



# **Premature Ovarian Insufficiency Study of Effectiveness of hormonal therapy (the POISE study)**

## **Sub-study Sample Processing Instruction Manual**

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## POISE Sub-study Sample Processing Instructions

### 1. Equipment per participant

For each participant, you should receive the following:

1 x Serum (gold top) vacutainer

1 x EDTA (purple top) vacutainer

1 x Sterile urine pot

**By the end of processing, you should have up to:**

1 tube of 1ml EDTA whole blood (Baseline only for participants consenting to storage of samples for genetic testing)

Up to 2 tubes of 1 ml serum (From gold vacutainer)

Up to 2 tubes of 1 ml EDTA plasma (From purple vacutainer)

1 Sterile urine pot

### 2. Set-up

You will need:

1 x Centrifuge set to 3000 x *g* (rcf)

1 x 1000 µl pipette

1 x rack to hold 1.8 ml tubes

1.8 ml tubes (Provided by study team).

An array of vacutainers, as balances

Class II Safety Cabinet (if required by local Health and Safety)

### 3. Important Notes

- Samples should be processed within 1 hour of collection.
- 2-3 hours window acceptable if 1 hour is not possible.
- The sample log should be completed including collection, processing, and freezing times so that any delays can be accounted for. The samples will still be of use, but delays must be documented.
- Aliquot numbers are a target, not a fixed minimum.
- When aliquoting EDTA whole blood at baseline (for participants who have agreed to storage of genetic material), remember to leave enough to generate EDTA plasma aliquots too. With a minimum of one EDTA (for genetics) and one EDTA plasma. If only one 1 ml sample can be obtained than EDTA plasma should be prioritised.
- Do not under-fill aliquot microtubes, as the expectation for analysis is that they will contain a very minimum of 500 µl (and ideally 1 ml).
- The exception to the “no underfill” rule is if you don’t have enough sample to make any full volume aliquots, it would be better to have one tube with as much as possible than no sample at all. If there is less than the required volume of any aliquot, make a note of the approximate volume on the sample log.
- It is preferable, though not mandated, that sub-study blood tests are taken on a day that the participant takes both oestrogen and progestogen in women taking cyclical HRT or on a day that the participant takes the combined oral contraceptive, rather than hormone free interval.

### 4. Processing

Check the time the bloods and urine were taken and complete all relevant fields on the sample log.

The Urine sample does not require processing, it should be labelled (as detailed in section 9) and frozen in a bag.

The gold serum vacutainer must sit at room temperature for 30 minutes before being spun, to enable complete clotting and prevent the serum clotting during centrifugation.

The EDTA vacutainer can be processed immediately.

## 5. Aliquoting – EDTA whole blood (At baseline only)

**BEFORE** centrifugation invert the **purple EDTA vacutainer 3 times**. Pipette **1 ml whole blood** into **up to 2** x 1.8 ml tubes. Discard the pipette tip. Seal aliquot tubes with lids. **DO NOT DISCARD VACUTAINER**. Re-seal the vacutainer securely.

## 6. Centrifugation

1. Check you have the correct centrifuge buckets and inserts available within the cabinet, ready to use.

2. Seal the vacutainers in the centrifuge buckets, balancing as appropriate.

3. Carefully place the buckets back in the centrifuge, ensuring they are seated in the rotor correctly, to avoid problems.

Spin all tubes at 3000 x g (rcf) for 10 minutes. Record the spin time on the Sample Log.

NB. Do not attempt to use the centrifuge without prior training. Incorrectly balanced centrifuges are dangerous.

## 7. Aliquoting – Serum/Plasma

1. Once the centrifuge cycle has finished, open the centrifuge and remove the buckets carefully to avoid disturbing the different blood layers. Do not unscrew the lids until the buckets have been returned to the safety cabinet, if using.

2. Unscrew the bucket lids taking care to avoid disturbing the different blood layers still.

**Serum** – Pipette **1 ml serum** from the gold-top, vacutainer into each of **up to 2** x 1.8 ml tubes. Discard the pipette tip. Seal aliquot tubes with lids. Discard vacutainer into a sharps bin.

