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## **BOFAS Registry**

### **Terms and Conditions and general information for users**

#### **Background**

The success of the Registry for BOFAS (British Orthopaedic Foot & Ankle Society) depends on the surgeons and their delegates who use it. We aim to achieve high levels of uptake of this registry and good data quality that will provide a valuable resource; this depends on the regular and accurate input of data by yourselves and your colleagues.

Because there are sensitive patient-identifiable data held in the registry to which users have certain access, data protection is a particularly strong theme in these terms. The success of the registry also depends on us all taking our data governance responsibilities seriously.

These terms and conditions cover your responsibilities as a user of the registry as well as setting out the principles of our role as a registry in looking after the data we hold, both in terms of security and appropriate usage.

Before we get to the terms and conditions, however, we set out our core registry principles.

#### **Registry Principles**

- This is an independent registry, governed by an independent, not-for-profit organisation (BOFAS), under the direction of surgeons in partnership with stakeholders.
- The Registry will establish policies and procedures that will govern data use, dissemination, and reporting, including the relationship with organizations external to the Registry, such as the Department of Health, patient groups, and any industry partners. We will be transparent with users about these policies and procedures; notifying you whenever they are published or updated.
- Core data elements to be captured by the Registry will be defined with input from stakeholder groups.
- We believe that for the most comprehensive collection of core data, the reporting system must maximize existing data collection systems and rely upon participating hospitals, and individual surgeon members for submission of data to the Registry.
- The security of Registry data, patient privacy and data integrity are of the utmost importance and will be protected by the manner of the Data Protection Act 1998, data access policies, and organisational and technical safeguards in partnership with our contracted Data Processor. Any user

may at any time contact us for information about the security arrangements and/or for copies of the security certifications from Amplitude Clinical.

- The collected data will be appropriately analysed once sufficient data has been collected. All analysis and interpretation of Registry data must be objective and scientific. Any interpretation of the data will carefully consider the quality, completeness and maturity of the data.

## **User terms and conditions**

### **Introduction**

The term '**BOFAS Registry**' or '**us**' or '**we**' refers to British Orthopaedic Foot & Ankle Society, which is responsible for the BOFAS Registry and whose registered office is Ling Phipp Chartered Accountants, Cliffe Hill House, 22-26 Nottingham Road, Stapleford, Nottingham, NG9 8AA.

The term '**you**' refers to the user or viewer of our Registry.

The following user policy is in force from Friday 1<sup>st</sup> December and replaces any previous user policy to which the individual user may have agreed. From this date:

- any new user will be required to agree to the following access and usage terms and conditions on first access;
- any existing user will be required to agree to the following access and usage terms and conditions on the next occasion when they access the registry.

By confirming your acceptance of these user terms and conditions, you are agreeing to comply with and be bound by the following terms and conditions of use, which govern the Registry's relationship with you. To access the Registry Portal you will be required to confirm your acceptance of these terms by ticking the relevant box. If you disagree with any part of these terms and conditions, please do not use this Registry and/or the sign up process. You are using the Registry and its services not as a consumer and you acknowledge that certain statutory consumer rights and protections do not apply to your use.

The use of this Registry is subject to the following terms of use. This document has the following sections:

- 1) Website
- 2) Data protection
- 3) Registry data access policies
- 4) Data publication
- 5) Disclaimer
- 6) Copyright notice
- 7) Suspension and termination

### **1) Website**

For any website(s) provided by the registry, the following terms apply:

- Access to our Website is permitted on a temporary basis, and we reserve the right to withdraw or amend the service we provide. We will not be liable if for any reason our Website is unavailable at any time or for any period.

