**A new relief inhaler for mild Asthma: The RELIEF Trial**

**Informed Consent Form**

**Final Version 1.3 07-Aug-2024**

**IRAS Project ID: 1006098**

**Name of Principal Investigator**:

**Participant Trial ID:**

**Please enter date of completion:**

D

D

M

M

M

Y

Y

Y

Y

D

(To be completed before randomisation)

|  |  |
| --- | --- |
|  | **Please initial box** |
|  | I confirm that I have read and understood the Participant Information Sheet, Version <insert current PIS version A or B, number, and date > for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
|  | 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 should I withdraw, then the information collected up to that point cannot be deleted and that this information may still be used in the trial analysis. |  |
|  | I understand that relevant sections of my medical notes and data collected during the trial may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (University of Nottingham), the Sponsor (University of Nottingham), NHS bodies, the trial research team and regulatory authorities where it is relevant to my taking part in this trial. I give permission for these individuals to have access to these records, to collect, store, analyse and publish information obtained from my participation in this trial and for a copy of this signed consent form to be sent to the Nottingham Clinical Trials Unit. I understand that my personal details will be kept confidential. |  |
|  | I consent for my GP practice clinical trial team to collect information about my asthma attacks and their treatment from my GP records for the duration of the trial |  |
|  | I agree to take part in the above trial. |  |

|  |  |
| --- | --- |
|  | **Please initial either box** |
|  | **Optional**  | **Yes** | **No** |
|  | I agree to be contacted about study interviews and be provided with more information to help me to decide if I would like to be involved.  |  |  |
|  | I agree for my contact details to be kept so that I can be informed in writing, including email, about relevant future research related to this area of research. I understand that there is no obligation, and I will just be informed of what the future research will involve.  |  |  |
|  | I would like to receive a summary of the results at the end of the trial and agree for my contact details to be retained and used for this purpose. |  |  |
|  | I understand that my name and telephone number will be held by Esendex (text messaging provider) and their subprocessors and will be used to contact me about trial follow-up by text message only. I give permission for this information to be retained by Esendex, even if I withdraw from the trial, for two years or until the end of the trial (whichever occurs first).  |  |  |

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Name of Participant Date Signature

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Name of person taking consent Date Signature

(You must be on the delegation log)

*Original signed ICF to be kept securely on the trial database and/or in a separate folder to the Investigator Site File. 3 copies: 1 for participant, 1 for the medical notes and 1 to be provided to the Nottingham Clinical Trials Unit.*