber Essentials certified suppliers.

### **What will happen if I no longer want to be part of the Database?**

- Inclusion is voluntary and patients may change their minds at any stage.
- Withdrawal will not affect the care you receive from any relevant service (e.g. if you are a patient from the NHS).

- You can withdraw your consent at any time by contacting your consultant or BSUG directly at [bsug@rcog.org.uk](mailto:bsug@rcog.org.uk).
- If you withdraw from the database, we will destroy all your personally identifiable information, but may continue to use the anonymous data collected up to your withdrawal for analytical and statistical purposes.

### **What if there is a problem?**

If you wish to complain, or have any concerns about how your personal data has been handled as part of this project, you should contact [bsug@rcog.org.uk](mailto:bsug@rcog.org.uk).

### **Who is organising and funding the project?**

Our BSUG database is funded directly through our BSUG membership subscriptions.

### **Who has reviewed the project?**

All medical research is looked at by an independent group of people, called a Research Ethics Committee, to protect patient's interests. However, as the main purpose of this project is clinical audit, ethics approval is not required.

### **Further information and contact details:**

You can contact BSUG in relation to data protection and this information sheet by writing to:

The British Society for Urogynaecology  
c/o Royal College of Obstetricians & Gynaecologists  
10-18 Union Street  
London  
SE1 1SZ

Alternatively, you can email us at [bsug@rcog.org.uk](mailto:bsug@rcog.org.uk).

We have also appointed a Data protection Officer ("DPO"). Our DPO is Evalian Limited and can be contacted by using the above email or postal address.

Please send your communication clearly indicating 'FAO the 'Data Protection Officer', your message will be passed directly to Evalian Limited for attention.

For more information on how we process your personal data please visit: <https://bsug.org.uk/privacy>.

Hospital Sticker  
Patient name:  
DOB:  
Hospital number:  
NHS number:

Title of Project: The British Society for Urogynaecology Database

### **STATEMENT OF CONSENT FORM**

1. I confirm that I have read the patient information sheet dated 25th July 2024 for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that the inclusion of my personal data is voluntary and that I am free to withdraw consent at any time without giving any reason, without my medical care or legal rights being affected. (However, any data processed up until this point may be anonymised and may still be processed for analytical and statistical purposes)
3. I understand that relevant sections of my medical notes and/or data collected during my treatment may be looked at by individuals from BSUG, the Regulatory Authorities or from the NHS Trust, where it is relevant to clinical audit and/or the Urogynaecology Database.
4. I understand that the de-identified information collected about me may be used to support research projects in the future, and may be shared anonymously with external researchers.
5. I agree to my information being included within The British Society for Urogynaecology Database.

Name of Patient:

Signature:

Date:

Name of Person Obtaining Consent:

For more information on how we process your personal data please visit:

<https://bsug.org.uk/privacy>