MRC Unit The Gambia

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Practical Strategies For Conducting Clinical Trials in The Gambia

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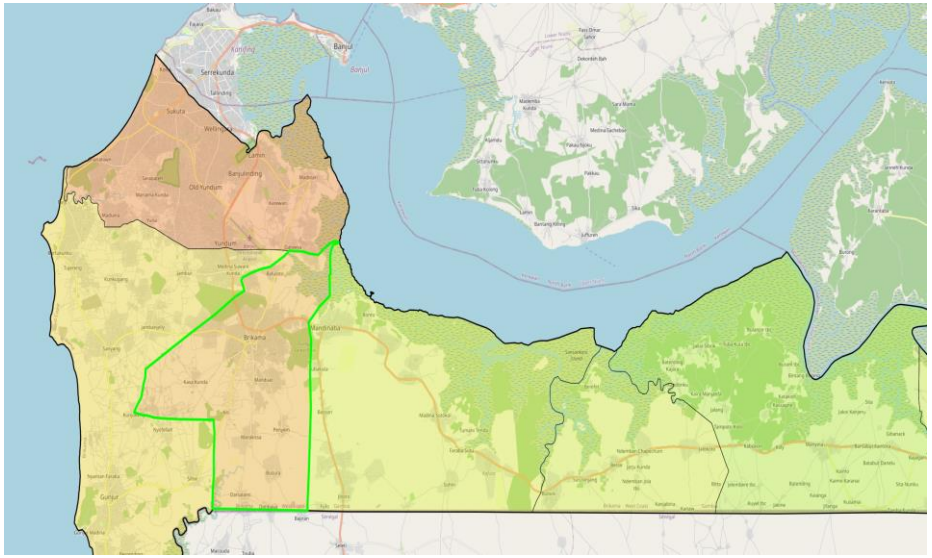
Background

- The MRC Gambia unit, has a 75-year history of operations in The Gambia
- Good relationship with the Ministry of Health and the Local communities.
- Currently 17 clinical trials are ongoing.
- Over the past 5 years, 29 clinical trials have been conducted across the country and within the subregion.

Background



- The Brikama Local Government area has a population of 688,000
- 9 districts
- Brikama is located in the kombo central district with a population of 140,000
- Sensitization and recruitment reach surrounding communities

https://www.citypopulation.de/en/gambia/admin/3__brikama/

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Brikama Trial Site

- The trial site is located within the premises of the Brikama district hospital.
- Site was opened in 2017.
- 5 clinical trials have been hosted at this site
    1. Pneumosil phase 3 trial
    2. Pneumosil 2+1 trial
    3. Men ACXWY phase 3 trial
    4. Novel Oral polio 2 phase 3 trial
    5. Serum Institute yellow fever phase 3 trial
- Enrolled 3805 participants out of 7863 across these trials enrolled at this site.

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Strategies employed before the trial

Translation and audio recording of Information sheet

- A team of experienced field staff translate the information sheet into multiple consent languages
- Audio recording is vetted by the communications department.
- The audio recordings are not used during the consent process but serve as a reference for agreed translations during sensitization and consenting

