

Summary Sheet

Tool:	REDCap User Guide: Data Entry, Survey Management and REDCap Randomisation
Purpose:	The Survey Management and Data Entry User Guide Template is used to assist users with entering data and other procedures and activities specific to the clinical trial.
Users:	Data Managers, Trial Managers, Chief Investigators.
Details:	The template should be customized to the protocol, the study's specific needs / circumstances, and the requirements of survey management and data entry. Sections may be edited or deleted as needed.
Best Practice Recommendations:	<p>Items in <i>blue italics</i> and enclosed in square brackets [] are instructional text that should be deleted prior to approval.</p> <p>Items enclosed in single <> are placeholders. Replace as clarified in the enclosed text.</p> <p>Remove this Tool Summary Sheet prior to use of this template.</p>

PCTU Approval for REDCap User Guide

Authorisation:	
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Date	17 March 2021

REDCap User Guide - Document Control

Version	Reason for Change	Author of change	Date Approved
1.0		RD, KM	17.03.2021



AD HOC

Focus groups to co-develop a primary care intervention to promote engagement in an online health community (OHC) for adults with asthma, a survey to recruit participants and a non-randomised feasibility study testing recruitment and the intervention.

REDCap User Guide

**(Data Entry, Survey Management and REDCap
Randomisation)**

Summary of Changes:

Version Number	Version Date	Affected Section(s)	Summary of Revisions Made:
1.0	09-AUG-2023		First User Guide for AD HOC Feasibility Study

2.0	19/09/2023	Section 7.0 onwards	Irrelevant sections removed, study-specific detail added
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1.0. General Data Entry Rules/Notes

Always be careful when entering data, check each screen before saving.

Always log out of database when not in use.

Always enter complete records and save, do not leave the form in the middle of data entry.

The system will timeout after ~10 minutes of inactivity.

Use the mouse or tab key (keyboard) to move between questions and mouse or arrow keys to select the answer. If an incorrect answer is selected, either click on the correct answer to change it or you can click on **reset** to clear the answer.

When you get to the end of a form, change the **Form Status** to COMPLETE (using the dropdown), then click on **Save & Go To Next Form** (use the dropdown to select, if not shown).

Please do ensure that at the end of each session you clearly log out and close the browser.



2.0. Help and Contacts

If you have any queries relating to the database, please contact the AD HOC study team by email on adhoc@qmul.ac.uk.

Please include as much detail about the issue as possible, including screenshots. We may forward your query to our data management team if appropriate.

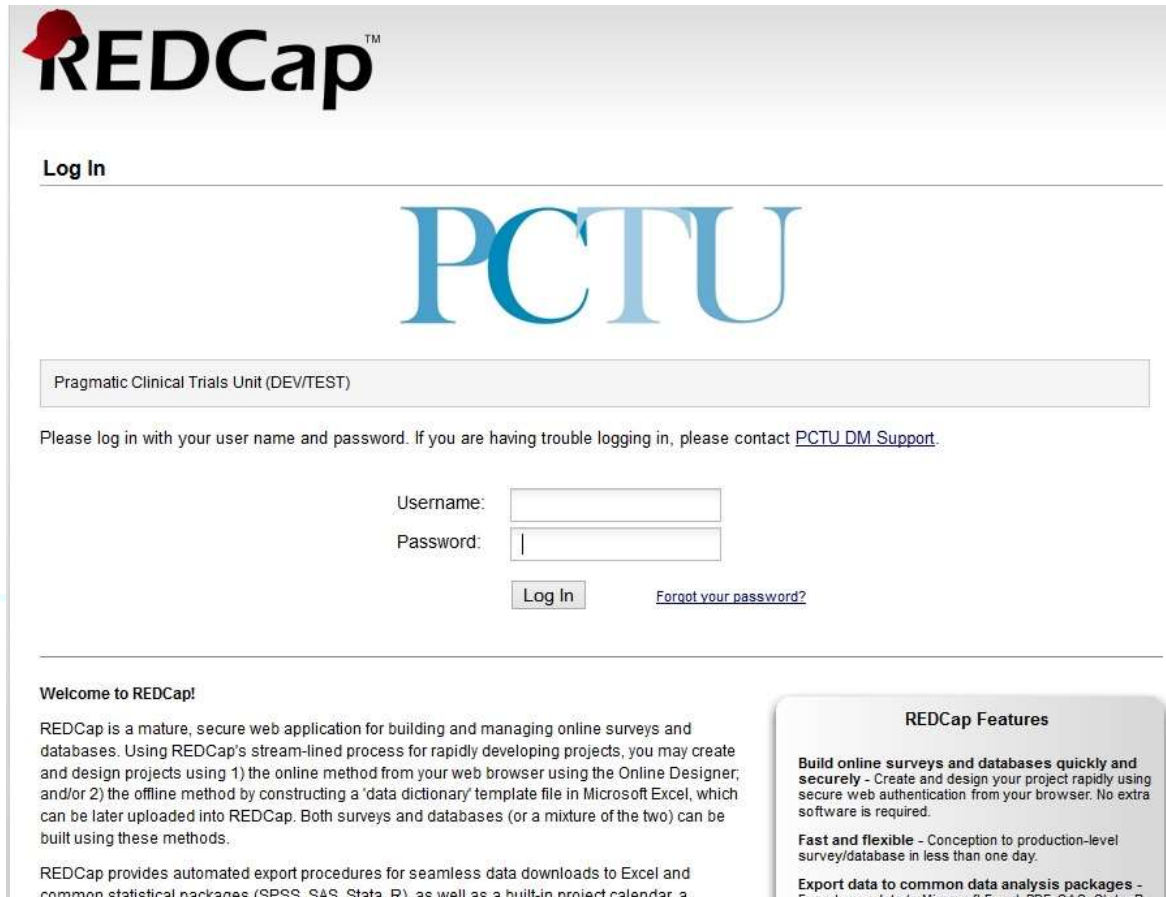
3.0. Logging on to the system

REDCap can be accessed through any of the latest internet browsers including Microsoft Internet Explorer or Microsoft Edge, Mozilla Firefox, Chrome and Apple Safari.

For training purposes, you will be asked to use the test database; please do not enter live data on the **test** system: <https://dm2.pctu.qmul.ac.uk>

Once you are fully trained, you will be given access to the **live** database, for participant data entry: <https://trials2.pctu.qmul.ac.uk/>

You will be presented with the following login screen:



REDCapTM

Log In

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Please log in with your user name and password. If you are having trouble logging in, please contact [PCTU DM Support](#).