**EDTA** – Pipette **1 ml EDTA plasma** from the purple-top vacutainer into each of **up to 2** x 1.8 ml tubes. Discard the pipette tip. Seal aliquot tubes with lids. Discard vacutainer into a sharps bin.

## 8. Supply and Printing of Barcodes

The study team will provide an excel spreadsheet containing barcode numbers. This will need to be uploaded to your local barcoding printer available in your laboratory. Please use labels suitable for your local printer to produce the barcode labels. If no printer is available, please use bar codes provided to manually add a number to the samples using your local suitable label stock.

## 9. Logging Sample Barcodes

Please refer to section 14 of this guide and follow steps 13-20 for instructions on how to log your barcodes in REDCap using a phone app. You will need to download the REDCap app and set it up on your phone prior to scanning a bar code. Steps 1-12 will take you through how to do this.

## 10. Freezing Samples

1. Ensure the samples have been correctly barcode labelled and logged in the redcap database as per section 9.
2. Put the aliquots in the next space in the current box in the minus -80°C freezer immediately, in the following order: Whole Blood, Serum, EDTA Plasma. (If -80°C is not immediately available then samples can be kept for up to 28 days at -20°C before transfer to -80°C).
3. Note the first and last positions occupied by aliquots from each participant you store, on the Sample Log.
4. If positions have been incorrectly recorded previously, ensure these are corrected on the Sample log.
5. Urine samples should be placed into an individual sealable plastic bag and frozen at -80°C immediately. (If -80°C is not immediately available then this sample can also be kept for up to 28 days at -20°C before transfer to -80°C).

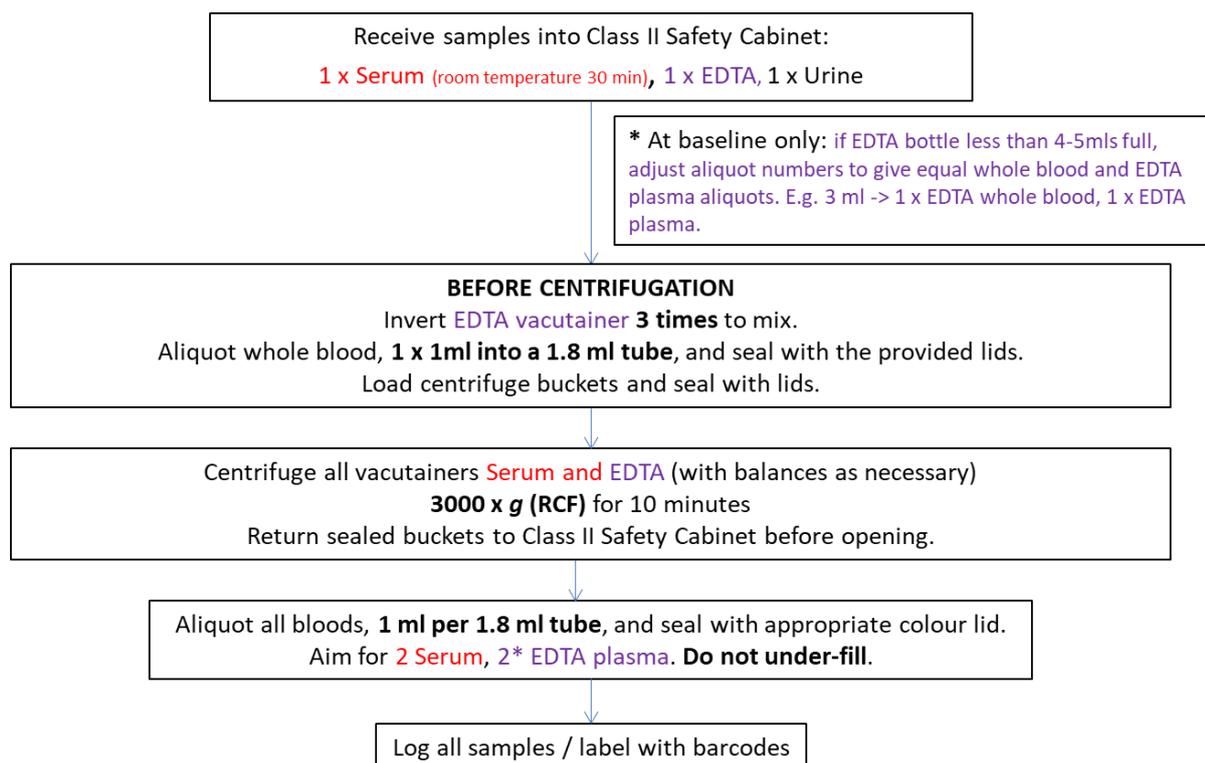
The temperature of the freezer should be monitored regularly, in accordance with existing regulations.

