Insert Trust Logo

DISCUS: Duroplasty for Injured cervical Spinal Cord with Uncontrolled Swelling

INFORMED CONSENT / CONSULTEE DECLARATION FORM

V6.0 dated 07Jan2025

IRAS Project ID	England 292031 Scotland 296518	**REC Reference**	England 21/LO/0216 Scotland 21/SS/0026
Site R&D ID Code		**Patient Name**	
DISCUS Trial ID *(DS-XXX-XXXX)*		**Patient Hospital/ Medical Record Number**	

Guidance Notes:

- *This consent form is used for **ALL** types of DISCUS consent in England/Wales/Ireland; including patient, hand witness or proxy consent. This consent form is used for Patient Informed Consent ONLY in Scotland.*
- *Please initial boxes if you agree, instead of ticking*
- *If the patient verbally consents but cannot sign, this is 'patient consent with the use of a witness' and not consultee. **Hand witnesses or consultees should use their own initials** and not the patient's initials when signing on behalf of the patient.*
- *Keep 3 copies of this consent form*
  - ***Original**: 1 to be kept in medical notes with corresponding patient information sheet.*
  - ***Copy**: 1 for Patient/Consultee to take.*
  - ***Copy**: 1 to keep as part of the study documentation in the site file with corresponding patient information sheet*

1	I confirm that I have read and understood the appropriate information sheet for DISCUS trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ▪ ***Type of Information Sheet:*** *(circle as appropriate) Patient or Proxy or Reconsent* ▪ ***Information Sheet Dated:*** ____ / ____ / ____ ▪ ***Information Sheet Version:***	*Initial:*
2	I understand that my/the patient's participation is voluntary and that I am/the patient is free to withdraw at any time, without giving any reason, without my/the patient's medical care or legal rights being affected.	*Initial:*
3	I understand that sections of any of my/the patient's medical records and data collected during the trial may be looked at by responsible individuals* from the University of Oxford, City St George's University London and from the relevant NHS Trust(s) where it is relevant to me/the patient taking part in research. I give permission for these people to have access to my/the patient's medical records.	*Initial:*
4	I give permission for my/the patient's personal information (including name, hospital identification number, NHS number or community hospital identification (CHI) number if applicable, name, date of birth and contact details) to be passed to the University of Oxford.	*Initial:*
5	I understand that I/the patient will be contacted by responsible individuals* about the outcome and about my/their experience with the trial. I give permission for these people to contact me/the patient.	*Initial:*
6	I agree/I agree as consultee for the patient to take part in the DISCUS study.	*Initial:*

7	I understand that the DISCUS trial office will need to be able to contact me/the patient to arrange questionnaire completion either on the phone, online or send paper versions via post, and to provide reminders to complete. I give permission for my/the patient's postal address, email address and telephone contact details to be kept and used for this purpose, on the understanding that they will be kept securely, separately to my/the patient's clinical information and accessible only to the study team.	*Initial:*
8	I agree to my/the patient's General Practitioner being informed of my/the patient's participation in the trial.	*Initial:*
9	I understand that the information held and maintained by _____ *(name of organisation(s) that will be providing data, including any NHS/HSC organisations)* may be used to help contact me/the patient or provide information about my/the patient's health status.	*Initial:*

**Responsible individuals are doctors involved in the study and other members of the research team.*

OPTIONAL SECTION: *The following answers do not affect participation in the main DISCUS trial.*		**Yes**	**No**
10	I agree to allowing the information collected about me/the patient to be used in an anonymous form to support other research in future.		
11	I agree to be contacted/for the patient to be contacted for future related studies.		
12	I agree to participate/for the patient to participate in the Mechanistic Substudy (if eligible)		
	a) If Yes, I understand that the Mechanistic Study involves placing probe(s) (pressure probe and/or microdialysis probe) next to the injured spinal cord to measure its pressure, metabolism and inflammation	*Initial:*	
	b) If Yes, I understand that, if a microdialysis probe is placed, then microdialysis samples will be stored for future analysis as described in the information sheet.	*Initial:*	

CONSENT GIVEN BY: (Please fill in rows as applicable)		
Name of Participant (If Patient Consents)	**Signature of Participant** (If Patient Consents)	**Date**
Name of Hand Witness (If Patient Verbally Agrees but Cannot Sign)	**Signature of Hand Witness** (If Patient Verbally Agrees but Cannot Sign)	**Date**
Name: Relationship to Patient:		
Name of Consultee (If Proxy Consent is Sought)	**Signature of Consultee** (If Proxy Consent is Sought)	**Date**
Name: Relationship to Patient:		

CONSENT TAKEN BY: (Site Use Only)		
Name of Person Taking Consent (Delegated Member of DISCUS Team)	**Signature of Person Taking Consent** (Delegated Member of DISCUS Team)	**Date**