Username:

Password:

[Forgot your password?](#)

Welcome to REDCap!

REDCap is a mature, secure web application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar.

REDCap Features

- Build online surveys and databases quickly and securely** - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.
- Fast and flexible** - Conception to production-level survey/database in less than one day.
- Export data to common data analysis packages** - Export your data to Microsoft Excel, SAS, Stata, R.

Open the link you have been sent and enter your username. The first time you access REDCap you will be prompted to create a password and a security question. If you forget your password you can reset it using the **Forgot your password?** Link on the login page. You will be prompted to enter your username to retrieve a temporary password to access your REDCap account.

The REDCap **live** system (section 3.3) is protected by **two-factor authentication** which would normally require you to verify your identity using another device (email, phone or any other security token device); every time you log in you will be presented with the screen below:

Two-step verification for REDCap login

Select an option below to complete the second half of REDCap's two-step verification login process. You will not be able to access REDCap until you have completed this verification step.




Email: Send an email containing your verification code to your email account.
Send to <account email address>

Please click the button and enter the 6 digit REDCap **verification code** you will receive **via email** as shown in the screen below... Please note that the verification code **expires after two minutes**, so if you miss this time window you will need to re-click the button to send another verification code.

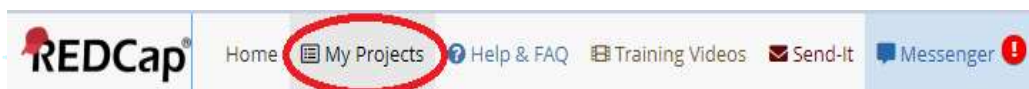
Enter your verification code

Enter the verification code that you obtained from

 **Email**

4.0. Accessing Projects

When you first log in to the system you will be presented with the REDCap **home page** with the following tabs at the top of the page.



Select the **My Projects** tab to see a list of projects which you are authorised to access (please refer to screenshot below), and select **ADHOC Feasibility** (in the test database this will show as ADHOC Feasibility (TEST)):

REDCap Home **My Projects** Help & FAQ Training Videos Send-It Messenger

This is PCTU's DEV/UAT instance of REDCap, and no real study data can be entered on to any of the databases - ONLY TEST DATA IS ALLOWED. Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

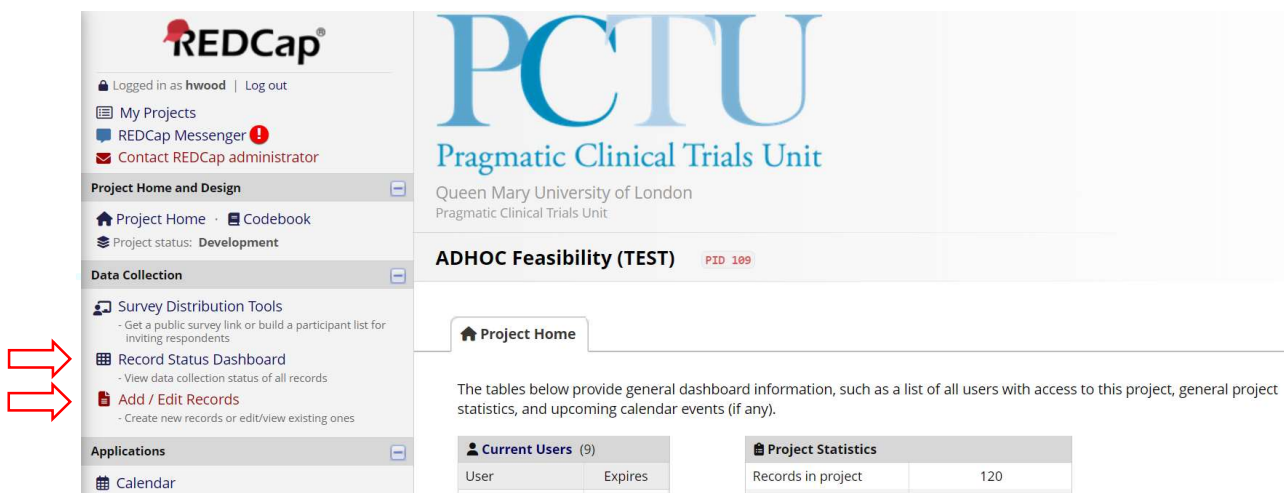
My Projects Filter projects by title

Project Title	Records	Fields	Instruments	Type	Status
ADHOC Feasibility (TEST)	120	228	3 forms 11 surveys		

This will take you to the Project home page of the study database where you can navigate to enter participant data (see section 5.0).

5.0. Home Page and Navigation

The **Project Home** Page looks like this, and shows an overview of the study:



The screenshot shows the REDCap interface for the 'ADHOC Feasibility (TEST)' project. On the left is a navigation panel with sections: 'My Projects', 'Project Home and Design' (containing 'Project Home' and 'Codebook'), 'Data Collection' (containing 'Survey Distribution Tools', 'Record Status Dashboard', and 'Add / Edit Records'), and 'Applications' (containing 'Calendar'). Two red arrows point to the 'Record Status Dashboard' and 'Add / Edit Records' options. The main content area features the PCTU logo, project name, and two summary tables: 'Current Users (9)' and 'Project Statistics' (showing 120 records in project).

On the left of the page you will always have your **navigation panel**, with links to all functionalities and applications you have access to according to your user role (see section 12). You can always click on **Project Home** to get back to this page, or on **My Projects** to get back to the list of projects which you have access to.

