**Study Specific Procedure**

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| **SSP Title:** | **eCRF COMPLETION GUIDELINES: INDIGO TRIAL** | | | |
| **SSP Number:** |  | Version and date: | 1.0 |  |
| **Category:** | Data Management | | | |
| **SCC/Protocol Number** | 25071 | | | |
| **Prepared by:** (Name and job title) | Yusupha Ceesay, Data Support Assistant | | | |
| **Signature and date\*** |  | | |  |
| **Reviewed by:** |  | | | |
| **Signature and date\*** |  | | |  |
| **Approved by:** (Name of Principal Investigator) |  | | | |
| **Signature and date\*** |  | | |  |
| **Date effective:** |  | | | |

\* to be hand-written

# Abbreviations, contractions and definitions

AE Adverse Event

CTU Clinical Trial Unit

DM Data Manager

DSA Data Support Assistant

fNIRS Function Near Infrared Spectroscopy

GCP Good Clinical Practice

HOME Home Observation Measure of the Environment

FC Field Coordinator

FS Field Supervisor

FA Field Assistant

GGMRC EC The Gambia Government/MRC Join Ethics Committee

ICD Informed Consent Document

INDiGO Improving infant Neurocognitive Development and Growth Outcomes with Micronutrients

IWC Infant welfare card

LSHTM London School of Hygiene and Tropical Medicine

JRC Junior Research Coordinator

MMN Multiple micronutrient

MoH Ministry of Health

MRCG MRC Unit The Gambia at LSHTM

N/A Not applicable

NC Nurse coordinator

NFA Nurse Field Assistant

PI Principal Investigator

RC Research Clinician

RM Research midwife

SI Sub-Investigator

SSP Study Specific Procedure

VA Village Assistant

WHO World Health Organisation

# Background

# Purpose and Scope

# Safety Precautions

# Equipment / Materials / Supplies / Reagents

# Responsible Persons

# Procedures

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| **Section** | **Description** | **Person(s) Responsible** |
|  | **CONSENT CRF** |  |
|  |  | FA |
|  | 3. Participant’s initial  Remarks: record participant initial as shown on the source document.  4.participant date of birth  Remarks: Record the date as recorded on the participant birth certificate, antenatal card, HDSS card/database, or other reliable documents as stated on ‘INDiGO\_SSP02\_InformedConsent\_v01\_Final’ or ‘INDiGO\_Clinical\_Trial\_Protocol\_v3.0\_250122’.  There are 2 digits for day (dd), 2 digits for month (mm), and 4 digits for year (yyyy). *Age of participant* will be auto calculated based on this question.  5. Date and time of consenting:  Remarks: Record the date as recorded on the signed ICD, and the time the consent is done by the trial staff.  6. was consent obtained  Remarks: Ask for the participants consent to participate in the study willingly. When she responds “No”, all other CRF will be disabled.  7. Language of consent  Remarks: Ask the participant the language she is most comfortable with, and consent in that language. If the consent is done in another language other than English, it must be done Infront of an impartial witness.  8.Was the consent done in the presence of, and to the satisfaction of, an impartial witness  Remarks: Ask the impartial witness if she is satisfied with the way the participant is consented, and if the participant fully understands the content of the consent to make informed decision.  11a. Source document (e.g. ID card, ANC card, and other source)  Remarks: with the study mobile device, take clear picture of the source document provided to you by the participant, and upload it.  12. Where is the participant from  Remarks: Ask the participant her village of residence and select ‘west kiang’ or ‘central kiang’ based on the cluster the village is located. |  |
| 7.1.2 | 13. Completed by  Remarks: This field is auto completed from the user login.  NOTE: leave “14. Verified by” empty for the supervisors or coordinators complete.  The FA/Data collector must save the form status as unverified. Once the supervisor or delegate verify the data, and complete “14. Verified by”, then He(s) should change the form status to complete before saving. |  |
| 7.1.3 | Tips for completion:   * This is completed one and it is first CRF completed for the participant, before enrolled into the tips. * All required field must be completed. * The “6.was consent obtained” must be yes before any other CRF is completed. |  |
| **7.2** | **ULTRASOUND SCAN** |  |
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| 7.2.1 | 2. Date of Scan  Remarks: This is date the ultrasound scan is performed on the study participant.  3.Pregnancy confirm by ultrasound scan  4. Cardiac activity  5. Type of gestation  Remarks: Confirm this by the visible feature from the ultrasound.  6a. CRL (mm)  Remarks: Enter the value returned by the Ultrasound scan machine. If the CRL is less than 10mm, the visit should be rescheduled to a more appropriate date.  16. Expected date of delivery (by scan)  Remarks: This is auto complete calculated date field. it is calculated based on the ‘1. Date of scan’, Gestational age- weeks, and Gestational age- days  17. Comments  Remarks: briefly describe anything that cannot be captured by other previous questions CRF. |  |
| 7.2.2 | 18. Completed by  Remarks: This field is auto completed from the user login.  NOTE: leave “20. Verified by” empty for the supervisors or coordinators complete.  The FA/Data collector must save the form status as unverified. Once the supervisor or delegate verify the data, and complete “20. Verified by”, then He(s) should change the form status to complete before saving.  19. Upload USS report  Remarks: take a picture of the ultrasound scan report on the ultrasound scan dashboard and upload the image.  20. Form verified by  Remarks: Supervisor selects the initial assigned to him/her on the dropdown menu, after verifying the accuracy and consistency of the data on the CRF; then change form status to complete before saving the CRF.    Please supply reason for data changes:  Remarks: After verifying, type “Verify CRF data” the successfully Save the CRF. |  |
| 7.3 | **Obstetric And Medical History** |  |
