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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, v1.4, 08 SEPT 2020, for the **BOPPP Trial.** 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 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, representatives of the sponsor, from regulatory authorities, or from the NHS Trust/ Health Board, or 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. 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 King’s College Hospital 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 **BOPPP Trial** Team to contact other UK NHS bodies to provide information about your health status. I give consent for my NHS number and date of birth to be shared with NHS Digital (or corresponding agencies in Wales, Scotland and Northern Ireland) in order for 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.
7. I agree to take part in the **BOPPP Trial**.

***To continue participating in the BOPPP Study you MUST consent to points 1-5 and 7 above and initial the corresponding boxes.***

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