You are only likely to need to use two options under the **Data Collection** section of the navigation panel:

Record Status Dashboard: Lists all participants against all events in the study (section 5.13)

Add/Edit Records: Click to select a participant and add data to their record (sections 6.0 and 7.0)

6.0. Adding a participant

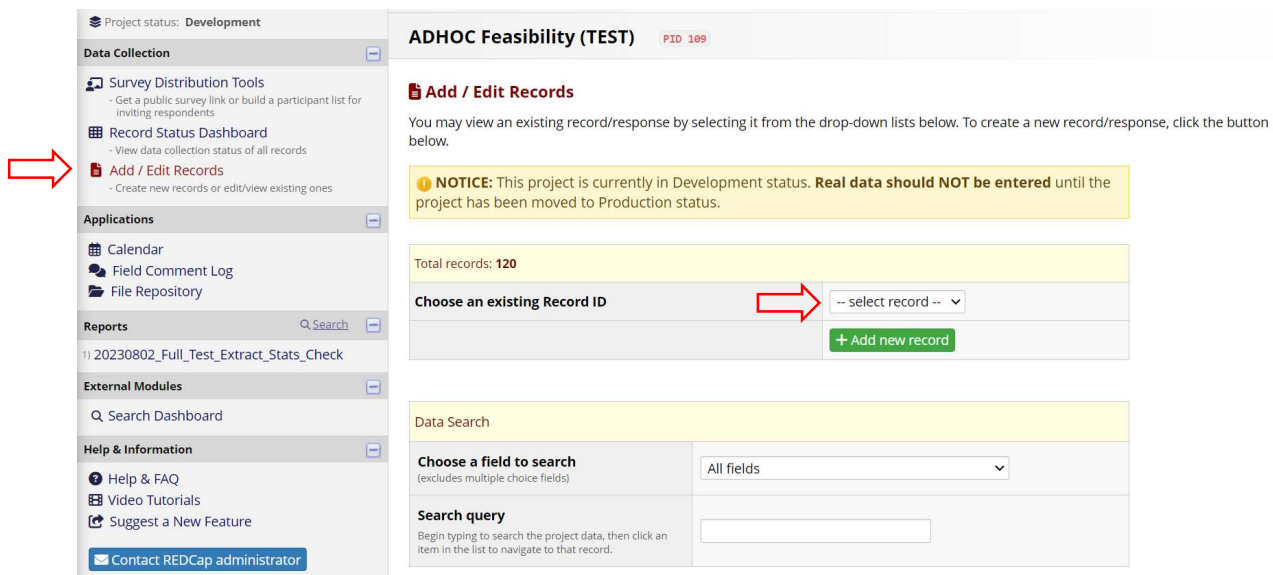
Please note that it is not possible to add new participants to the ADHOC Feasibility database. Participants are added when they complete an online survey sent to all eligible asthma patients by their practice manager via text message. A unique **Record ID** is generated when each online survey is submitted.

The AD HOC study team will have sent you a list of names and corresponding Record IDs for the patients you will be seeing to deliver the study intervention. Go to **section 8.0** for how to select a participant and add data to their record.

7.0. Data Entry

Accessing a Participant's record

To select a participant's record, click on **Add/Edit Records** in the navigation panel on the left of the screen:



Click on the dropdown arrow next to **select record** and scroll to select the correct **Record ID** for your patient (they are in numerical order). This will open the **Record Home Page** for this participant:

ADHOC Feasibility (TEST) PID 109

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:

● Incomplete ? Incomplete (no data saved) ?

● Unverified ✔ Partial Survey Response

● Complete ✔ Completed Survey Response

Record ID **127** [1127]

Data Collection Instrument	Pre-screening Survey	Baseline	Follow-Up	Supplementary
Ad Hoc Welcome Sheet <small>(survey)</small>	✔			
Consent		?		
Baseline-PID Form		?		
Asthma Health <small>(survey)</small>	✔	?	?	
Ehealth Literacy Scale <small>(survey)</small>	✔			
Eq5d5l <small>(survey)</small>	✔	?	?	
Phq8 <small>(survey)</small>	✔	?	?	
GAD-7 <small>(survey)</small>	✔	?	?	
About You Form <small>(survey)</small>	✔			
MARS <small>(survey)</small>		?	?	
General Self Efficacy Scale <small>(survey)</small>		?	?	
Asthma Exacerbations Questions <small>(survey)</small>		?	?	
Asthma OHC Engagement <small>(survey)</small>			?	
Withdrawal				?

You will see a series of green ticks under **Pre-screening Survey**, indicating that the participant has completed the online survey, and a grey button next to **Consent** under **Baseline**. This indicates that the participant is eligible for the Feasibility study (if not eligible, this grey button will not show).

You can also select a participant's record by clicking on **Record Status Dashboard** in the navigation panel on the left of the screen. This will take you to a grid showing all participants in the database, with each form under each event in the study:

ADHOC Feasibility (TEST) PID 109

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete ○ Incomplete (no data saved) ?
- Unverified ● Partial Survey Response
- Complete ● Completed Survey Response

Dashboard displayed: Default dashboard

Displaying record Page 2 of 2: "119" through "138" of **120** records 100 records per page

+ Add new record

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Record ID	Pre-screening Survey							Baseline							Follow-Up							Supplementary				
	Ad Hoc Welcome Sheet	Asthma Health	Ehealth Literacy Scale	Eq5d5l	Phq8	GAD-7	About You Form	Consent	Baseline-PID Form	Asthma Health	Eq5d5l	Phq8	GAD-7	MARS	General Self Efficacy Scale	Asthma Exacerbations Questions	Asthma Health	Eq5d5l	Phq8	GAD-7	MARS	General Self Efficacy Scale	Asthma Exacerbations Questions	Asthma OHC Engagement	Withdrawal	
119	✓	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
120 [1120]	✓	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
121 [1121]	✓	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
122 [1122]	✓	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
123	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
124	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
125	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
126	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
127 [1127]	✓	✓	✓	✓	✓	✓	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

Note the **Record ID** is on the left. Scroll down to find your patient's ID. Please note, you may need to select a different page to find the correct ID number – select the dropdown next to **Displaying record** for a list of pages. Again, you will see a series of green ticks under **Pre-screening Survey**, indicating that the participant has completed the online survey, and a grey button under **Consent** under **Baseline**. This indicates that the participant is eligible for the Feasibility study (if not eligible, this grey button will not show).

Whichever way you have accessed the participant record, you will next need to click on the grey button under or next to **Consent** in order to start the consultation with the patient and to start entering data.

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Completing Forms

General Points

All fields marked **must provide value* are required and must be completed. Fields not marked with an asterisk are not required and can be left blank. Leaving a required field blank will prompt the following message upon saving:

NOTE: Some fields are required!

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- **Date of visit**

Click **Okay** to go back to the form to complete the missing required fields. Please do not click **Ignore and leave record** or **Ignore and go to next form** – go back and enter the required data.

There are **9 forms** to complete under the **Baseline** event. Once you have clicked on **Consent**, you will see the list of forms in the **navigation panel**. The button for each form will change to green once it has been completed and saved.

