MAIN TRIAL: Aspirin vs Aspirin + Metformin

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

Chief Investigator: Dr Ajay Verma (sponsor ref: 0834)

CONSENT FORM

Participant ID: | 1 | 1 | - | | | - | | | |

Please **initial** box

1. I confirm that I have read and understood the Patient Information Sheet **version 3.0 dated 31 August 2023** 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 coded research data including any samples to be used, by the University of Leicester, other researchers, organisations, collaborators and commercial partners, both inside and outside of the UK for analysis related to this trial. ☐

6. I agree to my GP or any doctor treating me to be informed that I am taking part in this trial. ☐

7. I agree to take part in the above trial. ☐

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

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Optional section:

	Please indicate **initial** box Yes	No
8. I agree to the collection of rectal biopsies during my surveillance colonoscopy for the purposes of polyp research as part of this trial.	☐	☐
9. I agree that my coded research data including any samples can be stored and used for future ethically approved research by the University of Leicester. *NB. where samples are transferred to a research tissue bank, we will also retain/supply a copy of your signed consent form to the custodian of the samples*	☐	☐
10. I agree that my coded research data including any samples can be shared with other researchers, organisations, collaborators and commercial partners, both inside and outside of the UK for the purpose of future ethically approved research. *NB. where samples are transferred to another organisation or individual, we will also retain/supply a copy of your signed consent form to the custodian of the samples*	☐	☐
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