- From time to time, we may restrict access to some parts of our Website, or our entire Website, to users who have registered with us.
- You are responsible for ensuring that all persons who access our Website through your internet connection are aware of these Terms of Use, and that they comply with them
- The content of the pages of any Registry website is for your general information and use only. It is subject to change without notice.
- The Registry uses cookies. Details regarding specific cookie usage that applies to the registry is available as an Appendix at the end of this document.
- Any website may contain materials which are owned by or licensed to us. This material includes, but is not limited to, the design, layout, look, appearance and graphics. Reproduction is prohibited other than in accordance with the copyright notice, which forms part of these terms and conditions.
- All trademarks reproduced, which are not the property of, or licensed to the operator, are acknowledged on the website.
- From time to time, this website may also include links to other websites. These links are provided for your convenience to provide further information. They do not signify that we endorse the website(s). We have no responsibility for the content of the linked website(s).
- The content on any Websites, publicity or information materials associated with the Registry, including, but not limited to, the text, graphics, images, links, and other materials are for informational purposes only. The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment, and does not constitute medical or other professional advice. The Registry does not recommend or endorse any specific tests, physicians, products, procedures, opinions, or other information that may be mentioned on the Website or other materials.
- You may use our Website only for legitimate purposes. For instance, you may not use our Website:
  - In any way that breaches any applicable local, national or international law or regulation.
  - In any way that is unlawful or fraudulent, or has any unlawful or fraudulent purpose or effect.
  - To send, knowingly receive, upload, download, use or re-use any material which does not comply with our content standards, detailed below.
  - To knowingly transmit any data, send or upload any material that contains viruses, Trojan horses, worms, time-bombs, keystroke loggers, spyware, adware or any other harmful programs or similar computer code designed to adversely affect the operation of any computer software or hardware.

You also agree:

- Not to reproduce, duplicate, copy or re-sell any part of our Website unless in contravention of the Terms of Use allow it.
- Not to access without authority, interfere with, damage or disrupt:
  - any part of our Website;
  - any equipment or network on which our Website is stored;
  - any software used in the provision of our Website; or
  - any equipment or network or software owned or used by any third party.
- Unauthorised use of the website may give rise to a claim for damages and/or be a criminal offence.
- The Registry uses login information, including, but not limited to, IP addresses, ISPs, and browser types, to analyse trends, administer the Registry and track a user's movement and use.

- You must not misuse our Website by knowingly introducing viruses, trojans, worms, logic bombs or other material which is malicious or technologically harmful. You must not attempt to gain unauthorised access to our Website, the server on which our Website is stored or any server, computer or database connected to our Website. You must not attack our Website via a denial-of-service attack or a distributed denial-of service attack.
- We will not be liable for any loss or damage caused by a distributed denial-of-service attack, viruses or other technologically harmful material that may infect your computer equipment, computer programs, data or other proprietary material due to your use of our Website or to your downloading of any material posted on it, or on any website linked to it.

## **2) Data protection**

The data collected by this registry includes both personal data and sensitive personal data and falls under the remit of the Data Protection Act (1998). BOFAS is the Data Controller, and is registered with the Information Commissioner's Office (ICO) – Z2377643. BOFAS is contracted with a third party Data Processor, currently Amplitude Clinical, who provide software and data hosting for the registry.

BOFAS is currently working with the British Orthopaedic Association (BOA) to establish a new working structure for this and other T&O registries under the name TORUS (T&O Registry Unifying Structure). As part of this initiative it is envisaged that the BOA will become a Joint Data Controller for the Registry, and by agreeing to these terms and conditions, you are agreeing to this future arrangement for Data Controllorship. The purposes for the data processing are not due to change. Further information regarding TORUS can be found on the BOA website.

### **2.1 User Data – the Registry's use of your personal data**

- In order to be a registered user, the registry will be required to hold personal data about you, which may include your name, contact details, place(s) of work and GMC number. These data are used for the effective running of the registry, for contacting you in relation to the registry, to provide a record of the patients you have treated and in the interests of promoting high-quality care for patients.
- Your data will be stored securely and used only for these purposes.
- Under the Data Protection Act, you are entitled to make a Subject Access Request, to obtain a copy of the information we hold about you.
- By using the Registry under these Terms and Conditions, you agree to use of your data for the Registry purposes and under the Registry Principles discussed herein.

### **2.2 Patient data – your use of personal data about patients held on the registry**

Submission of data to the registry is voluntary but is welcomed and strongly encouraged.

The data collected by this registry includes both personal data and sensitive personal data regarding patients and falls under the remit of the Data Protection Act (1998). This includes: certain personal details (primarily name, date of birth and NHS number); details about the operation and relevant health conditions; and contact details. It could also include linked information about any future operation or complications, or from other health records.

Data submitted to the registry will be stored securely, in accordance with ICO and Data Protection Act requirements.

