Guideline number	**51.002A**	Version	**1.0**
Title	**Participant Information Sheet and Informed Consent Form Guidelines**		

Study Title:			
Sponsor(s):		**R&I Ref:**	
Chief Investigator:		**IRAS No:**	

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	Included:			Comments
	Yes	**No**	**N/A**	
Section 1: **General Information, Language and Formatting**				
Study title and Sponsor(s) logos	☐	☐		
Consistent versions of the PIS/ICF (starting on V1.0)	☐	☐		
Appropriate header & footer information	☐	☐		
PIS/ICF to include page numbering as X of Y format (e.g. 1 of 2)	☐	☐		
Consistent formatting, font and text size	☐	☐		
Sponsor, Funder and REC to be named (state that favourable opinion from REC has been obtained)	☐	☐		
Use language which is as non-technical as practical and understandable to the participant population *No language should be used that causes, or appears to cause the participant or their representative to waive any rights or release the NHSGGC or the investigator from liability*	☐	☐		
State the participant or legally acceptable representative will be asked to sign a consent form and will receive a copy of the signed and dated written informed consent form and any other written information provided to the participants	☐	☐	☐	
Section 2: **The Research**				
State the study involves research	☐	☐	☐	
State the purpose of the research	☐	☐	☐	
Include why the participant is being invited to take part in the study	☐	☐	☐	
Describe the study treatment(s) and interventions including IMPs & NIMPS	☐	☐	☐	
Licensing status of treatments or devices in UK/EU etc. in relation to study use	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Describe the study procedures to be followed, including all invasive procedures, number/duration of visits, types of visit (e.g. telephone, face-to-face) and potential for additional/unplanned visits	☐	☐	☐	
The participant's responsibilities e.g. fasting, wearing appropriate clothing, questionnaires, diaries etc.	☐	☐	☐	
Explain clearly what is research only and what is standard of care	☐	☐	☐	
The reasonably foreseeable risks or inconveniences to the participant covering all interventions e.g. CT scan, exercise test, contrast agent, samples etc.	☐	☐	☐	
The reasonably expected benefits, or generic statement if none	☐	☐	☐	
The alternative procedure(s) or treatment that may be available to the participant if they decide not to take part in the study	☐	☐	☐	
The compensation and/or treatment available to the participant in the event of trial-related injury and who to contact *Including the normal National Health Service complaints mechanisms are available if you wish to complain or have any concerns (Tel: 0141 201 4500, Email: ggc.complaints@nhs.scot).*	☐	☐		
The anticipated expenses or other payments the participant will, if any, for taking part in the study	☐	☐	☐	
State participation in study is voluntary and that they may decline to participate in, or withdraw from, the trial at any time without this affecting their current or future care	☐	☐		
State whether the participant has the option to withdraw from treatment or intervention but still remain in the study and if any data will still be collected e.g. long term health status *If CTIMP, state the law does require that any side effects the participant may suffer are documented and reported*	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study	☐	☐	☐	
The person(s) to contact for further information regarding the trial and the rights of trial participants	☐	☐	☐	
The foreseeable circumstances and/or reasons under which participation in the trial may be terminated	☐	☐	☐	
The expected duration of the participant's participation in the study	☐	☐	☐	
The approximate number of participants involved in the study	☐	☐	☐	
Contain information on any planned procedures for follow-up after the end of the trial including record linkage and/or plans for additional care that might be needed as a result	☐	☐	☐	
Section 3: **Samples & Analysis N/A** ☐				
State that biological samples may be collected, processed and reported as necessary for the purposes of the study	☐	☐	☐	
State if samples will be retained for future use/analysis, the name of organisation and location of the organisation that will retain the samples, how long for and who the samples and results may be shared with	☐	☐	☐	
State procedure for handling any retained identifiable samples and any plans to anonymise or destroy samples after analysis	☐	☐	☐	
The participant is informed that samples may be used in future research the limitation of this should be included e.g. within the disease area of the study. *State if use for future research is optional*	☐	☐	☐	
Explain participant's rights to withdraw their consent to use/storage of their samples (as long as the link to participant's identity is unbroken)	☐	☐	☐	
Explain if any genomic data will be obtained from the samples	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Section 4: **Data Privacy, Storage and Transfer**				
State whether personal identifiable data will be recorded *e.g. Name, address, phone number, email address, date of birth, NHS or CHI number etc.*	☐	☐	☐	*List this data if applicable:*
State how the study data will be coded to protect the identity of the participant	☐	☐	☐	
State each organisation/location(s) at which data and/or database(s) may be held and how long for	☐	☐	☐	
