SUMMARY OF CHANGES TO THE NHG DSRB INFORMED CONSENT FORM TEMPLATE *(21 Nov 2025)*

The latest version of the NHG DSRB Informed Consent Form Template (Version 15, dated 21 Nov 2025) has been updated to:

- *Include recommended language to fulfil the three (3) new consent elements introduced under ICH-GCP E6(R3) Section 2.8.10(f), (p) and (v), which will be effective 01 Jan 2026 and applies to all Health Sciences Authority (HSA)-regulated clinical trials,*
- *Incorporate the expanded explanation of what constitutes "methods of payment" as mentioned in the consent element in ICH-GCP E6(R3) Section 1.2.9 after further clarification with HSA,*
- *Add negative statements to comply with the Human Biomedical Research Act (HBRA) requirements for specific consent elements where a negative statement is required to be included, and*
- *Make other administrative and wording refinements for consistency, readability, and alignment across all applicable research templates.*

Please refer to the table below for more details.

Page on ICF Template	**Section of ICF Template**	**Section Title**	**Change From**	**Change To**	**Explanation**
Page 2	1	Study Information	Nil	**[If Investigators intend to recruit cognitively-impaired persons, where consent from their legal representative will be documented using this consent document, please add the following paragraph] If you are giving consent as a Legal Representative on behalf of a person who is unable to provide consent for himself/herself, please note that the word "you" refers to the person participating in this study.**	Added explanatory text to the Legal Representative for studies that involve Cognitive Impaired Participants and require a Legal Representative to consent on behalf of the research participant who is cognitively impaired.
Page 4	3	What procedures will be followed in this study	We will deposit data collected in this study, including the data we collect about you to public and/or controlled-accessed scientific databases.	We will deposit data collected in this study, including the data we collect about you to public and/or controlled-**access** scientific databases.	To correct terminology used

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Page 8	9	Reproductive Risks to You and Your Partner(s)	Nil	**9. Reproductive Risks to You and Your Partner(s)** **[If there are reproductive risks or inconveniences to the participant and his/her partner(s), please include the following sample language below. You may delete or modify as necessary] The effect of *(the study drug/intervention/investigation)* on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry. If you and your partner(s) are able to become pregnant, one (1) or both of you must use some form of effective birth control during the study. Your doctor will discuss the birth control methods approved for the study and the period of time birth control will be needed.** **If you or your partner(s) become pregnant during this study, you must stop taking *(the study drug)* and inform your doctor or the Principal Investigator immediately.**	For alignment with ICH GCP E6(R3) consent element 2.8.10(f). Added statements for studies when there are reproductive risks to the participant's partner(s)
Page 8	10	Possible Benefits from Participating in the Study	If you participate in this trial you may reasonably expect to benefit from the trial (investigation / intervention / drug) in the following way: (explain how participant might benefit)	If you participate in this trial you may reasonably expect to benefit from the trial (investigation / intervention / drug) in the following way: (explain how **the** participant might benefit)	Standardised phrasing, grammar and formatting across the document

Page on ICF Template	Section of ICF Template	Section Title	Change From	Change To	Explanation
Page 9	10	Important Information for Women Participants	10. Important Information for Women Participants [Delete or modify as necessary] The effect of (the study drug/intervention/investigation) on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study. If you become pregnant during this study, you must stop taking (the study drug) and call your doctor or the Principal Investigator immediately.	Nil	Removed this section as it has been incorporated into Section 9 Reproductive Risks to You and Your Partner(s)
Page 9	12	Costs & Payments if Participating in the Study	Nil	**[If the participant has to pay for costs related to his/her standard of care, please add the following statement. Delete or modify as necessary]**	Added explanatory text to distinguish between the scenarios when the participant has to pay or not
Page 9	12	Costs & Payments if Participating in the Study	Nil	**[If the participant will not incur any expenses as a consequence of his/her participation in the study, please include the following negative statement.] You will not incur any anticipated expenses as a consequence of participating in this study.**	Added explanatory text and negative statement if there are no anticipated expenses for the participant, to align with HBRA requirement
Page 9	12	Costs & Payments if Participating in the Study	Nil	**[If the participant will receive reimbursements/payments, please add the following statement. Delete or modify as necessary]**	Added explanatory text to distinguish between the scenarios when the participant will receive reimbursements/payment or not