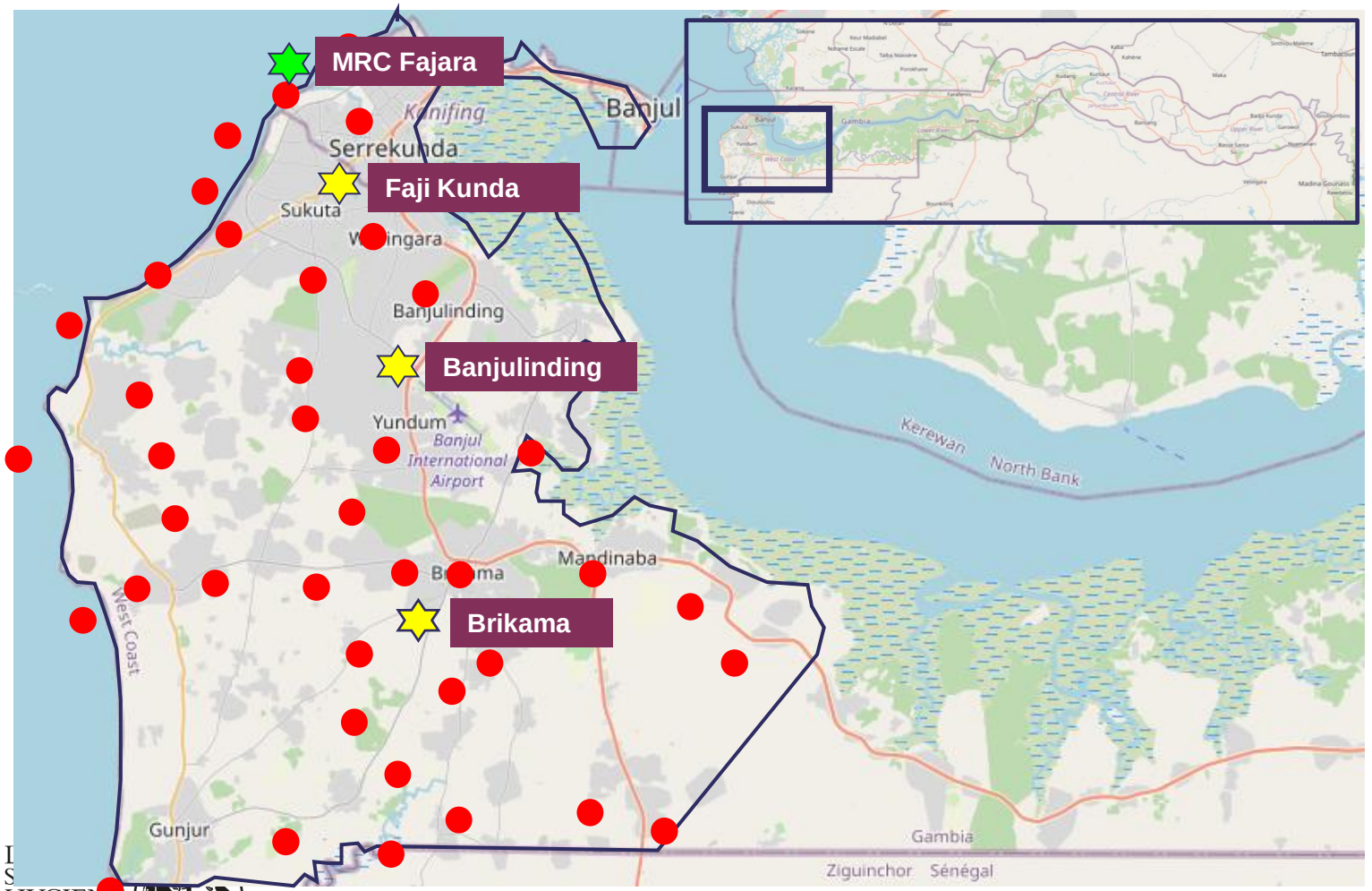
Strategies employed before the start of the trial

Community Sensitization

- Meetings with the “Alkalos” (village head) , community stakeholders and potential participants in target recruitment areas.
- Meetings with officers in charge (OIC) in the health centers in and around Brikama.

Meetings	Communities	Health Facilities	Total
Done	52	25	77
Pending	1	0	1
Total	53	25	78

Community Sensitization



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Community sensitization

- Provides an opportunity to interact with the “Alkalo” (village head) , religious leaders, womens groups and other stakeholders in target communities
- To introduce the study to the community, allowing opportunity for questions.
- Address rumors and misconceptions.
- Scout for impartial witnesses.
- Meetings with heads of health centers creates an enabling environment for our staff during individual sensitization.

Strategies employed when the trial starts

Individual Sensitization

- Strategy of Individual sensitization will depend on age of participants to be recruited
- Most of our studies involve infants and young children so we take advantage of immunization clinics
- Maintain a schedule of the immunization clinic days of health facilities in our target areas

Strategies employed when the trial starts

Individual Sensitization

- Field staff conduct one-on-one sensitization with potential participants.
- Sensitization and consent occur on separate days.
- Participants take a copy of the information sheet home to discuss with family.
- Participant information is recorded on sensitization forms.
- Completed sensitization forms entered into the participant tracking database.

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Strategies employed when the trial starts

SII-YFV Trial
LEO27754/YWF:02

Sensitization Form

MRC Unit The Gambia
at LSHTM

BRIKAMA

Sensitization Number

Is the infant already enrolled in another study?	Yes	No	If YES - STOP
Does the parent/guardian have the IWC in hand now?	Yes	No	If No - STOP

All details as written on IWC

Name:

Date of Birth: / /

Sex (M/F):

Mother's Name:

Father's Name:

Compound Head's Name:

Vaccination History (from IWC)			
Yellow Fever	Yes	No	If YES -STOP
MR or MMR	Yes	No	If YES -STOP
Men A	Yes	No	If YES -STOP

Other vaccination (in last 28 days – complete below if 'Yes') Yes ☐ No ☐

1.	/ /
2.	/ /
3.	/ /
4.	/ /
5.	/ /

Contact numbers

Africell:		Q-cell	
Gamcel:		Comium:	
Other numbers:		Or	

Study information

Has the study been explained to the parent/guardian?	Yes	No
Has the informed consent document been given to the parent/guardian?	Yes	No

Write '**SENT SII-YFV**' on the top of the IWC to indicate sensitization has taken place.

