**Informed Consent Form**

**Carvedilol versus variceal band ligation in primary prevention of variceal bleeding in liver cirrhosis - CALIBRE**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Site name: ……………………………………………** | | **Principal Investigator:……………………………………** | | | | **Participant Trial Number:** ii I ii I ii I ii | | | **Please initial each box to confirm consent ↓** | | | **1.** | I confirm that I have read and understood the information sheet, version number \_\_ \_\_ for the **CALIBRE 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, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used. | | |  | | **3.** | I understand that relevant sections of my medical notes and information collected during the study may be looked at by individuals from the **CALIBRE Study** Research Team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust/ Health Board, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records. | | |  | | **4.** | I agree to my GP being informed of my participation in this study and that they may be contacted by members of the research team for follow-up information. | | |  | | **5.** | Information collected that identifies me by name, e.g. consent forms as well as contact address and email, will be transferred from where it is collected and stored at the University of Birmingham during the trial and at a specialist archiving facility, in compliance with current regulations, after the trial. I agree to the transfer and storage of this information. | | |  | | **6.** | To permit the accurate follow-up of all participants it may be necessary for the **CALIBRE Study** Research Team to contact other UK NHS bodies to provide information about your health status. I hereby give consent for the use of information held and maintained by e.g. the Health and Social Care Information Centre and other central UK NHS bodies to contact participants or provide information about their health status by using my NHS number/ Community Health Index (CHI) or Health & Care number (H&C). | | |  | | **7.** | I agree to take part in the **CALIBRE Study**. | | |  | | ***To continue participating in the CALIBRE Study you MUST consent to points 1-7 above and initial the corresponding boxes.***  ***A witness is mandatory for remote consent.*** | | | | | |  | | | | | | | | |  |
| Name of participant:  **………………………………………** | Date:  **………………………………………** | Signature:  **………………………………………** |
| Name of person taking consent:  **………………………………………** | Date:  **………………………………………** | Signature:  **………………………………………** |
| Name of witness:  **………………………………………** | Date:  **………………………………………** | Signature:  **………………………………………** |

***Original to be filed in the Investigator’s Site File; 1 copy for participant; 1 copy to be kept with patient’s hospital record; 1 copy to be sent to BCTU***