Page on ICF Template	Section of ICF Template	Section Title	Change From	Change To	Explanation
Page 9-10	12	Costs & Payments if Participating in the Study	You will be reimbursed for your time, inconvenience and transportation costs as follows: • If you complete the study, you will be paid (insert payment amount). • If you do not complete the study for any reason, you will be paid (insert payment amount) for each visit you complete.	**You will be reimbursed for your time, inconvenience and transportation costs as follows:** • **You will receive *(insert payment amount, payment method e.g. cash, vouchers, and payment mode e.g. electronic cash transfers via PayNow)* for each visit.** [Please specify the overall amount, schedule of payment(s) and pro-ration if the participant does not complete the study. If other details are required from the participant for the payment e.g. mobile number and bank account details, please include to inform the participant too.]	The ICH-GCP E6(R3) Section 1.2.9 also specify that the "methods, amounts, and schedule of payments to trial participants" should be indicated in the ICF. HSA clarified that both the form of payment and mode of disbursement should be indicated. Therefore the explanatory text has been enhanced to also include details on the payment method and any other information required for the payment to be processed.
Page 10	12	Costs & Payments if Participating in the Study	Nil	**[If NO reimbursements/payments will be given, please include the following negative statement] You will not receive any payments or reimbursements for taking part in this study.**	Added explanatory text and negative statement for studies where participants will not be reimbursed for their participation, to align with HBRA requirement
Page 10	13	Voluntary Participation	In the event of changes to the development of your capacity to make decisions [i.e. when you reach the age of 21 years old], you will be contacted for further consent.	In the event of changes to the development of your capacity to make decisions [i.e. when you reach the age of **twenty-one (**21**)** years old**]**, you will be contacted for further consent.	Standardised phrasing, grammar and formatting across the document
Page 10	14	Withdrawal From Study	• *(Obligation for participant to return all study-related supplies, including unused study drug).*	• *(Obligation for **the** participant to return all study-related supplies, including unused study drug).*	Standardised phrasing, grammar and formatting across the document

Page on ICF Template	Section of ICF Template	Section Title	Change From	Change To	Explanation
Page 10	14	Withdrawal From Study	Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons *(Delete and modify if necessary)*:	Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one **(1)** or more of the following reasons *(Delete and modify if necessary)*:	Standardised phrasing, grammar and formatting across the document
Page 12	16	Confidentiality of Study and Medical Records	Nil	**[Please insert this paragraph for FDA-regulated studies. Otherwise, delete] A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.** **[If the study may be registered on other publicly accessible and recognised databases, please add the following paragraph. Delete or modify as necessary] A description of this clinical trial will be available on *(insert website(s) e.g. https://clinicaltrials.sg)*, as required by local laws or regulations. This website(s) will not include information that can identify you.**	For alignment with ICH GCP E6(R3) consent element 2.8.10(p). Added explanatory text and statements for studies when the studies may be registered on publicly accessible and recognised databases Note: If Investigators/Sponsors decide to register the trial, they need to include it in the ICF and specify the website. There is no need for a negative statement.

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Page 12	16	Confidentiality of Study and Medical Records	Nil	**[If the Sponsor and/or Investigator determine that it is appropriate to provide participants with the study results and/or information on their actual treatment when this information is available from the Sponsor, the following statement may be added. Delete or modify as necessary] When *(name of sponsor)* makes the study results and information about your actual treatment available, your doctor and/or the Principal Investigator will be informed. You may request for a copy of this information from your doctor or the Principal Investigator if you would like to know.**	For alignment with ICH GCP E6(R3) consent element 2.8.10(v). Added explanatory text and statements for studies when participants have the choice to request for study results and information about their actual treatment when it is available. Note: Investigators/Sponsors need to assess if it is appropriate to share the trial results/information of the actual treatment with the participant. If yes, a statement should be included in the ICF to inform the participant. If no, there is no need to include this.

Reference: DSRB Templates for Study Documentation (https://ethics.gri.nhg.com.sg/dsrbtemplates/) > Informed Consent Form Template (English) > 207-001: Informed Consent Form Template