Record ID **141** [baseline_arm_1][1141] [Select other record](#)

Event: **Baseline**

Data Collection Instruments:

- Consent**
- Baseline-PID Form
- Asthma Health
- Eq5d5l
- Phq8
- GAD-7
- MARS
- General Self Efficacy Scale
- Asthma Exacerbations Questions

You will need to complete each form in turn, showing the screen to the patient and either reading the text to them or asking them to read it themselves, and answer the questions as indicated by the patient. The majority of questions use buttons to select one answer from a choice of 4 or 5. If an incorrect answer is selected or the patient wants to change their answer, click the **reset** button, at the right of the screen, and then select the correct answer.

Consent

Click on the grey button under or next to **Consent** to open the **Consent Form**:

Editing existing Record ID **141**. [baseline_arm_1][1141]

Event: **Baseline**

Record ID 141


Consent Form

Title of Research Study: Focus groups to co-develop a primary care intervention to promote engagement in an online health community (OHC) for adults with asthma, a survey to recruit participants and a non-randomised feasibility study testing recruitment and the intervention - Feasibility study.

Thank you for your interest in this research.

Please indicate whether you agree with each of the following statements, then sign your name and date the consent form if you decide you want to participate in this research. Your electronic signature confirms that you are willing to participate, however, you are free to withdraw your participation at any time.

Full participant information sheet (PIS) is available [here](#)

Attachment:  [PIS_Feasibility_study_patients_V2.0_30.01.2023.pdf](#) (0.56 MB)

1. I confirm that I have read and understood the information sheet [version 2.0, 30.01.2023] for the above study; or it has been read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. Yes No

* must provide value reset

Participant name

* must provide value

At the top of the page, you will see the **Record ID** and further down the page, the **Participant name** – check that these are correct. Show the screen to the patient and either read the text to the patient or ask the patient to read it themselves. The first question confirms that the patient has **read the PIS** and had the opportunity to ask questions. They will have been sent the PIS to read beforehand, but if they want to look at it you can open the PDF using the link. Click the button next to Yes to continue to the next question.

Read through and answer the questions with the patient – each subsequent question appears once Yes is clicked (10 questions in total). Note that questions 8 and 9 are optional – the patient can answer No to these.

Ask the patient to add their **signature and date**, then add your **name, signature and date**.

To add your name, click in the box and type using the keyboard. To sign, click on **Add signature** to bring up the signature box and sign (as best you can) using the mouse. Click on **Save signature**. Click on **Today** to add today's date.

Participant name <small>* must provide value</small>	<input type="text" value="Helen Wood"/>
Participant Electronic signature <small>* must provide value</small>	Add signature
Participant signature Date <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> <small>D-M-Y</small>
Name of person taking consent <small>* must provide value</small>	<input type="text"/>
Clinician Electronic signature <small>* must provide value</small>	Add signature
Clinician signature date <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> <small>D-M-Y</small>



Add signature ✕

Participant Electronic signature* must provide value

SIGN HERE



Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form** (if a different option is shown, click on the dropdown to change it – other options are Save & Stay, Save & Exit Record).

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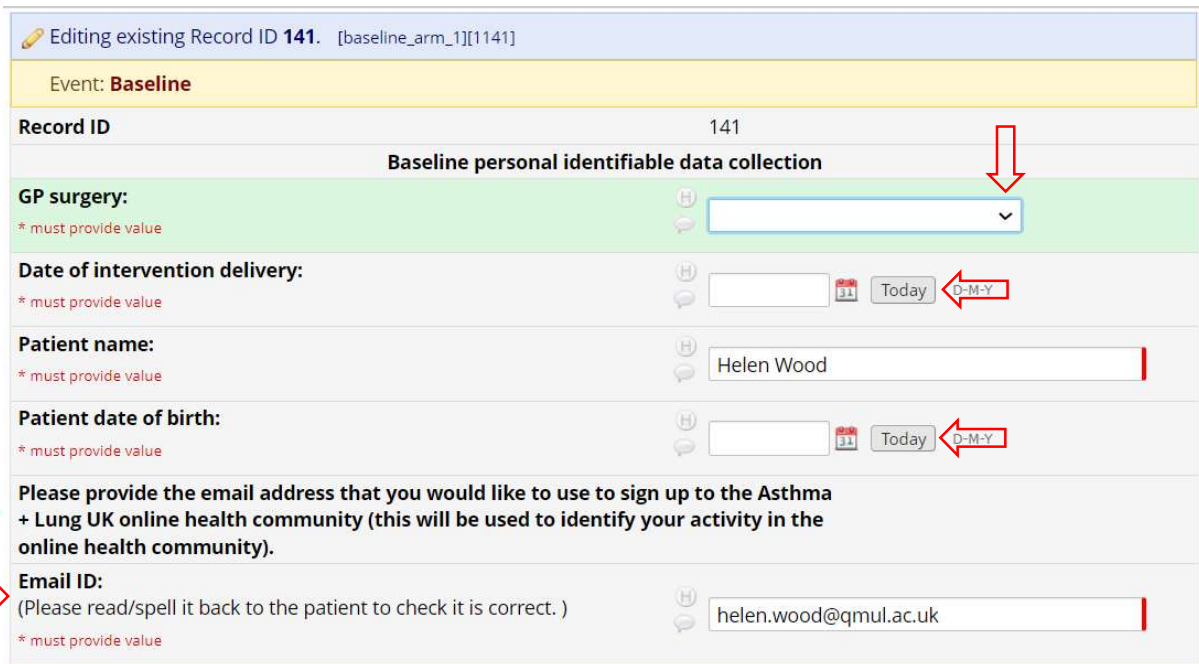
Form Status	<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> <input type="button" value="- Cancel -"/>
Complete?	<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> <input type="button" value="- Cancel -"/>
	<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> <input type="button" value="- Cancel -"/>
	<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> <input type="button" value="- Cancel -"/>



Baseline-PID Form

Select the **GP surgery** from the dropdown list and add the **date** (click on **Today**).

The patient's name and email address will have been auto-filled using data from the online survey they completed. Add their **date of birth** and check that their **email address** is correct and is the address they want to use to sign up to the Asthma Forum. If not, please edit it accordingly.



Editing existing Record ID 141. [baseline_arm_1][1141]

Event: **Baseline**

Record ID 141

Baseline personal identifiable data collection

GP surgery:
* must provide value

Date of intervention delivery:
* must provide value

Patient name:
* must provide value
Helen Wood

Patient date of birth:
* must provide value

Please provide the email address that you would like to use to sign up to the Asthma + Lung UK online health community (this will be used to identify your activity in the online health community).

