Trial number: ☐☐☐☐

CONFIDENTIAL WHEN COMPLETE

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

CALIBRE

RANDOMISATION FORM

PARTICIPANT DETAILS

Participant's DoB: D D / M M M / Y Y Y Y

		Not available
NHS Number (**Only for England & Wales**):	☐☐☐☐☐☐☐☐☐☐	☐
CHI Number (**Only for Scotland**):	☐☐☐☐☐☐☐☐☐☐	☐
H&C Number (**Only for Northern Ireland**):	☐☐☐☐☐☐☐☐☐☐	☐
Participant's Post code:	☐☐☐☐☐☐☐☐	☐

Initials: ☐☐☐☐ Sex: Male ☐ Female ☐

SITE DETAILS

Name of PI:	Site:
……	……

ELIGIBILITY CHECKLIST

*If the answer to questions 1 <u>or</u> 2 is **'NO'** the patient is **NOT** eligible to be randomised into CALIBRE*

1. Does the participant have liver cirrhosis as defined clinically, radiologically, with transient elastography (where liver stiffness in the clinician's opinion supports a diagnosis of cirrhosis) or on histology?
2. Does the participant have medium and/ or large varices that have never bled as defined in the BSG guidelines?

*If the answer to <u>any</u> of questions 3 to 10 is **'YES'** the patient is **NOT** eligible to be randomised into CALIBRE*

3. Is the patient's age < 18 years?
4. Is the patient a pregnant or lactating women?
5. Does the participant have a known intolerance or contraindications to beta-blockers including asthma?
6. Is the participant already on or has a past history of non-selective beta blocker use (such as carvedilol, nadolol or propranolol?)
7. Does the participant have a current or past history of variceal band ligation?

8. Does the participant have a malignancy or systemic disease that significantly affects 1 year survival?
9. Is the participant unable to give informed consent?
10. Does the participant have acute alcoholic hepatitis at the point of randomisation?
11. Has the participant had surgical or radiological porto-systemic shunts such as transjugular portosystemic stent-shunt (TIPSS)?
12. Has the participant had an organ transplant?

Is the patient eligible to be randomised into CALIBRE? **No** ☐ **Yes** ☐

Eligibility confirmed by (this must be a medically qualified doctor):

……

OTHER INFORMATION

Does the participant have hepatic decompensation?	No ☐	Yes ☐
Does the participant have alcohol-related liver disease?	No ☐	Yes ☐
What is the size of the largest varix?	Grade II ☐	Grade III ☐

CONSENT DETAILS

Has the participant given informed consent to be randomised into CALIBRE? No ☐ Yes ☐

Version of consent form used: ☐.☐ Date consent taken: D D / M M M / Y Y Y Y

TREATMENT ALLOCATION

Online randomisation: www.trials.bham.ac.uk/calibre (24 hours)

Telephone randomisation: 0800 953 0274 (UK toll free), 9AM to 5PM Monday – Friday (excluding Public Holidays and University of Birmingham closed days)

Treatment allocation: Variceal band ligation ☐ Carvedilol 12.5 mg od ☐

Trial number: ☐☐☐☐

Randomisation Form completed by:

You **must** have signed the CALIBRE site training log and CALIBRE delegation log

Name: …….. **(please print)**

Date: D D / M M M / Y Y Y Y **Signature:** ……..