## 11. Finishing and Clean Up

Return to the lab to tidy:

- Ensure the Sample Log is complete
- Clean the transport containers and return them to the shelf
- Tidy the tubes / lids / pipette tip boxes and other items within the safety cabinet
- Wipe down the safety cabinet surfaces using an approved disinfection method such as 70% IMS or laboratory disinfectant at an appropriate concentration for blood
- Once everything is cleaned and tidy, remove your PPE and wash your hands

## 12. POISE sub study Sample Processing Flow Design



### 13. POISE Sub study biomarker overview

**Remember: all bloods are taken fasted!**

#### **Baseline:**

##### **Point of care test**

- Blood glucose

##### **Trust Laboratory**

- Gold vacutainer - Fasting lipids, IGF-1, LFT's, Bone profile, U and E's, 25 OH Vitamin D  
Purple bottle - HBA1c
- Green vacutainer Karyotype (If clinically indicated and not already done as per PI instruction)

##### **Stored**

- Purple vacutainer (Plasma) + (Whole blood – for DNA)
- Gold vacutainer (Serum)
- Urine

##### **Additional**

- Systolic and diastolic blood pressure, height, weight, BMI, smoking status

#### **Month 3:**

##### **Point of care test**

- Blood glucose

##### **Laboratory**

- Gold vacutainer - Fasting lipids, IGF-1, LFT's, Bone profile, U and E's, 25 OH Vitamin D
- Purple vacutainer - HBA1c

##### **Stored**

- Purple vacutainer (Plasma)
- Gold vacutainer (Serum)
- Urine

**Additional**

- Systolic and diastolic blood pressure, weight, BMI, smoking status

**Year 1:**

**Point of care test**

- Blood glucose

**Laboratory**

- Gold vacutainer - Fasting lipids, IGF-1, LFT's, Bone profile, U and E's, 25 OH Vitamin D
- Purple vacutainer - HBA1c

**Stored**

- Purple vacutainer (Plasma)
- Gold vacutainer (Serum)
- Urine

**Additional**

- Systolic and diastolic blood pressure, weight, BMI, smoking status

**Year 2:**

**Point of care test**

- Blood glucose

**Laboratory**

- Gold vacutainer - Fasting lipids, IGF-1, LFT's, Bone profile, U and E's, 25 OH Vitamin D
- Purple vacutainer - HBA1c

**Stored**

- Purple vacutainer (Plasma)
- Gold vacutainer (Serum)
- Urine

**Additional**

- Systolic and diastolic blood pressure, weight, BMI, smoking status

## 14. Instructions for REDCap logging of POISE lab samples

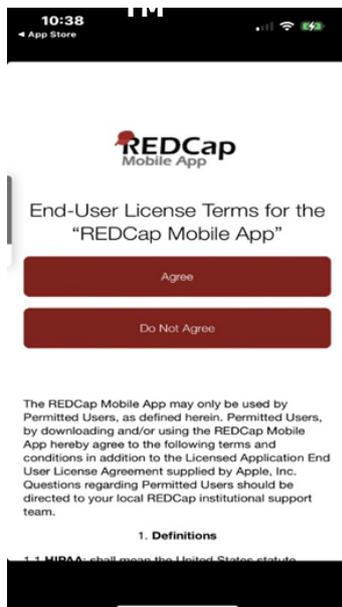
### Registering the mobile app and linking to the database