Email ID:
(Please read/spell it back to the patient to check it is correct.)
* must provide value
helen.wood@qmul.ac.uk

To add the date manually, for date of birth, click in the box and type using the keyboard, e.g. 1.1.23 or 1/1/23. Patients must be aged over 18 to be eligible. This will have been verified by the study team, but if you incorrectly enter a date after 01/09/2005, you will see a warning message and a warning box will pop up:



Alert

The value you provided is outside the suggested range (no limit - 01-09-2005). This value is admissible, but you may wish to double check it.


Close

Click on **Close**, correct the date entered and the warning will disappear.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

Asthma Health

This section includes the 5 questions of the **Asthma Control Test (ACT)** which most patients will be familiar with. **Select ONE answer for each question**, as indicated by the patient. The **ACT score** is automatically calculated and shown at the end.

Asthma Control Test	
This section is about your asthma symptoms. For each question, select the answer from the dropdown list that best applies to you.	
<p>In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or home?</p> <p><small>* must provide value</small></p>	<p> <input type="radio"/> All of the time <input type="radio"/> Most of the time <input checked="" type="radio"/> Some of the time <input type="radio"/> A little of the time <input type="radio"/> None of the time </p> <p style="text-align: right;"><small>reset</small></p>
<p>During the past 4 weeks, how often have you had shortness of breath?</p> <p><small>* must provide value</small></p>	<p> <input type="radio"/> More than once a day <input type="radio"/> Once a day <input type="radio"/> 3 to 6 time a week <input checked="" type="radio"/> Once or twice a week <input type="radio"/> Not at all </p> <p style="text-align: right;"><small>reset</small></p>
<p>During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?</p> <p><small>* must provide value</small></p>	<p> <input type="radio"/> 4 or more nights a week <input type="radio"/> 2 or 3 nights a week <input type="radio"/> Once a week <input checked="" type="radio"/> Once or twice in the past 4 weeks <input type="radio"/> Not at all </p> <p style="text-align: right;"><small>reset</small></p>
<p>During the past 4 weeks, how often did you have to use your rescue (blue) inhaler or nebuliser medication?</p> <p><small>* must provide value</small></p>	<p> <input type="radio"/> 3 or more times a day <input type="radio"/> 1 or 2 times a day <input type="radio"/> 2 or 3 times a week <input checked="" type="radio"/> Once a week or less <input type="radio"/> Not at all </p> <p style="text-align: right;"><small>reset</small></p>
<p>How would you rate your asthma control over the past 4 weeks?</p> <p><small>* must provide value</small></p>	<p> <input type="radio"/> Not controlled at all <input type="radio"/> Poorly controlled <input type="radio"/> Somewhat controlled <input checked="" type="radio"/> Well controlled <input type="radio"/> Completely controlled </p> <p style="text-align: right;"><small>reset</small></p>
<p>ACT score</p>	<p style="text-align: center;">  <input type="text" value="19"/> <small>View equation</small> </p>

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form** (if the patient isn't eligible to continue, click on **Save & Exit Form**).

EQ-5D-5L

The next section is a standardised questionnaire about **quality of life**, with 5 questions and a sliding numerical scale. **Select ONE answer for each question.** For the **sliding scale**, click on the slider and drag it up or down to the correct number, as indicated by the patient. The number is shown in the box below.

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

- 100 means the **best** health you can imagine. 0 means the **worst** health you can imagine.
- Please click on the scale to indicate how your health is TODAY.

* must provide value

100 - The best health you can imagine

50

0 - The worst health you can imagine

50

reset

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

PHQ-8

This is a standardised questionnaire about symptoms of depression, with 8 questions. **This section is not required – the patient can skip the whole section or any of the questions.** If they are happy to continue, select ONE answer for each question.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**. If any (or all) questions have not been answered, a warning box will pop up when you click save. Click on **exclude** and click **close**. Click on **Save & Go To Next Form** again.

WARNING: Data Quality rules were violated!

The Data Quality rules listed below were found to have discrepancies for this record. Review the table below to see which rules were violated so that the data values for the fields involved can be corrected, if necessary. You may exclude a result in the table by clicking the 'exclude' link on the right side, after which that rule will no longer be displayed for this record whenever the record is saved.

Rule(s) violated	Fields involved	Exclude
Rule #7: Please complete all the questions in this section (PHQ-8) [event-name]='baseline_arm_1' and ([phq8_1]='' or [phq8_2]='' or [phq8_3]='' or [phq8_4]='' or [phq8_5]='' or [phq8_6]='' or [phq8_7]='' or [phq8_8]='')	event-name: phq8_1: phq8_2: phq8_3: phq8_4: phq8_5: phq8_6: phq8_7: phq8_8:	exclude

Close

GAD-7

This is a standardised questionnaire about symptoms of anxiety, with 8 questions. **This section is not required – the patient can skip the whole section or any of the questions.** If they are happy to continue, select ONE answer for each question.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**. If any (or all) questions have not been answered, a warning box will pop up when you click save, as for the PHQ-8 above. Click on **exclude** and click **close**. Click on **Save & Go To Next Form** again.

MARS

The next section is a standardised questionnaire about **taking medication**, with 10 questions. If the patient queries which medication this is referring to, say that it refers to any/all medication that they take. **Select ONE answer for each question.**

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

General Self Efficacy Scale

This is a standardised questionnaire about how the person views their ability to perform tasks, with 10 questions. Select ONE answer for each question.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

Asthma Exacerbations Questions

This section is about any **asthma exacerbations** the patient may have had, **during the last 3 months**. There are 5 questions, asking about asthma symptoms with increasing severity and about time off work. For each question, if they answer Yes, this leads to a second question requiring further detail (branching questions). If they answer No, the branching question remains hidden.

This section is about any asthma exacerbations you may have had, during the last 3 months

During the last 3 months, have you experienced an onset or worsening of your asthma symptoms, but not needed to visit the GP or hospital?

