	FIDO Febrile Infant Diagnostic Assessment and Outcome Study	**►FAQs ◄**

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Recruitment and CRF completion

Who can recruit patients and collect initial data?

The participant's clinical staff will recruit patients and collect initial data by completing the CRF Form 1. CRF form 1 will only record standard clinical data (history and physical exam). These staff do not need to be GCP or study trained.

The CRF follow up forms (2 and 3) and taking of consent needs to be done by the research study team, who must be GCP trained, have received study specific training and be on the FIDO delegation log.

Do clinicians completing form 1 need to be on the delegation or training log and GCP trained?

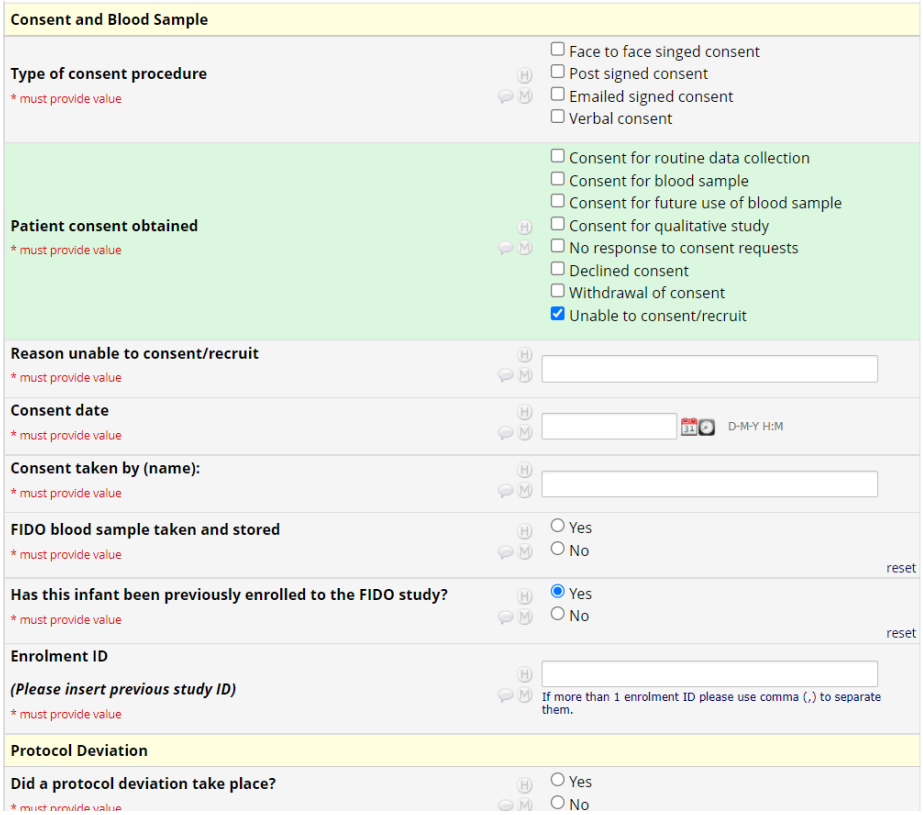
No. As this is observational study with no change in clinical practice and form 1 contains only routinely collected data. The clinician does not need to be on the delegation log or have GCP. They only need to be briefed of the study and requirements to complete form 1.

Can we plan to have our doctors complete a paper copy of the CRF 1, and for us to upload it later to RedCAP (as we did for PiC)?

Yes. However, the clinician should record CRF 1 or Form 1 contemporaneously. If the information on CRF form 1 is already being recorded on a local form and the clinical staff do not have capacity to complete form 1, the information can be copied from the local form by the study team at a later time.

Can a participant be re-enrolled into the FIDO study?

Yes. As far it is after the 7 day follow up period. On Form 3 you will find a tick box to indicate if the child has been previously enrolled and a subsequent box to enter the participants previous study ID.



Consent and Blood Sample	
Type of consent procedure * must provide value	☐ Face to face singed consent ☐ Post signed consent ☐ Emailed signed consent ☐ Verbal consent
Patient consent obtained * must provide value	☐ Consent for routine data collection ☐ Consent for blood sample ☐ Consent for future use of blood sample ☐ Consent for qualitative study ☐ No response to consent requests ☐ Declined consent ☐ Withdrawal of consent ☑ Unable to consent/recruit
Reason unable to consent/recruit * must provide value	
Consent date * must provide value	D-M-Y H:M
Consent taken by (name): * must provide value	
FIDO blood sample taken and stored * must provide value	○ Yes ○ No reset
Has this infant been previously enrolled to the FIDO study? * must provide value	◉ Yes ○ No reset
Enrolment ID ***(Please insert previous study ID)*** * must provide value	If more than 1 enrolment ID please use comma (,) to separate them.
Protocol Deviation	
Did a protocol deviation take place? * must provide value	○ Yes ○ No

Can I still recruit a child to the FIDO study if no FIDO bloods were obtained?