#### Pre-registration step;

1. Firstly, you will need to log into your sites main REDCap account using your assigned login details.
  - a. Once logged on click the option 'my projects' on the top left of the screen
  - b. Then choose and click the option "POISE Sample Tracker"
  - c. Once there, request API token from POISE Sample Tracking list to the left of the page
  - d. A token will be emailed to you in readiness for mobile app registration and use

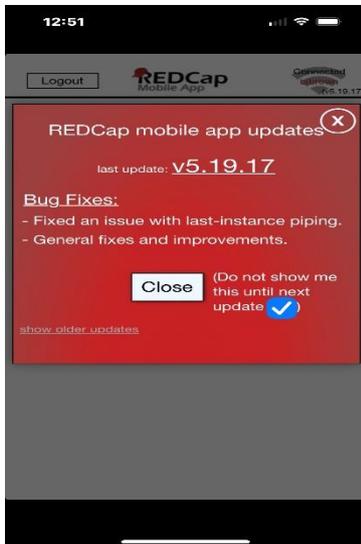
#### Registration steps;

2. On your mobile device find, install and download the REDCap app from your app store.  
(The app is available for the following platforms: iOS 6.0 or later (iPhone 4 and up, iPad 2 and up) and Android 4.3 or later (phones and tablets).



3. Once downloaded and opened a user agreement with details regarding terms and conditions will appear (see left). You will be required to read and agree to this prior to being able to move on to the next step.

4. Once agreed you will then see the screen to the right appear. When on this screen enter a memorable 6-digit pin for both admin and data collector roles and then register. If you intend to have only one user role permitted to work on the study then the pin can be the same. If you propose to have multiple users then the user pins will need to be different to the admin pin. Please note different pins for different user roles may be needed for instances involving staff sickness or other changes.



4a. This screen may then appear (see left), please click close and move on to step 5

5. After closing the previous screen, if applicable, and now registered, you will see the screen (see right)

Who is REDCap Mobile App's Audience?

[View](#)

## Create New App User

Why create two users?

[View](#)

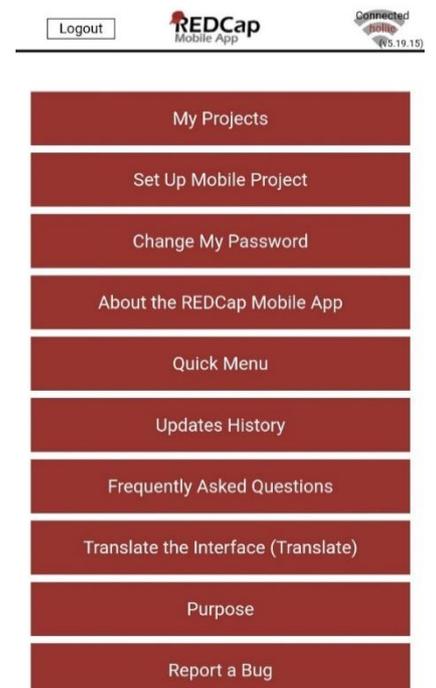
**Create Admin**

Admin Username:  
admin

6-digit Admin PIN:

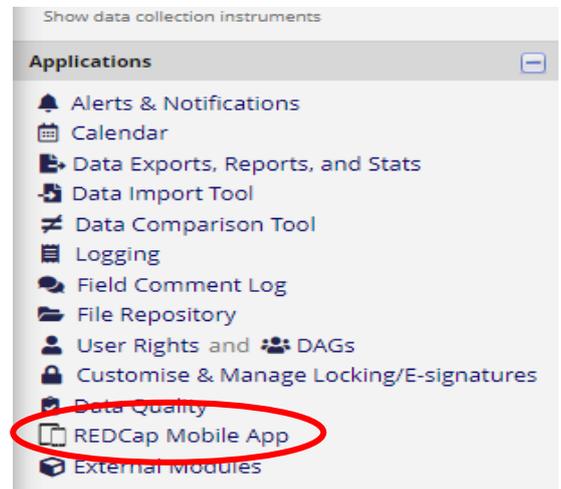
Re-enter 6-digit Admin PIN:

[Suggest Random Pin](#)



- To link the web browser to your mobile app accept the API token that you should have received via email after completing the pre-registration step outlined in step 1. You should be logged into your email account in order to locate it. Once you click the link this should take you to the main REDCap platform in a web browser where you should then login as normal.

