Beta-blockers Or Placebo for Primary Prophylaxis of oesophageal varices (**BOPPP Trial**).

**Informed Consent Form – Trial**

**Site Name:** ……………………………… **Principal Investigator:** ………………………………

**P**

Participant Identification Number (PIN):

***Please insert your initials in each box to confirm consent* ↓**

1. I confirm that I have read and understood the Participant Information Sheet, v3.0, 31 MAY 2023, for the **BOPPP Trial.** I have had the opportunity to think about it and to ask questions; I’m happy with the answers to any questions I asked.
2. I understand that I don’t need to take part and can withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. If I do withdraw, I understand that data collected up to that point may still 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 **BOPPP Trial** Team and representatives of the sponsor, of the regulatory authorities, of the NHS Trust/ Health Board, or of any other third parties 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 and other relevant healthcare professionals involved in my care 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. To permit the accurate follow-up of all participants it may be necessary for the **BOPPP Trial** team to contact other UK NHS bodies to provide information about your health status. I give consent for my name, NHS number and date of birth to be shared with NHS Digital. This allows the research team to access data on treatments I have received in hospital from the NHS (Health Episode Statistics) and death records held by the Office of National Statistics.
6. I agree to take part in the **BOPPP Trial**.

***To continue participating in the BOPPP Study you MUST consent to points 1-4 and 6 above and initial the corresponding boxes.***

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| --- | --- | --- |
| Name of participant  ………………………………………………….. | Date  …………………………………………………. | Signature  …………………………………………………. |
| Name of person taking consent  (if not PI)  ………………………………………………….. | Date  …………………………………………………. | Signature  ……………………………………………….. |
| Name of Principal Investigator  ………………………………………………….. | Date  ………………………………………………….. | Signature  ……………………………………………….. |

Original to be filled in the Investigator Site File

One copy for the participant

One copy for the patients’ hospital record

**Funders Disclaimer -** The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care