Yes. If the team are unable to obtain the FIDO blood sample during initial phlebotomy, the infant can still be included in the study by recording data on the CRF. As FIDO is on the NIHR portfolio, sites will get accruals for each recruit.

For eligibility, is it 90 or less old absolute age or 90 days or less with age corrected for prematurity?

Infants 90 days or younger, absolute gestational age if premature (<37 weeks) are eligible.

If a baby is admitted via GP straight to the ward, can they be included even though they haven't technically been through the assessment unit?

If the CRF form 1 can be completed, which requires that the clinician give a first-hand account of how the infant looked or examined on first clinical encounter in the hospital, then they can be included. This is something that would have to be discussed with the PI and research team at the site to see if it will be feasible to capture these patients.

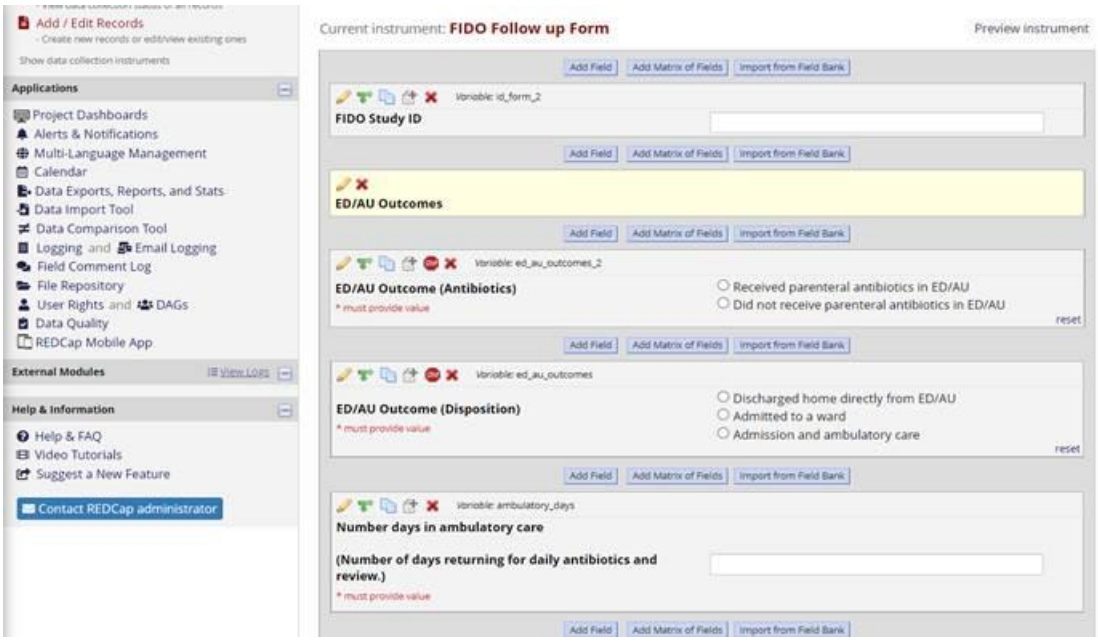
If a baby is seen in A/E and an initial exam is done but then gets seen by a senior doctor, is it still the original doctor who completed the initial CRF?

The initial part of the CRF pertaining to the babies first clinical contact with a health care professional/doctor is what we want recorded. Therefore, we want the original doctor who reviews the child to document their assessment and initial exam findings. A lot of things could have changed by the time the senior comes to review the patient.

For admission, are you counting an observation unit as an admission?
Anything other than ED/AU would be an admission. Short stay will be classed as admission

If the AU is attached to the wards and the child is referred by the GP, can the child still be included?
Yes, as far as the its the clinician in the AU making the first initials decision about admission and management. This will also depend on the flow of patients through your paediatric acute care service.