Version 1.1 11 Nov 2022

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SII-YFV Trial
LEO27754/YWF:02

Sensitization Form

MRC Unit The Gambia
at LSHTM

BRIKAMA

Sensitization Number 2 1 1 4 5 1 0

Address and Map – provide as much information as possible to ensure that another field worker or driver could find the house/compound

TALOKOTO

From Brikama health Centre go straight to Talokoto, a Compound next to the Imam's Compound.

Outcome of sensitization		
Is the participant's parent interested in taking part in the study?	Yes X	No

Other Comment/questions asked/concerns raised?

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Informed consent visit

- Participants greeted by senior field staff at reception.
- Participants details and eligibility is confirmed.
- Participant is matched with consenter and impartial witness based on the language.

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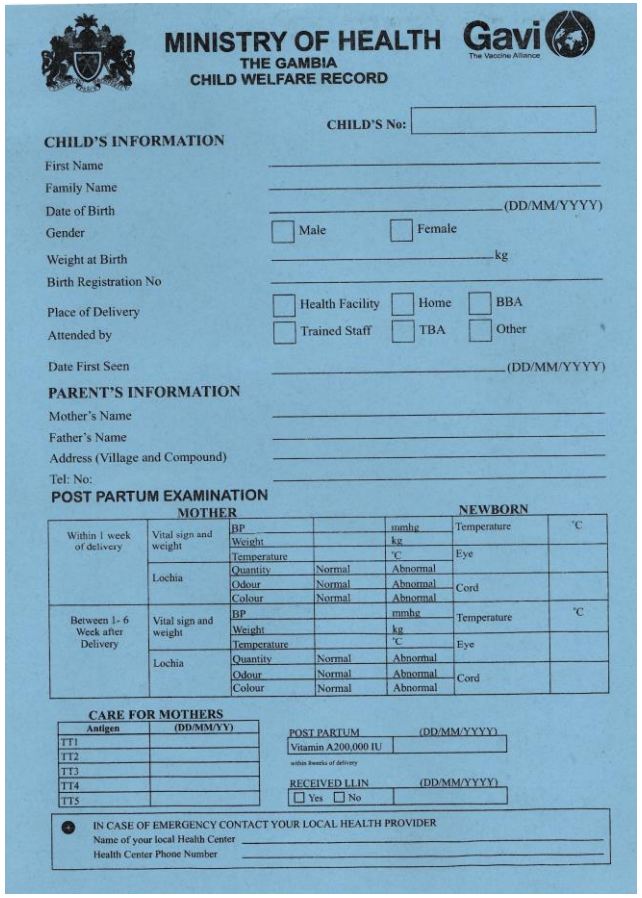
Informed consent visit



MINISTRY OF HEALTH
THE GAMBIA
CHILD WELFARE RECORD

Gavi The Vaccine Alliance

CHILD'S No: _____

CHILD'S INFORMATION

First Name _____
Family Name _____
Date of Birth _____ (DD/MM/YYYY)
Gender ☐ Male ☐ Female
Weight at Birth _____ kg
Birth Registration No _____
Place of Delivery ☐ Health Facility ☐ Home ☐ BBA
Attended by ☐ Trained Staff ☐ TBA ☐ Other
Date First Seen _____ (DD/MM/YYYY)

PARENT'S INFORMATION

Mother's Name _____
Father's Name _____
Address (Village and Compound) _____
Tel: No: _____

POST PARTUM EXAMINATION

		MOTHER			NEWBORN	
Within 1 week of delivery	Vital sign and weight	BP		mmhg	Temperature	°C
		Weight		kg		
		Temperature		°C	Eye	
	Lochia	Quantity	Normal	Abnormal		
		Odour	Normal	Abnormal	Cord	
		Colour	Normal	Abnormal		
Between 1- 6 Week after Delivery	Vital sign and weight	BP		mmhg	Temperature	°C
		Weight		kg		
		Temperature		°C	Eye	
	Lochia	Quantity	Normal	Abnormal		
		Odour	Normal	Abnormal	Cord	
		Colour	Normal	Abnormal		

CARE FOR MOTHERS

Antigen	(DD/MM/YY)
TT1	
TT2	
TT3	
TT4	
TT5	

POST PARTUM (DD/MM/YYYY)
Vitamin A200,000 IU _____
within 8weeks of delivery

RECEIVED LLIN (DD/MM/YYYY)
☐ Yes ☐ No _____

IN CASE OF EMERGENCY CONTACT YOUR LOCAL HEALTH PROVIDER
Name of your local Health Center _____
Health Center Phone Number _____