State if the consent form will be uploaded to a study database, and if so, organisation/location at which this will be held	☐	☐	☐	
State what happens to the participant's data should they withdraw from the study *Use HRA transparent wording: GDPR transparency wording for all sponsors - Health Research Authority with link to NHSGGC privacy policy: Data Protection & Privacy - NHSGGC*	☐	☐		
State any data that will be collected and transferred to a third-party, and whether these will be pseudonymised or include identifiable information. *The third-party organisations should be named and include data that will be shared after the end of the trial, and who will oversee this process*	☐	☐	☐	
State whether the participant has the option to withdraw from treatment or intervention but still remain in the study and if any data will still be collected e.g. long term health status *If CTIMP, state the law does require that any side effects the participant may suffer are documented and reported*	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Possible use of the participant's coded data for future research into their medical condition, or other specific medical conditions, unless the participant objects	☐	☐	☐	
State if record linkage will be carried out and that this will involve transfer of identifiable data to the organisations who hold the NHS datasets e.g. NHS Digital / Public Health Scotland	☐	☐	☐	
State in PIS/ICF who will have access to the participant's original medical records for what purpose and how this will be kept confidential *e.g. monitor(s), auditor(s), sponsor representatives, and the regulatory authority (ies) will have access to medical records/study data to ensure the trial is being carried out to appropriate standards. These groups have a duty of confidentiality and any information leaving the Board/Trust would be anonymised so that participants cannot be identified UNLESS consent for specific information in this category is requested*	☐	☐	☐	
That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study	☐	☐	☐	
The person(s) to contact for further information regarding the trial and the rights of trial participants	☐	☐		
Section 5: **Blinding & related processes N/A** ☐				
Description of trial design e.g. Open-label, double-blind	☐	☐	☐	
Description of how treatment or intervention is assigned and a description of randomisation process if required	☐	☐	☐	
The probability for random assignment to each treatment or intervention (e.g. 1:1)	☐	☐	☐	
Description of placebo	☐	☐	☐	
Availability of emergency unblinding including who can unblind	☐	☐	☐	
Use of a patient alert card	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Section 6: **Investigational Medicinal Product: Safe use of medicines N/A** ☐				
What medicines participants will be supplied with and how/when	☐	☐	☐	
How to correctly store medicine and reminder to keep out of the reach and sight of children	☐	☐	☐	
Requirement (or otherwise) to continue with usual medicines	☐	☐	☐	
Potential for usual medicines or dose of usual medicine to change as a result of trial participation	☐	☐	☐	
Detailed instructions of how medicine is administered including: Route of administration Who will administer and where How administered eg. Swallow whole with water Time of day eg. Morning Dosing in relation to meals Potential for dose changes Post-administration observation time Any other sources of information participant should be made aware of Any issues that participants may find unpleasant eg. palatability of IMP, size of oral tablet/capsule	☐	☐	☐	
Restrictions (medicine related) *For example:* *Driving/operating machinery and decision making* *Lifestyle restrictions eg. exposure to sunlight*	☐	☐	☐	
Drug – Drug Interactions (Those that are expected/clinically significant including COVID-19)	☐	☐	☐	
Vaccination: Restrictions and timing including for COVID-19 vaccinations	☐	☐	☐	
Drug – Food Interactions	☐	☐	☐	
Informing research staff when starting new medicines/vitamins/herbal preparations	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
Requirement to bring study medicines to each visit/return at the end of the study	☐	☐	☐	
Missed dose advice	☐	☐	☐	
Sick day rules/vomiting	☐	☐	☐	
Reminder to inform other healthcare professionals/carry alert card they are taking part in a clinical trial	☐	☐	☐	
Intention to inform the GP of participant's involvement in a study.	☐	☐	☐	
Section 7: **IMP Related Adverse Effects N/A** ☐				
Statement on known/unknown side effects	☐	☐	☐	
Statement that not all participants may experience side effects and general advice on how to report to the study team.	☐	☐	☐	
List of adverse effects and frequency (expressed as per SmPC requirements e.g. very common >1/10 etc.) *At a minimum all very common and common side effects should be listed and other adverse effects which are serious in nature.*	☐	☐	☐	
Detailed statements on any signs/symptoms the participant should be alert for and/or monitoring requirements particularly for those side effects which are serious in nature. *Include advice given on urgency and how to obtain appropriate help should the adverse effect occur.*	☐	☐	☐	
IMP: withdrawal of study medicine and exit strategy	☐	☐	☐	
When IMP might reasonably be expected to be withdrawn	☐	☐	☐	
Exit strategy and IMP availability post study	☐	☐	☐	
Advice on stopping medicines including warnings should participant wish to stop medicine	☐	☐	☐	

