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Document Title:	DOT MEDICAL HUMAN RESOURCE POLICY Patient Consent Policy	Effective Date:			01 Feb 2023		
		Revision №:			1		
Document Type:	Policy	Pages	1 of 2	Document Nº:	POL-008		

Dot Medical recognizes that Informed Consent documents are used extensively in hospitals and will provide relevant information to hospitals for the creation of Informed Consent documents when requested to do so.

Dot Medical also recognizes that some Product Suppliers request that patients complete a separate Informed Consent document, especially where there is a patient training element involved in the use of the product. In these circumstances Dot Medical will request the assistance of hospital staff to complete the form in line with hospital guidelines.

If any data is obtained from a patient, explicit written permission is obtained to utilize that data for the intended purposes only, in line with GDPR (2018) and Dot Medical-QSP-98 (GDPR).

Any patient data collected, or information collected on the Informed Consent form will be utilized, stored, and transferred only in accordance to GDPR (2018).

If there are any concerns about the capacity of the patient to provide a valid Informed Consent Form from a Product Supplier, then Dot Medical will be guided by the hospital protocols in place.

If a hospital or patient has a complaint related to Informed Consent or the collection of any data related to a patient, the complaint will be referred to the QA Manager who will capture the complaint according to Dot Medical QSP-062 (Complaints Procedure). The complaint will be reviewed by the Data Protection Officer of Dot Medical and the Registered Manager who will keep the CQC apprised appropriately.

All Dot Medical staff have received training in the Complaints Procedure and Clinical/Product Specialists have received training specifically on obtaining informed Consent.

Should a complaint about Informed Consent not be resolved, it will be escalated to the Managing Director. The Managing Director's decision is final, however if the complainant continues to be unhappy with the complaint response outcomes, they are at liberty to contact:

Local Government Ombudsman

Telephone: 0300 061 0614 Website: www.lgo.org.uk

And/or CQC

National Customer Services Centre

City Gate, Gallowgate, Newcastle upon Tyne, NE1 4PA

Telephone: 03000 616161, Website: www.cqc.org.uk



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Document Review

This policy will be reviewed every three years as detailed in QSP-051.

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Approved by:	Shirley A Foster	QA Manager	S.A.b.st	03 Feb 2023	

Revision Number	Author	Description of changes	Document Change Request Note Number	Effective Date
0	I Rankin	New Document	2020-037	16-Oct-2020
1	I Rankin	To review policy and change the document review period to 3 years, to bring the policy in line with QMS documentation.	2023-02	01 Feb 2023