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and relevant contact details to be entered

CONSENT FORM

Prehabilitation in Elective Patients Undergoing Cardiac Surgery (PrEPS)

Name of Researcher: [Recruiting Centre PI to be entered]

Participant Identification Number for this trial: __ __ __ __ __

Please INITIAL the box where you agree. Please note that statement 9 is optional:

1. I confirm that I have read the information sheet dated …….. (version ……..) for the above trial. I have has 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 data collected during the study, may be looked at by individuals from Newcastle Clinical Trials Unit, from regulatory authorities or from the NHS Trust, 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 anonymised information about me relevant to the trial will be held on a secure database, which is hosted on an external server and will be transferred to individuals within the research team including members at Newcastle and Durham University for analysis. All data will be anonymised using a participant identification number and stored securely on restricted servers for a period of 7 years after the end of the trial. Any publications resulting from this trial will not include any personal identifiable information ☐

5. 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 ☐

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6. I agree to my General Practitioner being informed of my participation in the trial, including any necessary exchange of information about me between my GP and the research team. ☐

7. I understand that if I lose the capacity to decide about my healthcare changes during the trial, ☐

   I will not be asked to undertake any further trial activity, however routinely collected information relevant to the trial may be collected.

8. I agree to take part in the above trial. ☐

Optional:

9. I have been offered the opportunity to take part in the trials activity monitor sub study. I have been provided with information and understand what this entails. I agree to take part in the sub study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes

PrEPS: Consent Form V4.0 1st July 2021 IRAS: 265113, REC 19/YH/0317