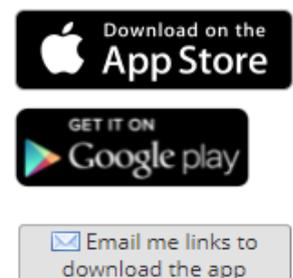
- Once logged in click on “my projects” and select “POISE Sample Tracker”. Then in the left hand navigation panel select ‘REDCap mobile app’ as shown to the right.



- This will then open the screen shown below in the web browser. (Please note that if you have followed the previous steps on your phone correctly you should see that you have already completed step 1 shown in the image and now be at point 2 detailed at step 2 shown in the image below)

### STEP 1: Download the app on your device

You must first download the REDCap Mobile App on your iOS, Android, or BlueStacks (Android emulator) device by clicking the appropriate icon below, or alternatively, if you are not currently on a mobile device, you can search the App Store or Google Play Store for 'REDCap' on your mobile device to find the app there to download. The app is available for the following platforms: iOS 6.0 or later (iPhone 4 and up, iPad 2 and up) and Android 4.3 or later (phones and tablets).



### STEP 2: Set up the mobile project on your device

You must have already downloaded the REDCap mobile app on your mobile device or tablet. To set up this project in the REDCap app:

- Open the app on your device.
- Click the 'Set Up Mobile Project' button.
- Click the 'Scan QR Code' button.
- Scan the QR code that you see displayed below.
- The project will automatically begin downloading and processing.

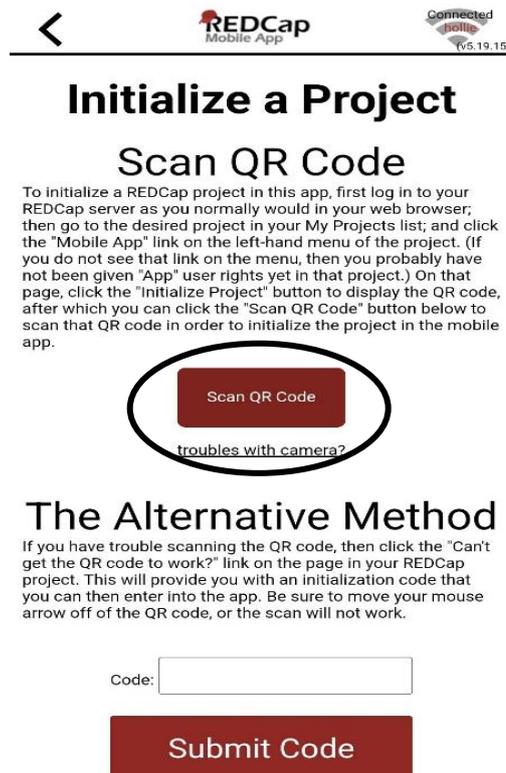


[Can't get the QR code to work?](#)