Some children will be discharged from the Ward to the Paediatric Ambulatory Care Team (PACT) for several days of iv antibiotics. Are you happy that we class these children as still being admitted and we will include days visiting PACT on the " length of stay in days(Wards)" ? The reason is, without the PACT service these children would stay in a hospital ward to receive their treatment.
We have added an option in form 2 on the REDCap database to reflect this. Please see below, we have included an extra option in disposition to include admission and subsequent ambulatory care. There is a follow up question to ask how many days the patient was ambulated for. As usual, at the end of the form 2, you will have to put how long the patient was admitted for as an inpatient.



Consent

The only question I didn't have time to ask was: Who is allowed to gain consent? For example, we have healthcare assistants, trial co-ordinators etc who work within our team who are training in obtaining consent. However, I know that some studies only allow nurses and doctors

Anyone with GCP and study specific training who is signed off as competent can take consent. if the person is not a member of the clinical team, they cannot make the first approach on the ward, a member of the clinical team must do that. This is less of an issue for doctors and nurses but can be an issue if using research associates.

What does initial non personal data recorded on the form relate to?
Is routine anonymized data is still included in the study, when the parent/guardian explicitly declines or does not return consent?

Routine clinical data will be collected: 1) if the parents has given consent or 2) after 2 communications via- email, letter or post and no response (within an 8-week period). If consent is declined routine data will not be included in the study. Residual blood samples will only be transferred for further analysis once consent is obtained. If consent is declined, residual blood samples will be disposed.

How long do inpatients parents' have to consent?

You can consent up to 8 weeks post initial presentation, as per the protocol.

The baby and parents are all covid positive and therefore we are unable to obtain written consent at the moment due to infection risks. Is there an option for verbal consent or do I have to wait until parents have done the 5 days isolation and feel ok?

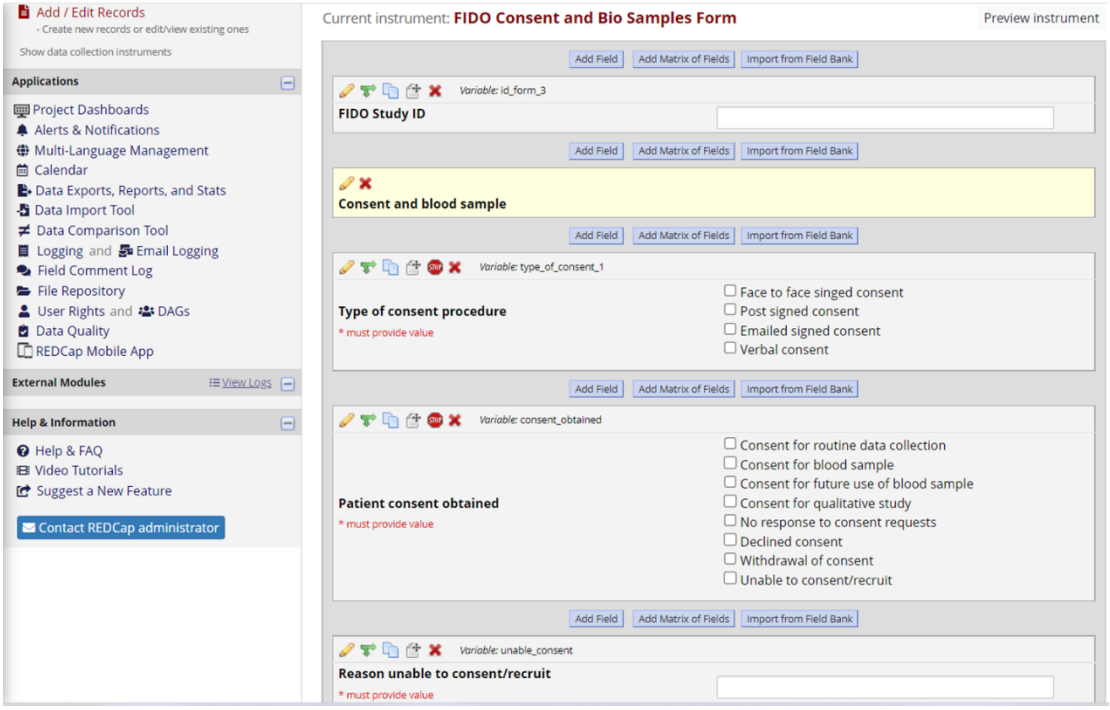
Virtual consent is an option as outlined in the protocol; however, a signature is still required via paper or email on the consent form. In this situation they can be given the PIS/consent form and then discussion take place over the phone about the study and if they are happy to consent, so you're not in the room with them. However, contacting them after a period of isolation is also fine.