SII-YFV Trial
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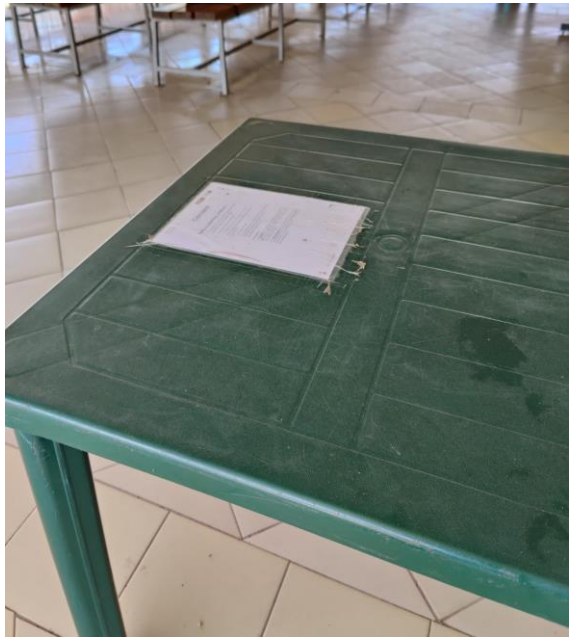
Consent

Before starting confirm:

1. The IWC the participant is available and a certified copy has been made
2. The age of the participant
   - At least 9 month but less than 12 months
3. That a parent/guardian who will provide consent is:
   - ≥ 18 years of age
   - The biological parent (if no ensure a Guardianship Statement [parents both out of country or deceased] is signed first)
4. Languages:
   - If **English** is to be used, the literacy level should be confirmed by asking the subject/parent/guardian to read and explain a section of the ICD. No impartial witness should then be present
   - If a **local language** is to be used, confirm both you and the impartial witness are fluent in the language of consent and that this is documented on your CV and the CV of the impartial witness.



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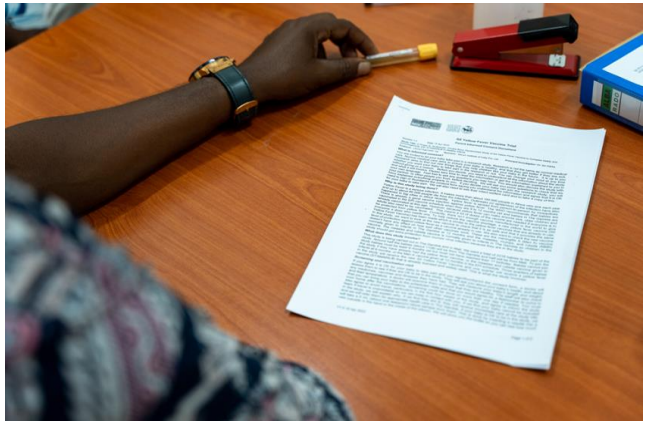
Informed Consent process

- In the presence of an impartial witness, the field worker explains each sentence of the information sheet to the potential participant.
- The participant can ask questions, answered by the field worker or a clinician
- A clinician will then go through 10 simple questions to assess participants understanding.
- A score of 9/10 or 10/10 indicates passing. If it's 9/10, the missed question is clarified
- If the score is 8 or less, the process is repeated by a different field worker, requiring all questions to be answered correctly on the second attempt.



SII Yellow Fever Vaccine Trial

Assessment of Understanding

Participant's Screening Number: |___|___|___|___|___|___|

Date of Assessment: |__|__|/|__|__|__|/|__|__|__|__|

Time of Assessment: |__|__|:|__|__| (24 hour)

Ask the participant's parent/guardian the following questions

Write the respondent's answer in the corresponding box (1st attempt or 2nd attempt) and count the correct answers

No	Question	Correct answer	1st attempt	2nd attempt
1	Babies in The Gambia already get vaccinated against yellow fever	T		
2	Your baby will only receive one vaccine injection at the first study visit	F		
3	You can decide if your baby gets the new yellow fever vaccine or the vaccine which is already used	F		
4	Your baby will have two blood samples during the study	T		
5	The study includes four clinic visits, including one visit which may be done over the telephone	T		
6	Your baby should continue to go to your local EPI clinic while they are in the study	F		
7	You should contact the study team if your baby is unwell during the study	T		
8	You can travel at any time during the study, and you do not need to tell us	F		
9	Once you have consented you cannot withdraw your baby from the study	F		
10	Reactions, including serious reactions can occur after any vaccine injection and could occur with the new vaccine.	T		
		Total		