Whilst there is no requirement for you to register individually as a Data Controller with the ICO, terms and conditions of usage of this Registry require you to abide by the Data Protection Act (1998). Any patient identifiable data must be kept secure.

As a user, you input and have access to and use of patient identifiable data through the registry. As a result, there are important responsibilities of which you must be aware, which are covered below.

Any lapse or breach in meeting the requirements set out here may result in further action being taken, which may, depending on the nature or severity, include: terminating your use of the registry; suspension from membership of the specialist society; disciplinary action by your trust, other employer or the GMC; and/or criminal or civil proceedings being taken against you.

Your responsibilities include the following:

- You will ensure appropriate security of your login details, and you will not allow anyone else to use your account log-in details to view, update or enter records on the Registry. This is considered a breach of security.
- You will contact the Registry immediately you suspect a breach of security. This includes a breach in security of the Registry database itself or a breach involving information that has been downloaded.
- You will ensure that explicit patient consent is sought, given and recorded.
- You understand that failure to correctly indicate the acquisition of consent will lead to the deletion of identifying data upon your patients' records.
- You are entirely responsible for indicating patient's consent where this is done on paper rather than electronically.
- When advising patients about the registry you shall use only approved Registry materials, primarily the Registry's current consent information and form and the Registry's website.
- Only necessary and appropriate data is to be recorded on the registry. In particular you should not submit any identifiable information about any patient other than that specified by the registry requirements.
- All data will be accurate, and up to date.
- In the event of a data breach, you will cooperate with the registry and/or hospital trust and/or any other body involved in the investigation and follow-up of this data breach.
- Informing the Caldicott Guardian within your NHS Trust of your intention to contribute to the registry, and obtaining their approval before commencing. (A full list of Caldicott Guardians can be found at <https://digital.nhs.uk/organisation-data-service/our-services#CG>.) Each Private Hospital should also be informed of their proposed data submission to the Registry. An approved information pack can be downloaded from the Registry Website (<https://www.bofas.org.uk/Registry/Getting-Started>).

## **2.3 Delegates**

- If you wish to nominate a delegate to use the registry on your behalf, they must be registered as an individual delegate linked to your account.

- Where you grant access to appropriate individuals to act as delegates for your account, you remain responsible for the data entry upon your patients entered by said individuals and for their actions in relation to the use of the registry and data contained within it.
- Any individual(s) you nominate as delegates to use the registry on your behalf, must as a minimum:
  - Be contracted (usually through an employment contract) under an arrangement in which they have signed a confidentiality agreement and through which any breach of data confidentiality is potential a disciplinary offence;
  - Be provided with secure IT facilities from which to access the registry;
  - Be aware of their data protection responsibilities and given training to ensure their knowledge is up to date;
  - Be, to the best of your knowledge, trustworthy and not have prior history of being unreliable or unsuitable for access to Personal Data.
- In the case of you subsequently finding any delegate to be unreliable or unsuitable for access to Personal Data, you shall ensure that his or her access to Personal Data through the Registry is withdrawn immediately. If you suspect a breach of security of Registry data, this must be reported as stated in the previous section.
- You shall ensure that your delegates are aware that Personal Data should only be accessed for Registry Purposes and not for their own private purposes.
- You should review your list of delegates every six months to ensure it continues to be up-to-date.

## 2.4 Downloading/Using reports and data

- You may only download stored information via reports, for appropriate use in line with the purposes set out for the Registry. This can include but is not exclusive to appraisal / revalidation, audit, research, and teaching purposes.
- Where a report containing Patient identifiable data is downloaded, particular care must be taken and it is your responsibility to ensure that a breach of this data is avoided. Measures that should be taken include:
  - Saving the file only on a device that is suitably secure and not on portable media;
  - Using only a password-protected file;
  - Using the file only within a suitably secure IT infrastructure, for example with appropriate security on external routes into its organisation, such as internet firewalls and secure dial-in facilities;
  - Sharing this information only where necessary and always only with other clinicians or staff members within your unit or trust, for example for audit, revalidation or patient follow-up purposes;
  - Ensuring the complete deletion of the file, and that any printed materials are disposed of securely, for example by shredding.