Can parents opt out of the blood sample collection on the consent form?

Yes, the bloods section on the consent form is optional and if left blank then the parent didn't consent to blood samples taken or processed.

If patients decline the study or there is a language barrier is there a way to take out there information from the redcap system and do we remove them from the data linkage system?

Yes, the updated REDCap will contain an area to document if patient declines/withdraws/unable to consent. All data will be removed except the initial screening question of age and presentation with a fever in form 1. Also, only data on consent will be kept, to report if consent declined/withdrawn/unable to consent/recruit as shown in form 3 (which is the admin form). This will form the screening process for FIDO to establish a baseline population.



Blood sampling questions

How will the blood sample be processed at our site?

There is a dedicated SOP describing how blood samples should be processed. In brief, the blood sample will be spun down at sites and the separated plasma will be stored in a single tube and frozen. This processing should be completed within 24 hours of taking the blood sample. QUB will get in contact when samples are required to be shipped.

Can blood samples for the FIDO study be taken via a heel prick?

Yes- blood taken via a heel prick is fine if sufficient volume can be obtained. As stated in the biological sample SOP, we require 0.5ml-1ml of blood to be collected. As blood samples are only to be taken as part of routine phlebotomy and not as an additional event, it is unlikely that adequate volume could be obtained from a heel prick alone. If a blood sample is taken via a heel prick this must be noted on the FIDO sample log.

Will bloods obtained after 24hrs or the following day from time of admission be used for the FIDO study?

No. Bloods should be obtained during first initial routine phlebotomy. This should be done during the first initial presentation to the ED or AU. If the extra ml of blood is not obtained at this time the child can still be included as part of the observational study and CRF forms 2 and 3 should still be completed.

Should we inform parents about their bloods being taken but not being able to process?

Yes. As we are requesting consent from parents/guardians to participate the study, if we have information about the bloods sample if taken or processed. The parent should be informed.

The SOP for sampling mentions to store the plasma in a purple edta. Is this another edta from the one it is collected in or do we put it in a cryo bottle the FAQ seems to state EDTA so not sure?

For collecting the FIDO biological sample during phlebotomy, the EDTA is recommended (some sites have different colors for EDTA bottles. Liaise with your laboratory personnel and see what's available in your own site.). For the storage of processed samples in use a -80C freezer, cryo bottles will be used labeled with the FIDO study ID.

What is the minimum sample volume needed for transfer to the FIDO team?

0.5mls of plasma, if less than this please contact the FIDO study team.

Site set up

Who can be the independent Doctor contact on the patient information sheet?

This can be any clinician that is not part of the study team or research team (not on the delegation log) but has been briefed on FIDO to discuss it adequately with a parent.

What are the requirements to for sites to get sponsor green light?

1.) completed OID with payment details filled
2.) completed SIV
3.) Capacity and capability assessment confirmation.

What do sites need to get setup completed?

1.) email address of team members needing access to complete form1 and form2, and also manage redcaps.
2.) twitter handles of the site and team members
3.) Completed video training of REDCaps

What is the ethics committee name for the PIL?

Office for Research Ethics Committees Northern Ireland (ORECNI) - Health and Social Care Research Ethics Committee (HSC REC B)

Other

Is funding provided for this study?

Research Cost: £50 per patient who have bloods taken and if no bloods no payment. Capped at 400 participants for bloods during the study period. The £50 payment per stored sample is to cover the costs including the EDTA bottle for storing the frozen plasma. We will also cover the shipping costs separate to the per sample payment. **Service support coset:** Due to the observational nature of the study the only cost incurred will be for blood samples taken. Sites will still get accruals for recruiting to the observational part of this study as it NIHR portfolio adopted.

Can we co-recruit patients in the FIDO study with other trials currently going on?

Yes. As far it doesn't affect blood sampling or the outcome of the study. If you recruit a patient before another study, then it shouldn't be an issue. If a child is recruited and there is conflict around blood sampling, then the child can be recruited to the observational arm. If the competing study will affect diagnostic testing, treatment and decision to admit the study population, then the infant cannot be included in the study.

Will sites have to conduct the interviews for the qualitative aspect of the FIDO study?

No, the interviews will be conducted by the central FIDO team trained in Qualitative methodology.

Is there any telephone review included in the study?

There will be no telephone review at 7 days as the central study committee agreed that it might be too onerous for research team at sites. We will only collect data on reattendance to the study site when filling in the follow up data.

Is there a PI associate role in the study?

Yes