**INFORMED CONSENT ASSESSMENT FORM**

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| **DATE SUBMITTED** | Click or tap to enter a date. | **FIERC PROTOCOL CODE** | Click or tap here to enter text. |

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| **PROTOCOL TITLE** | Click or tap here to enter text. |

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| **PRINCIPAL INVESTIGATOR** | Click or tap here to enter text. | **INSTITUTION / DIVISION** | Click or tap here to enter text. |

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| **TYPE OF REVIEW** | **FULL REVIEW** | **EXPEDITED REVIEW** |

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| **INSTRUCTIONS**  **To the Principal Investigator:** | Please put 🗹 if the study protocol contains the specified assessment point and indicate page and paragraph number where it is found. |
| **To the Primary Reviewer:** | Please evaluate how the assessment points below have been properly addressed by the study protocol, as applicable by confirming the submitted information indicate your comments in the space provided. Specify your action to be taken under “RECOMMENDED ACTION” and your conclusion under “SUMMARY OF RECOMMENDATION”. Please sign the space provided for the primary reviewer. |

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| **INFORMED CONSENT REVIEW** |

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|  | **To be filled out by the PI** | | | | **To be filled out by the Primary Reviewer** |
| **ESSENTIAL ELEMENTS**  **(as applicable to the study)** | Indicate if the study protocol contains the specified assessment point | | | Page and paragraph where it is found | **REVIEWER COMMENTS** |
| 1. Statement that the study involves research *(UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement describing the purpose of the study (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Study-related treatments and probability for random assignments (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Study procedures including all invasive procedures *(UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Site-specific recruitment including appropriateness of identified recruiting parties *(NEGRIHP 2022, page 31 item 1.4 & UPM REB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Responsibilities of the participant (*UPM REB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Expected duration of participation in the study (*UPM REB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Approximate number of participants in the study (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator’s brochure *(UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Risk for allowable use of placebo (*if applicable) (UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Reasonably expected benefits; or absence of direct benefit to participants, as applicable *(UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Expected benefits to the community or to society, or contributions to scientific knowledge *(UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Description of post-study access to the study product or intervention that have been proven safe and effective (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Alternative procedures or treatment available to participant (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Anticipated **payment**, if any, to the participant in the course of the study, whether money or other forms of material goods, and if so, the kind and amount (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Compensation (or no plans of compensation) for the participant or the participant’s family or dependents in case of disability or death resulting from study-related injuries (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Anticipated **expenses,** if any, to the participant in the course of the study (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. **For research involving children and adolescents,** statement that consent will be obtained if the participant reaches legal age in the duration of the study, as applicable (*UPM REB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Applicable assent age brackets in children:   0-under 7: No assent  7-under 12: Verbal Assent  12-under15: Simplified Assent Form  15-under 18: Co-sign informed consent form with parents  *(NEGRIHP 2022, pages 141-142, Integrity of the*  *child and respect for autonomy & UPMREB*  *FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Applicable assent for non-legally consenting adult   *(NEGRIHP 2022, page 16 item 8 &*  *UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage *(NEGRIHP 2022, page 19 item 12.14 & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Possible direct or secondary use of participant’s medical records and biological specimens taken during clinical care or in the course of this study, as applicable. Plans for the destruction of collected biological specimens at the end of the designated storage period will be outlined. Alternatively, details regarding storage duration, facility type, location, access protocols, and potential future utilization will be provided. Participants retain the right to refuse future use, storage, or request the destruction of materials.   *(NEGRIHP 2022, page 19 item 12.15 and 12.16 & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement that the participant or participant’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation (*UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Foreseeable circumstances and reasons under which participation in the study may be terminated *(ICH GCP 4.8.10.r & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Sponsor, institutional affiliation of the investigators, and nature and sources of funds *(NEGRIHP 2022, page 19 item 12.12 & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider *(NEGRIHP 2022, page 20 item 12.18 & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Person(s) to contact in the study team for further information regarding the study, whom to contact in the event of study-related injury *(ICH GCP 4.8.10.q & & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Statement that the FNRI IERC has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:   **Name of FNRI IERC Chair / Head of Secretariat**  **Address:** Planning and Evaluation Unit, Food and Nutrition Research Institute, DOST Compound, Bicutan, Taguig City  **Email: fierc@fnri.dost.gov.ph**  *(NEGRIHP 2022, page 20 item 12.22. & UPMREB FORM 2(D) 2012, 28/05/2024)* | **YES** | **NO** | **N/A** |  |  |
| 1. Comprehensibility of language used *(NEGRIHP 2022, page 16 item 12 & UPMREB FORM 2(D) 2012, 28/05/2024 )* | **YES** | **NO** | **N/A** |  |  |
| **RECOMMENDED ACTION**  **APPROVE**  **MINOR REVISIONS REQUIRED**  **MAJOR REVISIONS REQUIRED**  **DISAPPROVED**   |  | | --- | | **SUMMARY OF RECOMMENDATIONS:**  **1.**  **2.**  **3.**  **4.**  **5.** |  |  | | --- | | **JUSTIFICATION FOR RECOMMENDED ACTION:** |  |  |  | | --- | --- | | **PRIMARY REVIEWER:**  Click or tap here to enter text.  **Signature over Printed Name** | Click or tap to enter a date.  **Date:** | | | | | | | |