By using this registry you understand that:

- You give the Amplitude Support Team rights to edit or correct any non-clinical data in your system that is directly prohibiting the patient or other authorised users from completing their data entry tasks e.g. email address, spelling mistakes in name or address, password resets, deleting duplicate pathways created in error where no clinical data is associated and so on. A log is kept of all changes and reports can be provided at any time.
- The data collected will be used in line with registry policies, for example on access to data and publication of data (both covered below). These policies are made available

in full by the Registry in this document and/or on its website. These policies may require changing and updating over time, and all users will be advised of any changes.

- In future a variance analysis policy will be developed and published, along with other policies as needed; all users will be advised of any new policies as these are developed. Where appropriate, we will consult users on the development of these policies.

### **3) Registry data access policies**

#### **3.1 Access to user's own data (on patients they have inputted)**

- The user will have full access to the data collected regarding patients that she/he has treated and entered into the dataset. This access will be provided via reporting tools. The user will be required to take account of data governance implications where such data are downloaded (covered above).
- The individual data provided may be used for presentation at the discretion of the surgeon submitting data but no individual patients should be identifiable.
- At the present time, the data quality and completeness are areas of continued development for the registry and we do not envisage that any users would be seeking to produce independent publications based on data from the registry at this stage. In due course, the registry will develop a policy for independent publication of registry data, but in the meantime any registry user considering such publication must first approach the registry to discuss this.
- For any publication that does occur: (a) the Registry must be acknowledged as the source of data in any publication (including electronic versions) in which the Registry is quoted, and (b) if any data analysis results produce small numbers of patients, publication of these numbers must be suppressed to avoid potential breaches of confidentiality.
- Express Research and Ethics approval from your local institution must be in place for specific data to be utilised for research purposes.

Users will not have access to patient-identifiable data for patients other than those they have treated.

#### **3.2 Data Access within the registry**

The following people may have access to all data held in the registry (at least in principle, though they may not in fact access it). They all are bound by strict confidentiality requirements in relation to their usage:

- a) Certain Amplitude Clinical staff who work on the registry;
- b) Some or all members of the steering group for the registry, for administrative/registry management purposes;
- c) Any staff employed by the Specialist Society or Registry to work on the registry (either currently or in the future) may have access to the data.

#### **3.3 Data Access by Third Parties**

Identifiable surgeon level outcome data will not be released unless required by law or where there is a strong professional obligation for the Society/Registry leads to do so (e.g. on the grounds of patient safety). If the Society has serious patient safety concerns regarding a surgeon or unit, that have not been resolved through dialogue with that surgeon or unit, we have a responsibility to pass this on, confidentially, to the relevant local lead or national body for follow-up. In any such instances, should that local lead or national body request access to data, including the data audit trail, the Society/Registry will carefully consider that request, including the legal position in relation to sharing such data. We envisage that such instances will be very rare indeed.

#### **4) Data Publication**

- The Registry recognises the growing expectation nationally for the publication of unit-level outcomes based on registry-type data. We believe that it may take some considerable time for data to be sufficiently mature for its use to be appropriate in this context, but once the registry reaches this stage of maturity, we would intend to contribute to unit level publication. In the meantime, the registry considers it could be appropriate to publish (at unit level), information on whether the unit is or is not participating in the registry and, if appropriate, the level of compliance.
- The Registry does not support the principle of surgeon-level publication.
- Publication of general registry information, such as typical outcomes from procedures in patients with different demographics, will be included in registry publications, such as annual reports.
- Patient-level data will not be published. If any data analysis involves small numbers of patients, publication of these numbers will usually be suppressed to avoid potential breaches of confidentiality.
- These positions are shared by all the emerging registries in T&O and supported by the British Orthopaedic Association.

#### **5) Disclaimer**

- Every effort is made to keep the Registry website and the Registry itself up and running smoothly. However, BOFAS takes no responsibility for, and will not be liable for, the website or Registry being temporarily unavailable due to technical issues beyond our control.
- Any listing of suppliers' components in the Registry database does not indicate approval of such components by the Registry, or BOFAS or any regulatory body.
- Where registry users are also subscribers to the Amplitude ProOne system or (through their trust or similar) to the Amplitude ProEnterprise system, they should note that the user agreement provided here relates solely to data held on the registry and governs the relationship between BOFAS and the registry user in relation to that data and use. Other separate agreement(s) may apply between that individual and Amplitude in relation to the use of other products and services, and these are the responsibility of the individual user or their trust.