Section 8: **Pregnancy & Contraception N/A** ☐				
Inclusion of women who are pregnant, planning pregnancy or breastfeeding	☐	☐	☐	
Inclusion of Women of Childbearing Potential (WoCBP)	☐	☐	☐	
For WoCBP: Acceptable forms of contraception and minimum duration of contraception use after last exposure to IMPs	☐	☐	☐	
For men: Acceptable forms of contraception and minimum duration of contraception after last exposure to IMPs	☐	☐	☐	
For participant's partners: Acceptable forms of contraception and minimum duration of contraception after last exposure to IMPs	☐	☐	☐	
Requirement for appropriate contraception to be practiced prior to study consent/IMP exposure	☐	☐	☐	
Information on potential risks to unborn child if exposed to the IMP/NIMP	☐	☐	☐	
Requirement for pregnancy testing for WoCBP (inclusion and study visits)	☐	☐	☐	
PV statement included on follow-up of any pregnancies	☐	☐	☐	
Include contact details for the sponsor of the trial	☐	☐	☐	
Section 9: **Consent Form**				
Trial name and PI name clearly documented	☐	☐	☐	
Clear instructions to initial each box, including all optional boxes	☐	☐	☐	
Statement to confirm the Participant has understood the PIS with space for PIS version and date	☐	☐	☐	
Statement to confirm the participant is free to withdraw at any point, with no impact on their medical care	☐	☐	☐	
Statement regarding who will review their medical notes/data (e.g. Sponsor representatives, auditors and MHRA representatives)	☐	☐	☐	
Statement to confirm where study data is held, whether identifiable data will be held, whether data will be transferred/shared and if data and samples will be used for future research	☐	☐	☐	

Statement that GP will be informed of participant's involvement in a study when applicable	☐	☐	☐	
Explicit consent for obtaining any genomic data from samples	☐	☐	☐	
That by signing the consent form, the participant agrees to take part in the study/trial	☐	☐	☐	
Make provision for the participant, or legally acceptable representative, and the person who obtained the informed consent discussion to sign and personally date or alternatively use another ethically approved process e.g. electronic means	☐	☐	☐	
Make provision to ensure there is always a place for Witness Consent e.g. **Witness statement** (for those mentally capable but physically unable to sign consent) I hereby confirm that _____was fully informed of the study as Name of patient (PRINT NAME) detailed in the Patient Information Sheet and that informed consent was freely given. _____ _____ _____ Witness (PRINT NAME) Date Signature _____ Designation / relation to participant	☐	☐	☐	
Make provision for the participant, or legally acceptable representative, and the person who obtained the informed consent discussion to sign and personally date or alternatively use another ethically approved process e.g. electronic means	☐	☐	☐	

Section 10: **Other PISs & ISFs N/A** ☐				
All necessary PISs and ISFs have been completed as per SOP 51.002 and are appropriate for population *e.g. Participants with Incapacity and Paediatrics*	☐	☐	☐	
If a separate assent form used, state if the participant is capable of forming an opinion, the participant can decide not to participate even if their parent(s) or legal representative have given consent	☐	☐	☐	
Any supplementary PIS/ICFs (e.g. Paediatric, Phase 1, Studies with GMOs) incorporate any specific elements or wording required by local regulations including how to obtain the research results, in an appropriate format	☐	☐	☐	

Guideline signatories

Prepared by Signature	Louise Ner Date
Approved by Signature	Melissa Robert Date

Document history

Version	Date	Description
1.0	30/06/2025	First Release