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FLARE Participant Consent Form

Participant ID:

Short Title: FLexor repAir and REhabilitation (FLARE) Trial

Chief Investigators: Mr Matthew Gardiner, Consultant Hand and Plastic Surgeon, Frimley Health NHS Foundation Trust and Ms Emma Reay, Consultant Hand and Wrist Surgeon, South Tees Hospitals NHS Foundation Trust

If you wish to take part in the FLexor repAir and REhabilitation (FLARE) Trial, **please place <u>your initials</u> in each of the boxes below, sign and date this form.**

Please initial each box

1. I confirm that I have read the FLARE Patient Information Sheet [VX.X DD/MM/YYYY] for the above study. I have had the opportunity to consider the information, ask questions and have had the answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that my eligibility for randomisation into the FLARE Trial will be confirmed during my surgery and that, if I am: ☐
   a. ELIGIBLE - I will receive tendon repair either with fixation of one tendon or fixation of both tendons and that the decision on which treatment I receive is made at random by a computer programme.

   b. NOT ELIGIBLE - My surgeon will provide routine treatment for my tendon repair.

4. I understand that relevant sections of my medical notes and/or data collected during the study may be looked at by responsible individuals from the University of York, the Sponsor, the NHS Trust, or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

5. I understand that the information collected about me will be used to support other research which has ethical approval in the future, and may be shared anonymously with other researchers or third parties. ☐

6. I agree to my General Practitioner being informed of my participation in the study and being advised of any significant information relating to my health that arises during the study. ☐

When completed: 1 for patient; 1 for the Investigator Site File; 1 to be kept in medical notes; 1 for York Trials Unit.

This study is funded by the NIHR Health Technology Assessment programme (Grant number NIHR133784). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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7. I agree to this consent form and other data collected as part of this study to be kept at the University of York ☐

8. I understand that records relating to me will be kept confidential. No information will be released or printed that would identify me without my permission unless required by law. ☐

9. I understand and agree that the research team will securely store my identifiable details for five years, in order to contact me in future regarding this study, or other related studies (e.g. telephone/text/email). Identifiable details, including a copy of the consent form, will be available only to the research team, other than for purposes of monitoring and audit. ☐

10. I agree to take part in the FLARE trial. ☐

11. **OPTIONAL:** I agree to be contacted by telephone/email about taking part in a patient experience interview towards the end of my involvement in the FLARE Trial. YES ☐ NO ☐

_____	_____	_____
Name of Participant *(please print)*	Date *D D/ M M/ Y Y Y Y*	Signature of Participant
_____	_____	_____
Name of Witness *(please print)*	Date *D D/ M M/ Y Y Y Y*	Signature of witness
_____	_____	_____
Name of Person Taking Consent *(please print)*	Date *D D/ M M/ Y Y Y Y*	Signature of Person Taking Consent

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