#### **6) Copyright notice**

This website/ database and its content are copyright of BOFAS. All rights reserved.

Any redistribution or reproduction of part or all of the contents in any form is prohibited other than the following:



- you may print or download to a local hard disk extracts for your personal for non-commercial use only, subject to the Data Protection Policy above.

You may not, except with our express written permission, distribute or commercially exploit the content. Nor may you transmit it or store it in any other website or other form of electronic retrieval system.

## **7) Suspension and termination**

We will determine, in our discretion, whether there has been a breach the standards expected in the course of your use of the Registry. When a breach of these terms has occurred, we may take such action as we deem appropriate. Failure to comply with our terms of use, and may result in our taking all or any of the following actions:

- Immediate, temporary or permanent withdrawal of your right to use of the Registry and the Website.
- Issue of a warning to you.
- Legal proceedings against you for reimbursement of all costs on an indemnity basis (including, but not limited to, reasonable administrative and legal costs) resulting from the breach.
- Further legal action against you.

We exclude liability for actions taken in response to breaches of these terms. The responses described in this policy are not limited, and we may take any other action we reasonably deem appropriate.

To the extent permitted by law we hereby expressly exclude all conditions, warranties and other terms which might otherwise be implied by statute, common law or the law of equity.

In no event shall we be responsible for any direct, indirect or consequential loss or damage incurred by any user in connection with our Website or Registry, or in connection with the use, inability to use, or results of the use of our Website or Registry, or any websites linked to our Website and any materials posted on it.

This does not affect our liability for death or personal injury arising from our negligence, nor our liability for fraudulent misrepresentation or misrepresentation as to a fundamental matter, nor any other liability which cannot be excluded or limited under applicable law.

## Appendix



### **BOFAS Registry: Information about our use of cookies**

Our Registry website uses cookies. This helps us to provide you with a good experience when you browse our website and also allows us to improve our site. By continuing to browse the site, you are agreeing to our use of cookies – for registered users, the acceptance of these cookies is part of the agreement to our terms and conditions.

A cookie is a small file of letters and numbers that we store on your browser or the hard drive of your computer if you agree. Cookies contain information that is transferred to your computer's hard drive.

We use the following cookies:

- **Strictly necessary cookies.** These are cookies that are required for the operation of our website. They include, for example, cookies that relate to the secure log in and that automatically log you out after a period of inactivity.
- **Functionality cookies.** These are used to recognise you when you return to our website. This enables us to personalise our content for you. At present there is one such cookie in use, which works in the worklist functionality for surgeons to remember your preferences.

You can find more information about the individual cookies we use and the purposes for which we use them in the table below:

Cookie	Name	Purpose	More information
Authorisation Cookie	.ASPXAUTH_<sitename> .ASPXAUTH_<sitename>_pp	This cookie is essential to the operation of the site and is used to track current authentication status.	This cookie is HTTP Only and thus is not accessible in client side script and is only served over secure encrypted connections. Additionally the cookie itself is encrypted.
Session Helper Cookie	ASP.NET_SessionId	This cookie is essential to the operation of the site and is used to help us reduce load on our	This cookie is HTTP Only and thus is not accessible in client side script and is

		servers.	only served over secure encrypted connections. Additionally the cookie itself is encrypted.
Doctor ID Helper Cookie	DoctorId	This cookie helps us with tracking delegation and is used for error reporting	This cookie is HTTP Only and thus is not accessible in client side script and is only served over secure encrypted connections. Additionally the cookie itself is encrypted.
Server Time Offset Cookie	serverTimeOffset	This cookie is essential for the operation of the site and is used to track minor time differences between the client and the server	
Session Expiry Cookie	session_expiration sess.exp.pp	This cookie is essential to the operation of the site and is used to notify the user if they've been inactive and are in danger of having their session expired. It is also used to redirect the user to the login page after expiry (avoiding accidental data input where the session has expired)	
Worklist Preferences Cookie	udb.wl	This cookie is used to remember the last selected date and type for the worklist so they can be restored when returning to the worklist	

You block cookies by activating the setting on your browser that allows you to refuse the setting of all or some cookies. However, if you use your browser settings to block all cookies (including essential cookies) you may not be able to access all or parts of our site.

All cookies listed above are session cookies: once the browser is closed the cookies are also removed.