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| **IMPORTANT: Current UK Data Protection Regulations**In providing this information you agree for your contact details to be retained on a database maintained by the Birmingham Clinical Trials Unit (BCTU). From time to time we may contact you in order to update you about our clinical trials, or to invite you to relevant trials meetings. We would be grateful if you would take the time to complete the following consent statements relating to the storage and handling of your contact details: **Please indicate whether you give consent:** |
| · For your contact details to be passed on to academic third parties | No | Yes |
| · For your contact details to be passed on to commercial third parties | No | Yes |
| Under the current UK Data Protection Regulations, the University of Birmingham must make any records pertaining to you available upon written request.  To do so please contact Legal Services, University of Birmingham, Edgbaston, Birmingham, B15 2TT.  A small charge may be made. Your details will be kept indefinitely.  Your records are regularly reviewed and updated.  If you find any of your details are incorrect, please contact the **CALIBRE**Trial Manager at the BCTU. |

**For new centres wishing to participate in the CALIBRETrial**

The lead local researcher for a multi-centre Trial is the local **Principal Investigator**. This role carries certain responsibilities:

day-to-day responsibility for the conduct of the research,

responsibility for ensuring the agreed protocol is followed

helping care professionals ensure participants receive appropriate care while involved in the research

the integrity of records and ensuring they are kept confidential

reporting adverse reactions.

All research sites require approval from the Trust/ Health Board Management that the research may take place. No patients can be approached for consent until all approvals are in place.

 *The* ***CALIBRE*** *Trial Office can assist in the approval process if the following information is provided. The Trial Office will complete the necessary paperwork and return to the PI for signature and submission.*

 · It is the role of the Trust/ Health Board/ Health Board to assess whether the local PI has the necessary training and experience to undertake the research described in the proposal.

· The Trust/ Health Board will want to have some indication of relevant recent research experience and current research commitment. This is usually a recent certificate of attendance at a good Clinical Practice (GCP) course.

· The Trust/ Health Board needs to know other members of the research team who will have a significant research role (eg. staff who will consent patients, research nurses). Do not give names of individuals whose involvement is part of their normal service duties.

· All researchers should comply with the requirements of the Research Governance Framework for Health and Social Care. This document can be found at: [www.doh.gov.uk/research](http://www.doh.gov.uk/research/index.htm)

· The Trust/ Health Board will also wish to be reassured that the PI has time to undertake the proposed project and sufficient time to supervise any other staff involved in the project.

· The Trust/ Health Board will want reassurance that the person taking consent locally is appropriate for the task, by being aware of the nature of that process and familiar with “best practice” and that this person should have sufficient time and expertise to answer all questions that might be raised by the trial participants.

· The Trust/ Health Board will want to see the participant information sheet and Trial consent form on Trust/ Health Board headed paper. If you can send us a blank sheet, we will print off a batch of forms for you.

· Your local PALS office (or equivalent) will serve as a source of independent advice for participants.

· The Trust/ Health Board will also want to know whether there will be any local deviations from the protocol, how are participants identified for the Trial and who makes the first approach. This form will help the **CALIBRE**Trial Office work the protocol around your local practice.

**CALIBRE Site Practical Arrangements Form**

## **PRINCIPAL INVESTIGATOR**

Name: …………………………………………………………………………………………

Position: …………………………………………………………………………………………

NHS Trust/ Health Board Employer: …………………………………………………………………………………………

Address:

……………………………………………………………………………………………………………………………………

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Telephone: Fax:

 Email:

Do you hold a current substantive or honorary contract with the NHS organisation or accepted by the NHS organisation? (circle answer)

 Yes No

Please provide a **current,** **signed, CV** for the PI

## **Contacts for Heads of Department**

We need contact details for heads of the appropriate service departments. They are required to authorise the SSI application prior to R&D approval. Please discuss the Trial with them soon.

Consultant Gastroenterologist or Hepatologist:

Email: Telephone:

**CALIBRE Trials Office Contact**

Please give a contact name for the administration of the trial at your site. This may be a Trial Co-ordinator, Research Nurse or administrative person who will form the first point of contact with the**CALIBRE**Trial Office

Name:

Role:

Email: Telephone:

**CALIBRE Site Practical Arrangements Form**

Questions to address interest in clinical question and trial design

 Do you currently and/or in the near future have any *competitive* clinical trials in the same patient population?

 Yes No

If yes, can you give the name of these trials?

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Are you in receipt of, or intend to apply for, funding for Research Nurse support for CALIBRE?

 Yes No

Questions to assess if recruitment is achievable

Please estimate the number of new cases of patients with medium or larger varices that have not bled in your institution in a year?

 How many patients with varices ***that fulfil the eligibility criteria*** would you to expect to ***see*** per year?

 How many of these patients with varices that fulfil the eligibility criteria, would you expect to ***enrol*** into the trial per year?

 ≤3 4-8 9-12 12-18 >18

### Experience of Principal Investigator in Clinical Trials

Does the proposed PI have a regular weekly variceal banding list in their job plan?

Yes No

Has the proposed PI been a PI, or is a PI for any other trials?

Yes No

 Do you have current GCP training?

 Yes No

Questions to assess trial role of site

 Which trial functions will your site perform? (tick all that apply)

 Randomising Patients Treating Patients

 Following up Patients Referring Patients

 If your site is referring patients, will this be outside your Trust/ Health Board? Yes No

Can you please confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services?

  Yes No

**Recruitment of non-English speakers**

Use of relatives to translate is discouraged.

What services are available at your centre?

Member of staff with shared language Language line

PALS Professional translator

## **Endoscopy/Clinics**

Please describe the patient pathway you envisage for **CALIBRE**trial participants, including average waiting times for relevant stages:

1. Does your pathway allow patients randomised to variceal band ligation access to endoscopic treatment and follow up as recommended in the BSG Guidelines (Tripathi D, et al. U.K. guidelines on the management of variceal haemorrhage in cirrhotic patients. Gut. 2015 Nov;64(11):1680-704. doi: 10.1136/gutjnl-2015-309262)?

Yes No

1. Would you be willing to see patients who have been randomised to the carvedilol arm two weeks after the start of treatment?

Yes No

1. Does the pathway allow all patients in CALIBRE access to clinic follow-up with a frequency no more than six monthly?

Yes No

Are there any issues you foresee in the **CALIBRE** trial? Do you have any questions?

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**CALIBRE Site Practical Arrangements Form**

## **Checklist**

Completed Practical Arrangement Form Yes No

PI CV Yes No To follow

CV of other investigator Yes No To follow

**Please return all the forms to the CALIBRE Trial Office:**

**calibretrial@trials.bham.ac.uk** **or**

**CALIBRE Trial Office**

**Birmingham Clinical Trials Unit**

**Institute of Applied Health Research**

**College of Medical and Dental Sciences**

**Public Health Building**

**University of Birmingham**

**Edgbaston**

**Birmingham**

**B15 2TT**

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***Thank you***