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|  | 1. ANC number   Remarks: Request the antenatal card from the participant to collect the ANC number.   1. Do you know the age at which you attain menarche   Options: Yes or No  Remarks: Confirm this by asking the participant. If the participant remembers, select ‘Yes’ and provide the age in years to question 2a. Provide age (years).   1. In total (including this current pregnancy) how many times did you get pregnant in your entire life regardless of the outcome of the participant.   Remarks: Confirm this by asking the participant and enter the integer value. If the value is more than 0, confirm question 4., 5., 6. By asking the participant, and enter the integer value. Question 7., and 8. Are auto calculated field base question 3., and 4., 5. Respectively.  9) If at least one livebirth or stillbirth, did you ever give birth by Caeserean.  Options: ‘Yes’ or ‘No’  Remarks: confirm this by asking the participant, provided the integer value for question 4., or 5. or both 4., and 5. is/are greater than 1.  10) Have you used contraception in the last year  Options: ‘yes’, ‘No’, or ‘I don’t want to disclose  Remarks: Confirm this by asking the participant. Inform the participant she is at liberty not to disclose if she doesn’t want to. If the participant responded ‘Yes’, select the appropriate option(s) by asking the participant. If the participant responds ‘No’ select the appropriate option for (11a) would you have used contraception if it were available) after asking the participant.  12) Have you ever been told by a doctor or other health worker that you have high blood pressure or hypertension  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant.  13) Have you ever been treated for worms  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant.  14) Have you ever been told by a doctor or other health worker that you have high blood sugar or diabetes  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant.  15) Have you ever been told by a doctor or other health worker that you have heart disease or a chronic heart condition  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant.  16) Have you ever had seizures unrelated to pregnancy/postpartum  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant.    17. Do you have any other medical condition diagnosed before pregnancy  Options: “Yes”, “No”, or “Don’t know”  Remarks: Selecting the appropriate option after asking the participant. If the participant responded “Yes”, provide appropriate detail after confirming question (17a. Please provide further detail) by asking the participant.  18. Is the participant currently on any medication that continues during pregnancy  Options: “Yes”, or “No”  Remarks: Confirm this by asking the participant. If “Yes” confirm the medications on (18a. Provide list of drugs) by asking the participant.    19. Does anyone in the participant’s immediate family suffer from diabetes and/or hypertension.  Options: “Yes” or “No”  Remarks: Confirm this by asking the participant. If participant responds “Yes”, provide response to (19a. Diabetes) and (19b. Hypertension).  19a. Diabetes  Options: “Parent”, “Sibling” or “None”  Remarks: Confirm this by asking the participant and choose the appropriate option.  19a. Hypertension  Options: “Parent”, “Sibling” or “None”  Remarks: Confirm this by asking the participant and choose the appropriate option.    20. Teenage pregnancy (check ‘Yes’ if the age of the participant is/was 13 to 19 years in current or previous pregnancies)  Option: “Yes” or “No” or “Unknown”  Remarks: confirm this by observing or asking the participant. If “Yes” confirm the age of the participant (between 13 to 19 years) by checking participant antenatal card, birth certificate, HDSS data or other source documents as mentioned on the protocol.  21. Elderly primigravida (>= 35 years) (if the participants’ age at first pregnancy was >= 35 years)  Option: “Yes” or “No” or “Unknown”  Remarks: confirm this by observing or asking the participant. If “Yes” confirm the age of the participant (>= 35 years) by checking participant antenatal card, birth certificate, HDSS data or other source documents as mentioned on the protocol.  22. Previous large-for gestational age (LGA) baby (>= 3.5kg)  Option: “Yes” or “No” or “Unknown”  Remarks: select the appropriate option by confirming the fetal weight from the ultrasound scan.  23. Previous small-for gestational age (SGA) baby (<2.5 kg)  Option: “Yes” or “No” or “Unknown”  Remarks: select the appropriate option by confirming the fetal weight from the ultrasound scan.  24. Previous twins  Option: “Yes” or “No” or “Unknown”  Remarks: Confirm this by asking the participant. |  |
|  | **Socioeconomic And Demographic** |  |
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|  | 1. What is your ethnicity?   Dropdown: “Mandinka”, “Wollof”,” Sarahule”, “Jola”, “Fula”, or “Other”  Remarks: Confirm this by asking the participant and choose the appropriate option. If the participant responds “Other”, complete (1a. Please specify your ethnicity) further asking the participant for the specific ethnicity.   1. What is your marital status   Dropdown: “Married”, “Single”, or “Unwilling to disclose”  Remarks: Confirm this by asking the participant and choose the appropriate option. If the participant responds “Married”, complete (2a. How many co-wives do you have) further asking the participant for the number of co-wives.  2b. How many members does the household have.  Remarks: Confirm this by asking the participant.   1. What is the primary construction material of the housing unit's exterior walls   Dropdown: “Reinforced concrete”, “Brick”,” Cement bricks”, or “Mud or earth bricks”  Remarks: Confirm this by asking the participant.   1. What is the primary fuel source your household uses for cooking   Dropdown: “gas fuel (methane from tank, biogas)”, or “wood-based (charcoal or firewood)”  Remarks: Confirm this by asking the participant.   1. What is the primary fuel source your household uses for lighting? |  |

# Appendix

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| **Appendix number** | **Title** (as referenced on the appendix) |
| Appendix 01 | Document Version History |
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# References

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| Protocol |
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# Attachments

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| **Attachment number** | **Title** (as referenced on the attachment) |
| Attachment 01 | List title of the attachment |
| Attachment 02 | List title of the attachment |
| Attachment 03 | List title of the attachment |

**Appendix 01 Document Version History**

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| --- | --- | --- | --- |
| **Version number** | **Change history** | **Author** | **Date** |
| *State Version* | *Provide brief account of the changes* | *Name of author* | *Same as implementation date* |