* must provide value

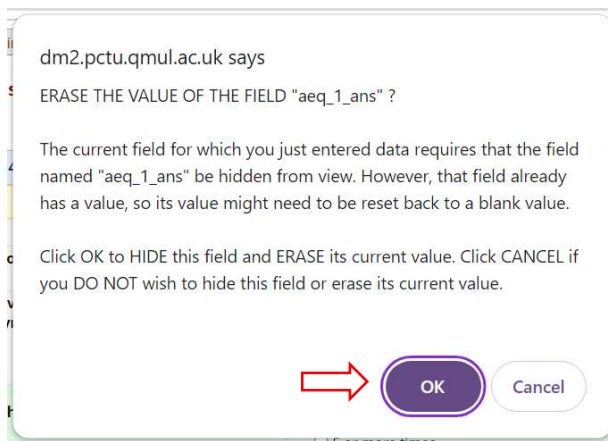
Yes No

If Yes, how many times has this happened in the last 3 months?

* must provide value

Once 2-4 times 5 or more times

If, having answered Yes and answered the branching question, you try to change the answer of the first question to No, a warning will pop up because the answer to the branching question will no longer be valid. Click **OK** and the answer to the branching question will be deleted.



Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Exit Form**. This is the final form, so the option to Save & Go To Next Form will not be shown. This will take you back to the **Record Home Page** and you will see 9 green dots under **Baseline** – indicating that all forms have been completed. At this point, **no further data entry is required** and you can move on to the intervention delivery. Logout of REDCap at this point, or at the end of the consultation.

✓ Record ID 141 successfully edited.

Record ID 141 [1141]

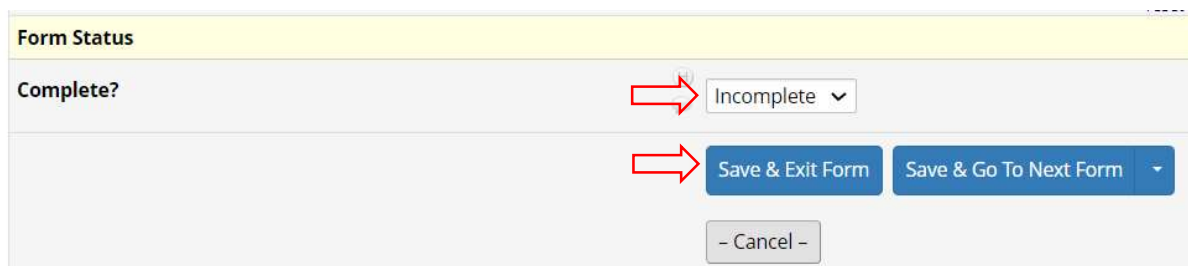
Data Collection Instrument	Pre-screening Survey	Baseline	Follow-Up	Supplementary
Ad Hoc Welcome Sheet (survey)	✓			
Consent		●		
Baseline-PID Form		●		
Asthma Health (survey)	✓	●	○	
Ehealth Literacy Scale (survey)	✓			
Eq5d5l (survey)	✓	●	○	
Phq8 (survey)	✓	●	○	
GAD-7 (survey)	✓	●	○	
About You Form (survey)	✓			
MARS (survey)		●	○	
General Self Efficacy Scale (survey)		●	○	
Asthma Exacerbations Questions (survey)		●	○	
Asthma OHC Engagement (survey)			○	
Withdrawal				○

8.0. Participant withdrawal

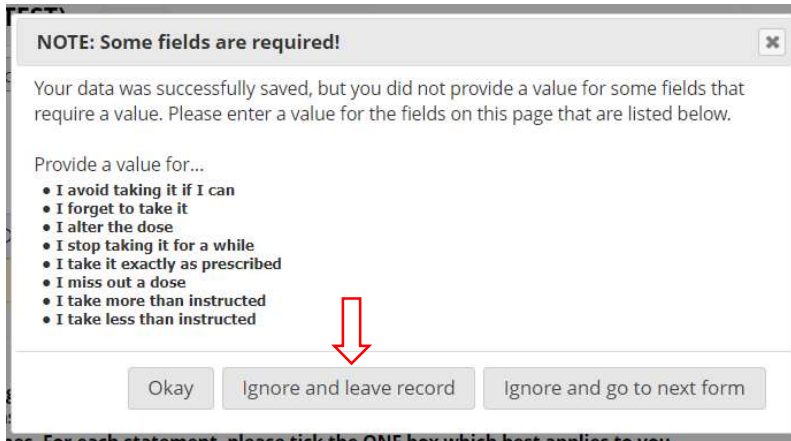
If a patient decides to withdraw

Participants are free to withdraw from the study at any point without needing to give an explanation. If a patient decides during the baseline consultation that they don't want to take part in the study, then that is absolutely within their rights to do so. Please reassure the patient that their withdrawal will have no impact on their future care and thank them for their time.

You will need to terminate the data entry and consultation at this point. If you are part way through one of the forms on REDCap, leave the **Form Status** as INCOMPLETE and click on **Save & Exit Form**.



If you are on any form other than the PHQ-8 or GAD-7, a warning box will pop up to prompt you to complete the missed questions. You should click on **Ignore and leave record**.



Please give the patient the AD HOC tote bag, pen and gift card, but do not include the patient leaflet. If they have any questions which you cannot answer, please advise them to contact the AD HOC Study team on adhoc@qmul.ac.uk.

Recording a withdrawal

Please record the patient withdrawal in the **Site File** and **email the AD HOC Study team** adhoc@qmul.ac.uk to inform us of the withdrawal and reason (if given). Please include the patient's **Record ID and the GP surgery name and date of consultation**, but do not send any identifiable patient details.

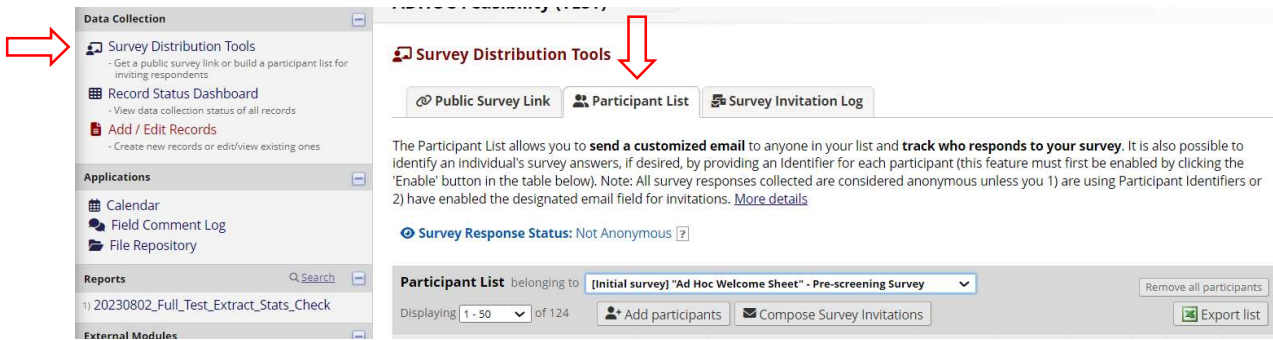
The study team will complete the withdrawal form in REDCap. If a **Read Code** has been added to the patient's record indicating their participation in the AD HOC study, this will need to be removed.