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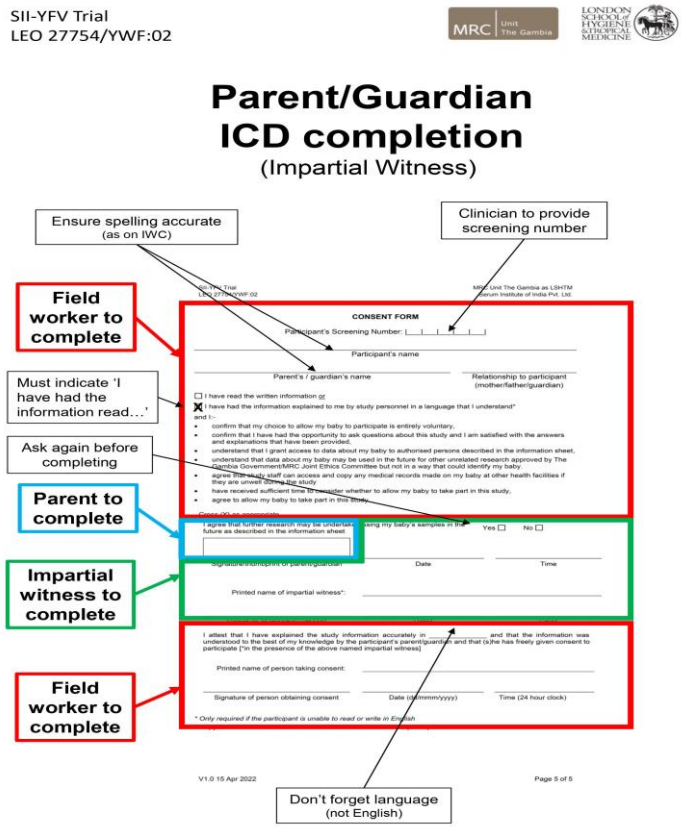
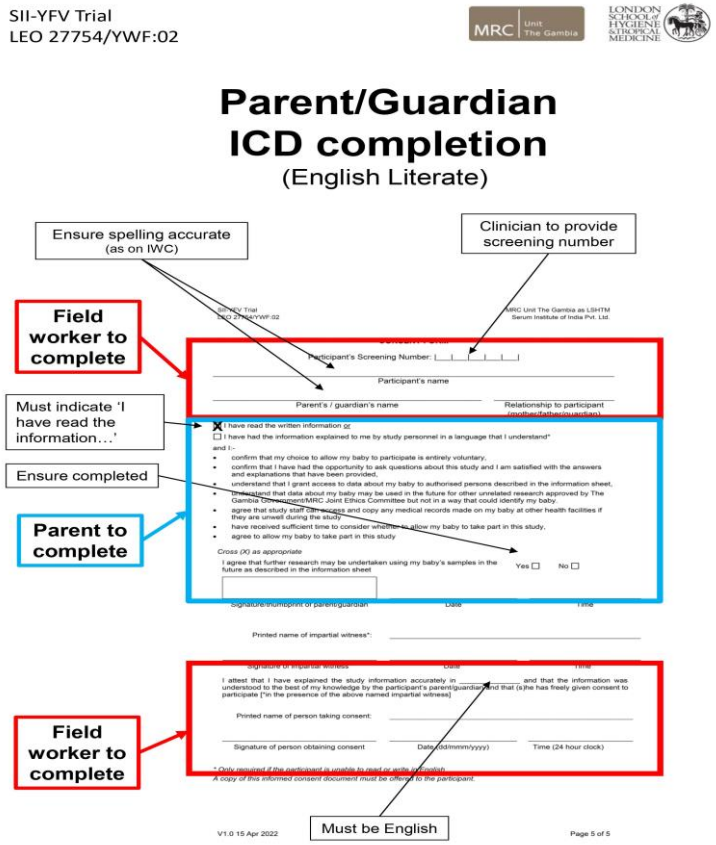
Informed Consent process

- Once the participant passes assessment of understanding, the informed consent form is signed.
- The signed form is reviewed by a clinician.
- A second review is done by a clinical trial assistant before the copy of the consent form is given to the participant. This is to ensure that any error is corrected while the participant is still in the clinic.