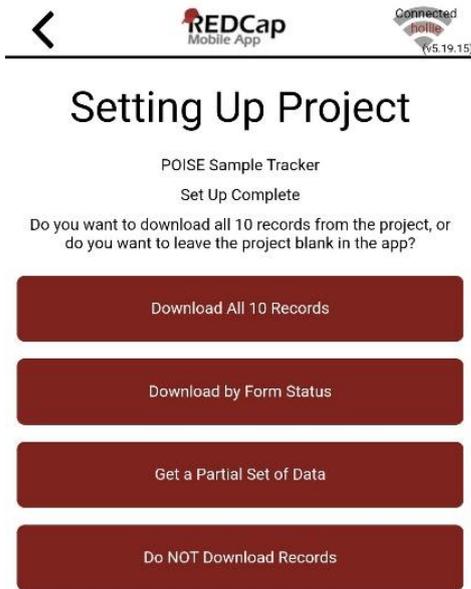


9. In the mobile app click on 'Set Up Mobile Project' (point 2 of step 2 from above image)

10. This should bring up the screen shown below. From here click 'Scan QR Code' then scan the QR code displayed on your web browser. If scanning the QR code does not work in the mobile app click on 'troubles with camera?' and follow the instructions according to your type of phone, or if still not working follow instructions under 'The Alternative Method'.



11. Once set up the screen seen right will appear. If the details in the red button look correct click on the button, this will take you to the below screen. If the details do not look correct check login details used and QR code.



12. Click on the option of download you wish on the screen shown to the left.

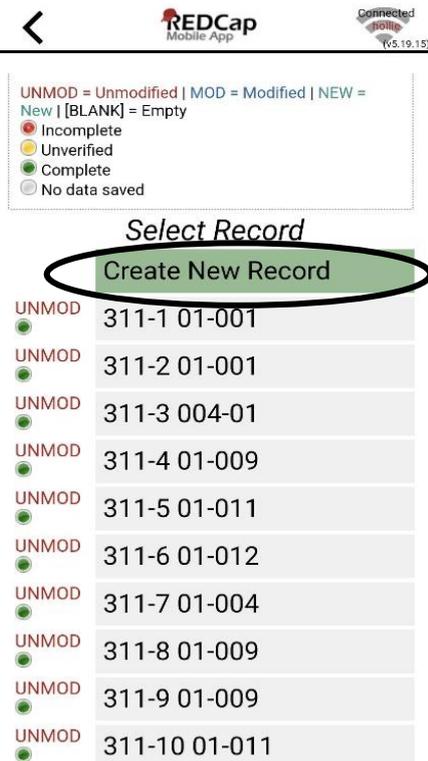
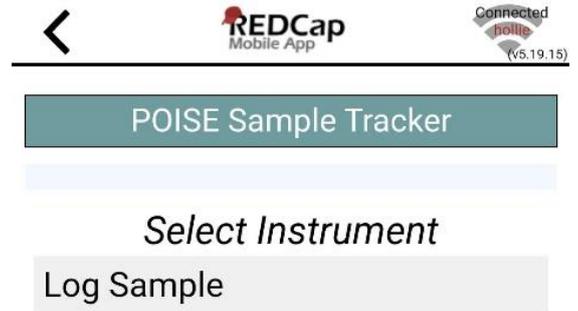


### To add data and scan a barcode



13. Following the download above or after logging in to the REDCap app and clicking on 'My Projects' and selecting the 'POISE sample tracker' the screen on the left will appear. To collect data via this screen click on 'Collect Data' (see ringed item left).

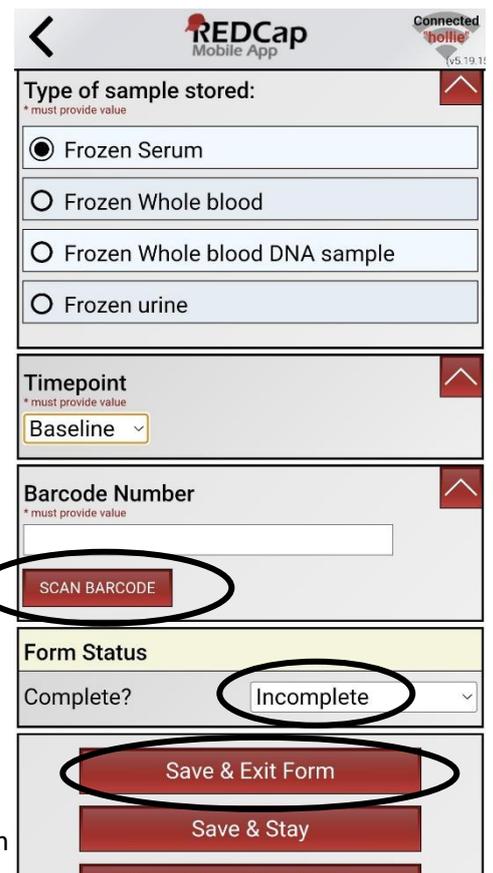
14. This will open the below screen. From there click 'log sample'.