9.0. For the AD HOC Study team only

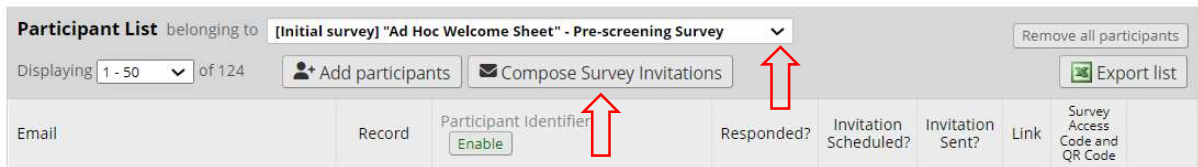
Please note this section is for the attention and use of the ADHOC Study team only, not for clinicians.

Sending the follow-up questionnaire

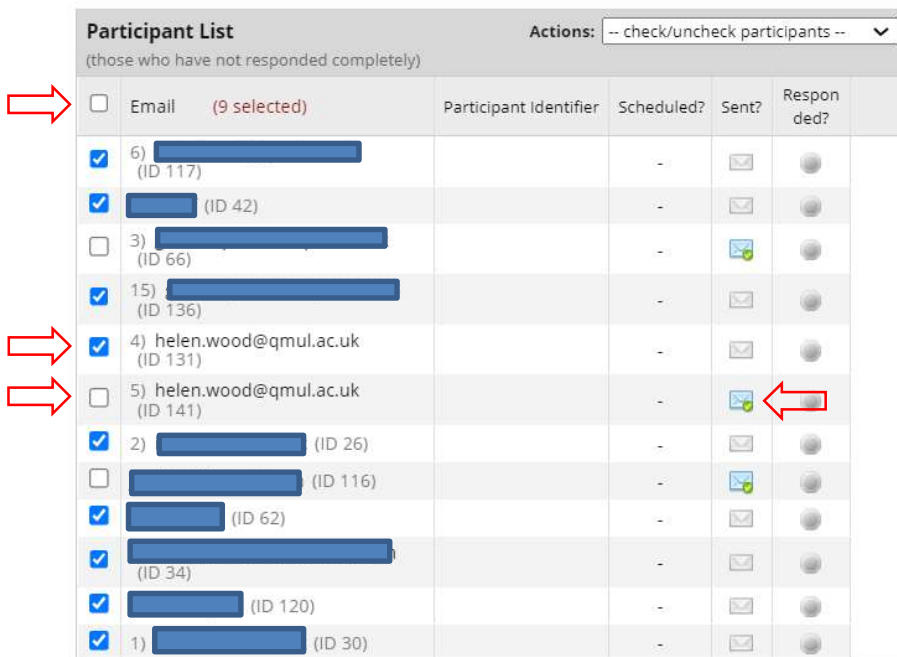
From the navigation panel, under **Data Collection**, click on **Survey Distribution Tools**, and select the **Participant List** tab.



Change the Participant List belonging to to 'Asthma Health – Follow-Up' using the dropdown, and click on **Compose Survey Invitations**.



This will open a pop up. On the right of the pop up there is a list (in alphabetical order) of the email addresses for all survey participants who are eligible for the feasibility study but HAVE NOT completed the follow-up questionnaire. **Blue ticked boxes** will show next to those addresses where the follow-up questionnaire hasn't yet been sent; **unticked boxes** will show next to those addresses which have been sent the questionnaire, but not yet completed it. For the latter, there will also be a blue envelope with green tick under **Sent?**. The **Record ID** is shown in brackets under or next to the email address.