Visual aids for informed consent process





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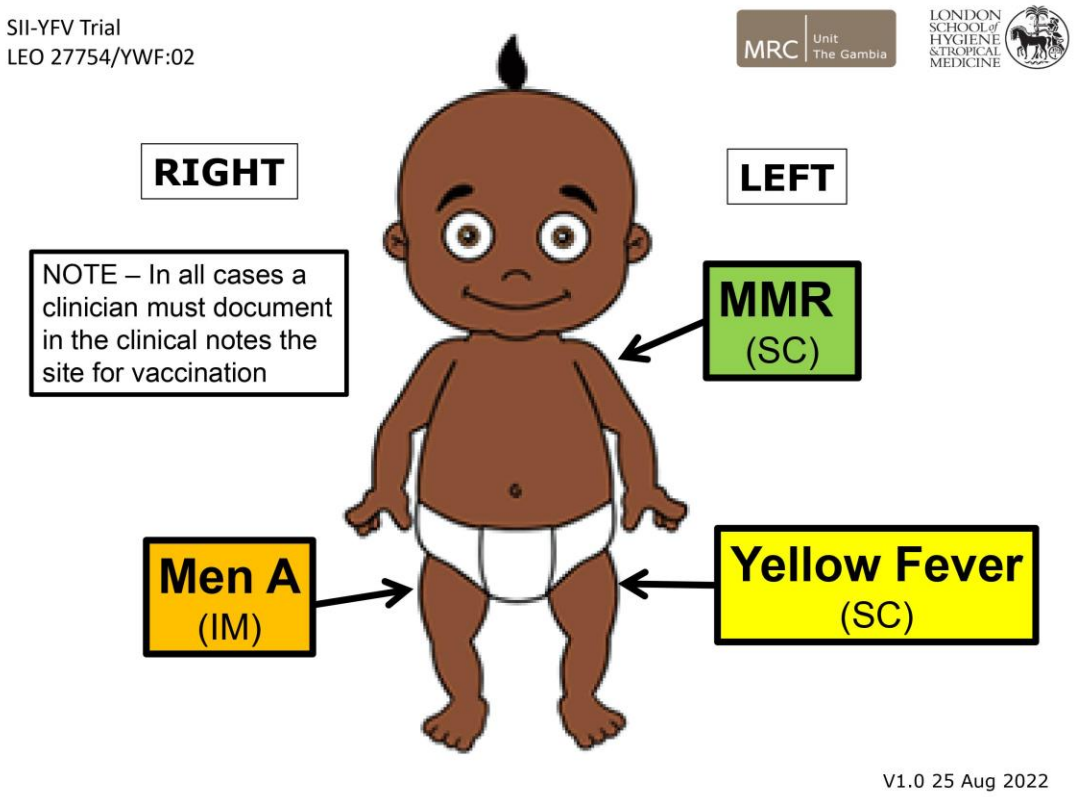
Visual aids for informed consent process



