[Insert Hospital Logo]

Participant Consent Form

Participant Identification Number: | | | | | | |

Study title: **Surgical fixation versus non-operative management for patients with stable thoracolumbar fractures: A feasibility study**

Study Acronym: Pragmatic Randomised Evaluation of Stable Thoracolumbar fracture treatment Outcomes (PRESTO)

If you wish to take part in the PRESTO study, **please place your initials in each of the boxes below, sign and date this form.**

Please ***initial*** each box

1. I confirm that I have read the information sheet [VX.X XXXXXXXX] for the above study. I have had the opportunity to consider the information, ask questions and have had these 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 relevant sections of my medical notes and/or data collected during the study may be looked at by responsible individuals from the study team, 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. ☐
4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers and third parties. ☐
5. 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. ☐
6. I understand that the information held and maintained by the Health and Social Care Information Centre, other central UK NHS bodies or authorised third parties may be used to help contact me or provide information about my health and/or health care. ☐
7. I agree to this consent form and other data collected as part of this research study to be kept at York Trials Unit, 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. ☐
9. I understand and agree that the research team will securely store my identifiable details 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 above study. ☐

In addition to the above, please initial the 'Yes' box if you are happy to be approached for an interview for this study. You can opt out of taking part in the interviews by putting your initials in the 'No' box. This will not affect your participation in the trial.

Yes ☐ **No** ☐

Name of participant (*please print*)	Date DD/MM/YYYY	Signature of participant
Name of witness, if necessary (*please print*)	Date DD/MM/YYYY	Signature of witness
Name of person taking consent (*please print*)	Date DD/MM/YYYY	Signature of person taking consent

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

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