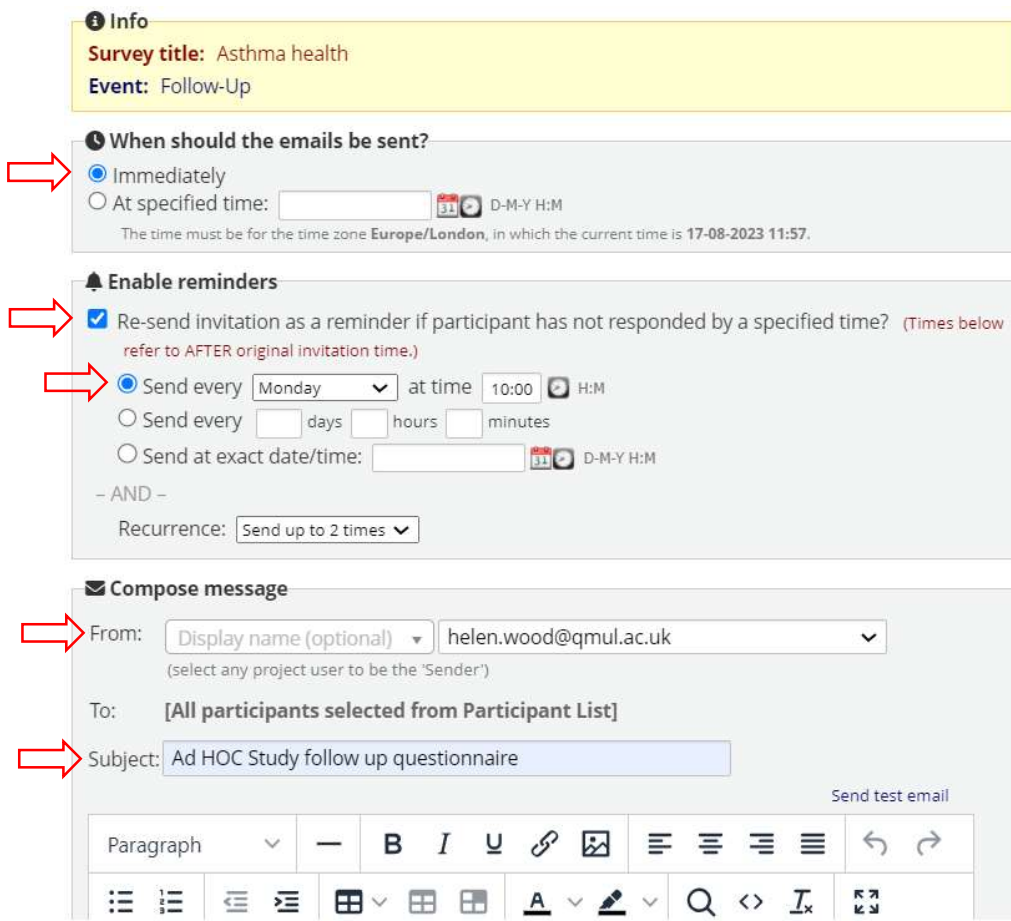


<input type="checkbox"/>	Email (9 selected)	Participant Identifier	Scheduled?	Sent?	Responded?
<input checked="" type="checkbox"/>	6) [redacted] (ID 117)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	[redacted] (ID 42)		-		<input type="checkbox"/>
<input type="checkbox"/>	3) [redacted] (ID 66)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	15) [redacted] (ID 136)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	4) helen.wood@qmul.ac.uk (ID 131)		-		<input type="checkbox"/>
<input type="checkbox"/>	5) helen.wood@qmul.ac.uk (ID 141)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	2) [redacted] (ID 26)		-		<input type="checkbox"/>
<input type="checkbox"/>	[redacted] (ID 116)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	[redacted] (ID 62)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	[redacted] (ID 34)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	[redacted] (ID 120)		-		<input type="checkbox"/>
<input checked="" type="checkbox"/>	1) [redacted] (ID 30)		-		<input type="checkbox"/>

You can either send the email with the follow-up questionnaire to all those addresses with blue ticked boxes (i.e. those that haven't received it), or select specific address(es) by **unchecking all** using the box next to **Email** then checking the one(s) you want to send it to.

Once you have selected the address(es) you want to email, move to the panel on the right of the pop-up screen. Select **immediately** to send the questionnaire straight away. Select **Enable reminders** and specify when you want reminders to be sent (1 week and 2 weeks after the initial email: select the weekday and time at which you are sending the first email and for recurrence, select send up to two times).

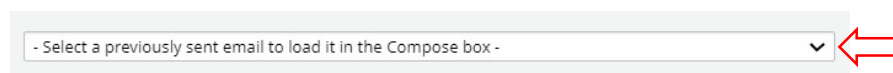
Under **Compose message**, change the **From address** to ADHOC@qmul.ac.uk and **Display name** to AD HOC Study Team, and add the **Subject** (AD HOC Study follow-up questionnaire).



The screenshot shows the email configuration interface with several sections highlighted by red arrows:

- Info:** Survey title: Asthma health; Event: Follow-Up
- When should the emails be sent?:** Immediately; At specified time: [calendar icon] D-M-Y H:M. Note: The time must be for the time zone Europe/London, in which the current time is 17-08-2023 11:57.
- Enable reminders:** Re-send invitation as a reminder if participant has not responded by a specified time? (Times below refer to AFTER original invitation time.)
 - Send every **Monday** at time **10:00** H:M
 - Send every [] days [] hours [] minutes
 - Send at exact date/time: [calendar icon] D-M-Y H:M
- Compose message:**
 - From:** Display name (optional) [] helen.wood@qmul.ac.uk []
 - To:** [All participants selected from Participant List]
 - Subject:** Ad HOC Study follow up questionnaire

The first time the follow-up survey is sent, the text of the email will need to be composed, but subsequently, you can re-use the same email by using the dropdown next to **Select a previously sent email...**, below the body of the email.



The screenshot shows a dropdown menu with the text: - Select a previously sent email to load it in the Compose box - [dropdown arrow]. A red arrow points to the dropdown arrow.

Check the text of the email and double check all the details entered/selected before clicking **Send Invitations** at the bottom right of the screen.

Survey link

Please note, the **URL** for the **AD HOC eligibility survey** can be found under the **Public Survey Link** tab on **Survey Distribution Tools**, should you need it (note that the URL shown in the screenshot below is that for the TEST database survey).

Survey Distribution Tools

 Public Survey Link

 Participant List

 Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

 **Public Survey URL:** 

Completing the withdrawal form

If a participant requests to withdraw from either the survey or the feasibility study, the **Withdrawal form** will need to be completed on REDCap by a member of the AD HOC Study team. The Withdrawal form is located under the **Supplementary** event in the patient record.

To begin, click **Yes** next to **Participant withdrawn...** and this will open the rest of the form.

Withdrawal

Editing existing Record ID 141. [supplementary_arm_1][1141]

Event: **Supplementary**

Record ID 141

THIS FORM IS FOR PARTICIPANTS WHO WISH TO WITHDRAW FROM THE **AD HOC** FEASIBILITY STUDY AND THEREFORE NO FURTHER CONTACT SHOULD BE MADE. **ONLY** COMPLETE THIS FORM IF THE PARTICIPANT HAS REQUESTED TO WITHDRAW FROM THE **AD HOC** FEASIBILITY STUDY OR IF ANOTHER PARTY (E.G. CLINICIAN) HAS DECIDED THAT THE PARTICIPANT SHOULD BE WITHDRAWN.

IF A PARTICIPANT COULD NOT BE CONTACTED FOR FOLLOW-UP THEY ARE NOT AUTOMATICALLY WITHDRAWN.

Participant withdrawn from AD-HOC feasibility study? Yes No ←

* must provide value

Form Status

Complete? Incomplete

Save & Exit Form Save & Stay

- Cancel -

Complete the questions, including the additional branching questions, as relevant.

Participant withdrawn from AD-HOC feasibility study? Yes No

* must provide value

GP surgery:

* must provide value

Date the participant was withdrawn Today D-M-Y

* must provide value

Who requested withdrawal?:

* must provide value

Primary reason for withdrawal

* must provide value

Point at which participant was withdrawn

* must provide value

Once the form is complete, change the **Form Status** to COMPLETE and click **Save & Exit**.

The AD HOC Team may be informed of a participant withdrawal by the participant themselves or by their GP practice. The PI may also decide that a participant should be withdrawn. If notification comes to the team from the participant or from the PI, the **GP practice should be informed** at the earliest opportunity, as per the relevant SOP (**ADHOC feasibility SOP_03 Participant withdrawal**) and be requested to follow the procedures therein.