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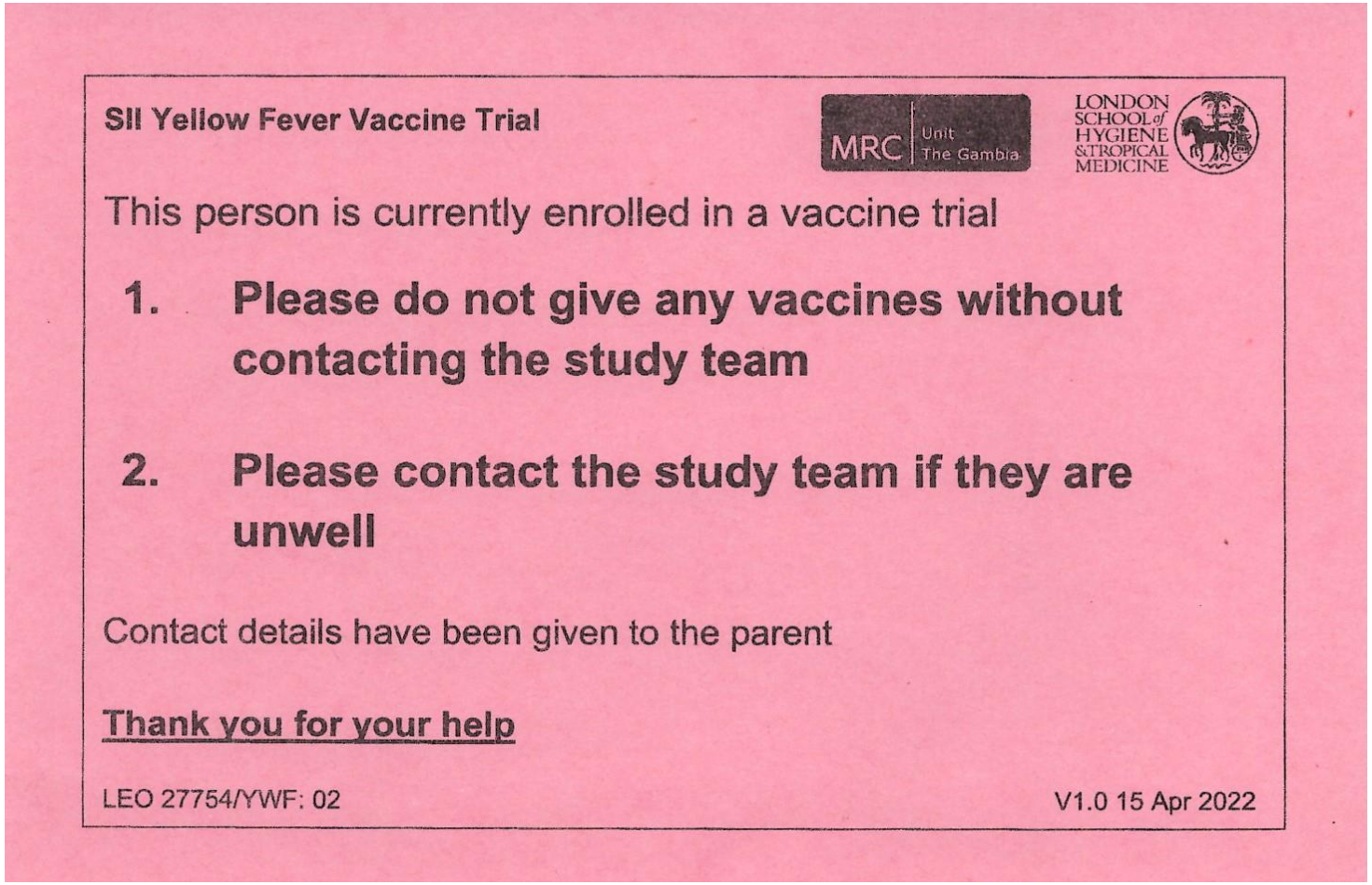
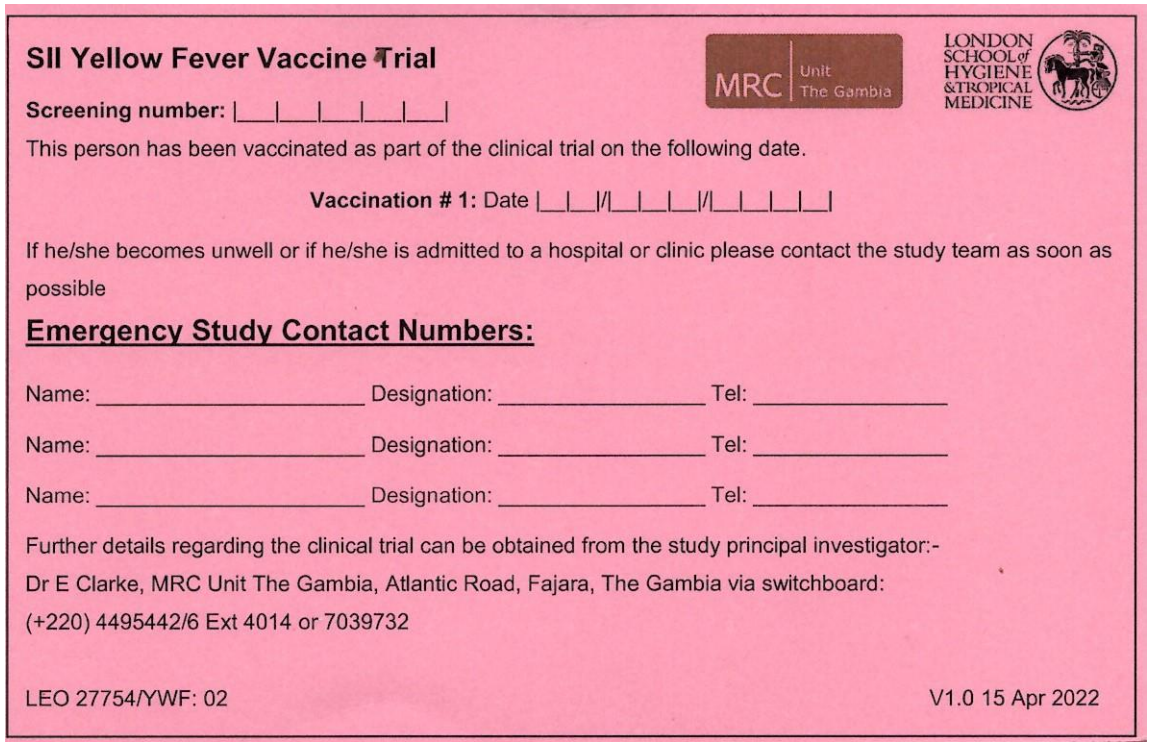
Concluding the enrolment visit

- After informed consent, participants proceed with trial procedures following the protocol and standard operating procedures.
- For participants who will require home visits , a home visit form is completed.
- Participants are introduced to the fieldworker who will conduct the home visit.
- Participants are given a trial-dedicated phone on a closed user group(CUG).
- Reminders and notices are attached to the infant welfare card to indicate trial participation

Reminder/retention tools



Reminder/retention tools



SII Yellow Fever Vaccine Trial

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Screening number: |___|___|___|___|___|

This person has been vaccinated as part of the clinical trial on the following date.