15. This will open the select record screen (see left). From here to enter a new sample click on 'Create New Record' or to edit an existing record click on the desired record.

16. From there fill in the appropriate details requested in the form, possibly using the web browser to check correct date of birth and initials as well as participant ID. To scan the barcode click on 'SCAN BARCODE' which should open a camera for you to scan, making sure the line goes through the centre of the code. Once read the number will be auto filled. If camera does not work the number can also be manually entered.

17. Once the form is complete and you are happy with the details entered. Mark the form as 'complete' and then 'save & exit form' using the drop down and button as shown on the right.



## Syncing data with the database



### Send Data to Server

#### POISE Sample Tracker

To send back the data collected in the mobile app and push it with your project on the REDCap server, press the button below and begin the process of sending the data.

Begin Send of All Data

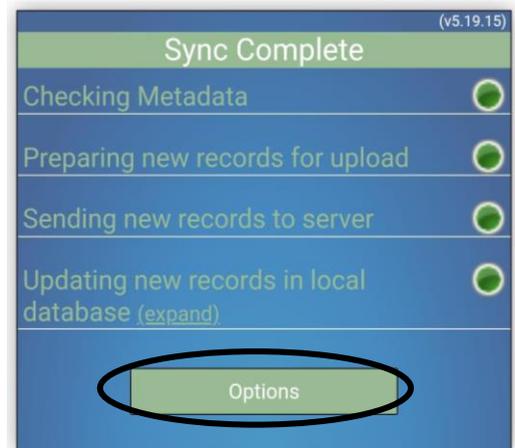
Select a Partial Set of Records

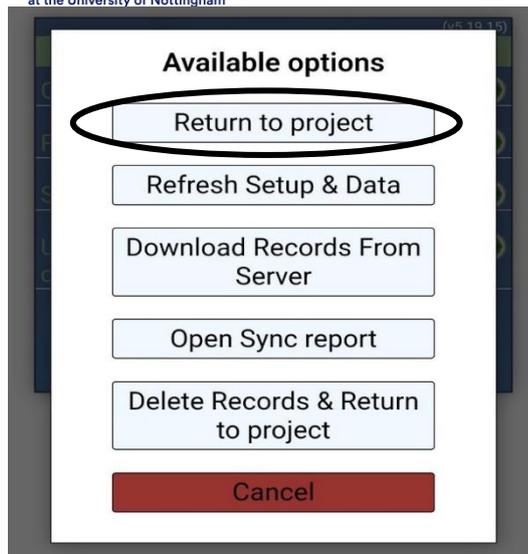
Send Data will look at only new and modified data.

Your project uses autonumbering. The numbers assigned to your records may be reassigned upon upload due to conflicts. Please check the sync report to view any possible reassignments after upload. If a record ID is not reassigned, no message will be made.

19. Once data sync is successful the screen shown to the right should be displayed. From here click on 'options' (ringed).

18. Once saved another menu will appear to sync the data entered to the web server. Click on 'Sync Data to server'. After this the screen to the left will appear. Click on the option you want to use.





20. This will bring up the menu seen left. Then to return to the homepage click 'Return to project'.

Appendix 1. Sample Storage log

Study ID/PIN	Date sample collected	Time samples collected	Time sample processing started	Person processing	Number of aliquots made		Location of samples	Comments/date transferred to UCL freezer
					Serum			
					Plasma			
					Whole blood for DNA			
					Serum			
					Plasma			
					Serum			
					Plasma			
					Serum			
					Plasma			
					Serum			
					Plasma			

					Serum			
					Plasma			
					Serum			
					Plasma			