Imperial College London

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Consent form

GRACE

Site ID:	Initials:
Participant Trial ID:	Principal Investigator Name:

Full Title of Project: GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial).

Study Protocol number: 22HH7932

Is verbal consent being provided via telephone? (please initial one option):

☐ Yes – Please read each statement to the participant. Once the participant agrees to each statement, please provide the initials of the person taking consent (i.e. the researcher) in each box

☐ No – Participant to read the consent form and they write their own initials in each box

Please initial box

1. I confirm that I have read and understand the participant information sheet version ..... dated ..... for **GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial)** and have had the opportunity to ask questions which have been answered fully.	
2. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected.	
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London, from my NHS Trust or hospital site from regulatory authorities where it is relevant to my taking part in this research.	
4. I agree to my data (which includes my identifiable data [name, email address and contact telephone numbers]) being entered onto a secure database held at the	

University of Edinburgh, in accordance with the Data Protection Act 2018 and that members of the research team from Imperial College London will have access to these contact details so that they can contact me.	
5. I understand that if I am eligible for the study, a member of the research team from Imperial College London will have access to my identifiable data to allow contact (via telephone, email, SMS or written) at 7, between 21 and 35 days and 90-days after my surgical procedure to collect follow-up data	
6. I understand that data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.	
7. I understand that my pseudonymised data will be accessed by the University of Edinburgh for the analysis	
8. If during the study my clinical care team determine that I have lost capacity to provide informed consent, I will be withdrawn from the study and any identifiable data collected with consent would be retained and used in the study	
9. I consent to take part in GRACE	

Optional consent section (please initial the appropriate box)

10. I agree to my GP, or any other doctor treating me, being notified of my participation in this study.

Give consent ☐ Do not give consent ☐

11. I agree for information collected about me to be used to support other research or in the development of a new treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).

Give consent ☐ Do not give consent ☐

12. I give/do not give consent for my data to be linked with appropriate national databases, including Hospital Episode Statistics (HES), as well as for longer term follow-up in the event the trial is extended.

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Give consent ☐ Do not give consent ☐

13. I give/do not give consent to be contacted in the future with regards to this study, should the study be extended.

Give consent ☐ Do not give consent ☐

14. I give / do not give consent to being contacted about the possibility to take part in other research studies.

Give consent ☐ Do not give consent ☐

_____	_____	_____
Name of participant	Signature	Date
_____	_____	_____
Name of person taking consent (if different from Principal Investigator)	Signature	Date

1 copy for participant; 1 copy for Principal Investigator 1 copy for hospital notes

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented and stored in double sided format