**MAIN TRIAL: Aspirin vs Aspirin + Metformin**

**COLO-PREVENT: A platform for developing COLOrectal cancer PREVENTion therapies**

**Chief Investigator:** Professor Anne Thomas (sponsor ref: 0834)

# CONSENT FORM

Centre ID: ☐☐ Participant ID: ☐☐☐

Please **initial** box

1. I confirm that I have read and understood the Patient Information Sheet **version 2.0 dated 06 June 2022** for the above 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, without my medical care or legal rights being affected. ☐
3. I understand that if I withdraw from the trial for any reason, my data and samples collected up to that point will still be used in the trial. ☐
4. I understand that relevant sections of my medical notes, GP records and/or trial data may be looked at by responsible individuals from the trial team, the Sponsor, the Leicester Clinical Trials Unit (LCTU), NHS Trust Host Organisation, GP Practice, or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records. ☐
5. I agree for my pseudonymised (coded) samples and pseudonymised (coded) data to be used, by the University of Leicester, academic and industry partners. This may involve samples and data being sent to other centres, both inside and outside the UK and the EU. ☐
6. I agree that my pseudonymised (coded) samples and/or trial data may be shared with our research collaborators in other academic institutions and industry partners for future research. *A copy of this consent form may be shared with the custodians of those samples as evidence of my consent.* ☐
7. I agree to undergo the tests and investigations as described in the participant information sheet. The nature of the tests and investigations and any possible risks have been explained to me. [If my safety bloods at visit 1 are not within the trial's requirements, I understand that this consent will be void (invalidated) and I will not progress onto the trial] ☐
8. I agree to my GP or any doctor treating me to be informed that I am taking part in this trial. ☐
9. I agree to take part in the above trial. ☐

***This is a double-sided document. Please turn over to sign and for additional section***

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## Optional section:

| | Please indicate **initial** box Yes | No |
|---|---|---|
| 10. I agree to the collection of rectal biopsies during my surveillance colonoscopy for the purposes of polyp research as part of this trial. | ☐ | ☐ |
| 11. I agree to my contact details being stored on a secure database by the University of Leicester (and the Leicester Clinical Trials Unit) for the purpose of contacting me about future research. | ☐ | ☐ |
| 12. I agree for the research team to obtain information about my health status for up to 10 years after the end of the trial, from routinely collected healthcare data held and maintained by the Bowel Cancer Screening System (BCSS), National Cancer Registration and Analysis Service (NCRAS) and other organisations. I understand my NHS number, date of birth, gender and ethnicity will be kept for this purpose and that if I agree to this, my research samples will be linked to my health data for up to 10 years after the end of this trial. | ☐ | ☐ |

| _____ | _____ | _____ |
|---|---|---|
| **Name of Patient** | **Date** (dd/mm/yyyy) | **Signature** |
| _____ | _____ | _____ |
| **Name of Person obtaining consent** | **Date** (dd/mm/yyyy) | **Signature** |

*Original to be kept for Investigator Site File. 2 copies: 1 for participant; 1 for medical notes*