Vaccination # 1: Date |__|__|/|__|__|__|/|__|__|__|__|

If he/she becomes unwell or if he/she is admitted to a hospital or clinic please contact the study team as soon as possible

Emergency Study Contact Numbers:

Name: _____ Designation: _____ Tel: _____

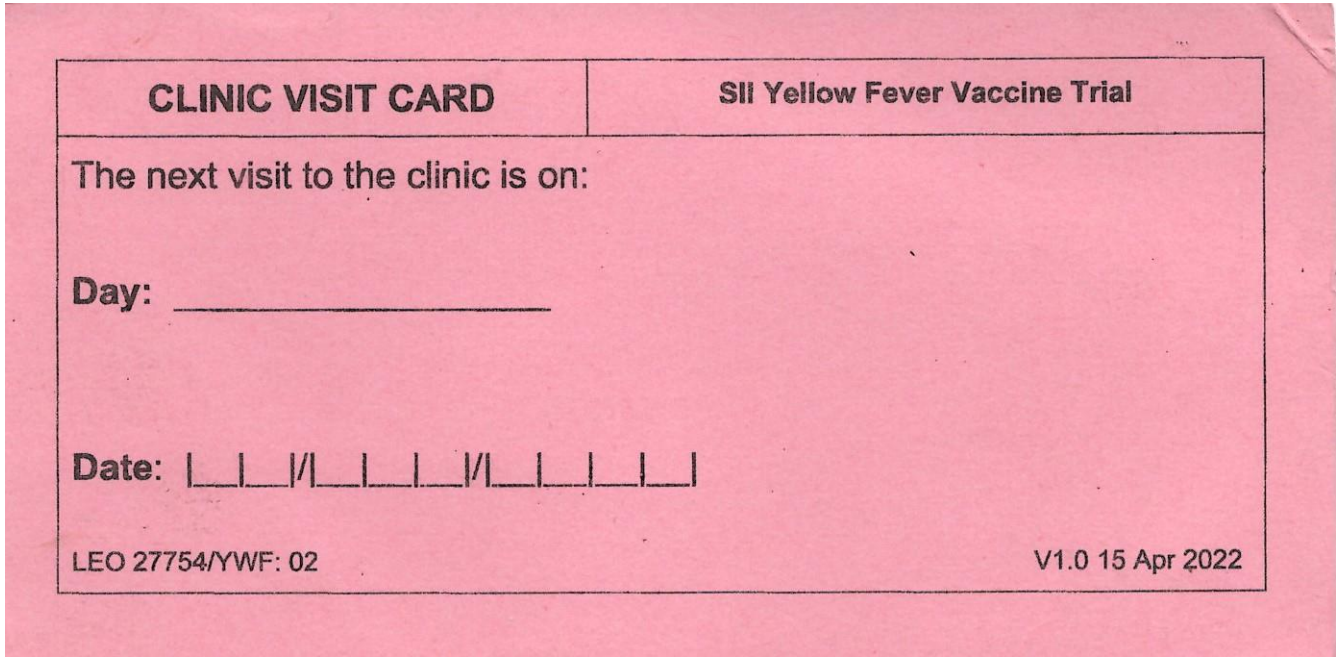
Name: _____ Designation: _____ Tel: _____

Name: _____ Designation: _____ Tel: _____

Further details regarding the clinical trial can be obtained from the study principal investigator:-
Dr E Clarke, MRC Unit The Gambia, Atlantic Road, Fajara, The Gambia via switchboard:
(+220) 4495442/6 Ext 4014 or 7039732

LEO 27754/YWF: 02 V1.0 15 Apr 2022

Reminder/retention tools



CLINIC VISIT CARD	SII Yellow Fever Vaccine Trial

The next visit to the clinic is on:

Day: _____

Date: |__|__|/|__|__|__|/|__|__|__|__|

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Reminder/retention tools

Strategies employed at the end of the trial

Open days

- Community engagement event for recruitment areas.
- Attendees: Ministry of health, traditional and religious leader and the general public.
- Feedback on completed trial results and their public health implications.
- Appreciation for community support in clinical research.


HRCG at LSH
OPEN DA

Acknowledgements

- Prof. Ed Clarke
- Clinical trial staff
- Trial participants
- Ministry of Health, The Gambia
- CTU lSHTM and MRCG at LSHTM

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Thank you

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