# The GenOMICC Study

## Genetics of Mortality in Critical Care

**Completion guide for REDCap data entry**

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THE UNIVERSITY of EDINBURGH
Baillie Gifford Pandemic Science Hub

ROSLIN

# REDCap – electronic case report form

- REDCap is the electronic database we use to collect clinical data.
- We call each record an ‘electronic case report form’ or 'eCRF' for short.
- We link each eCRF to a participant sample, so it is essential that samples are labelled with a GCC_ID that matches their eCRF entry.
- We will let you know each month if we have any data queries relating to your eCRFs.

# Getting Started

- GenOMICC REDCap access can be requested by emailing the study team **genomicc@roslin.ed.ac.uk** and providing your:
  - name
  - email address - (must be an NHS email)
  - site (hospital) name

- Each site has its own REDCap data entry group and participant ID stickers. If data is being added across more than one site within your Trust, please let us know and we will set up additional REDCap accounts for you.

- Log-on details will be emailed directly to all new users.

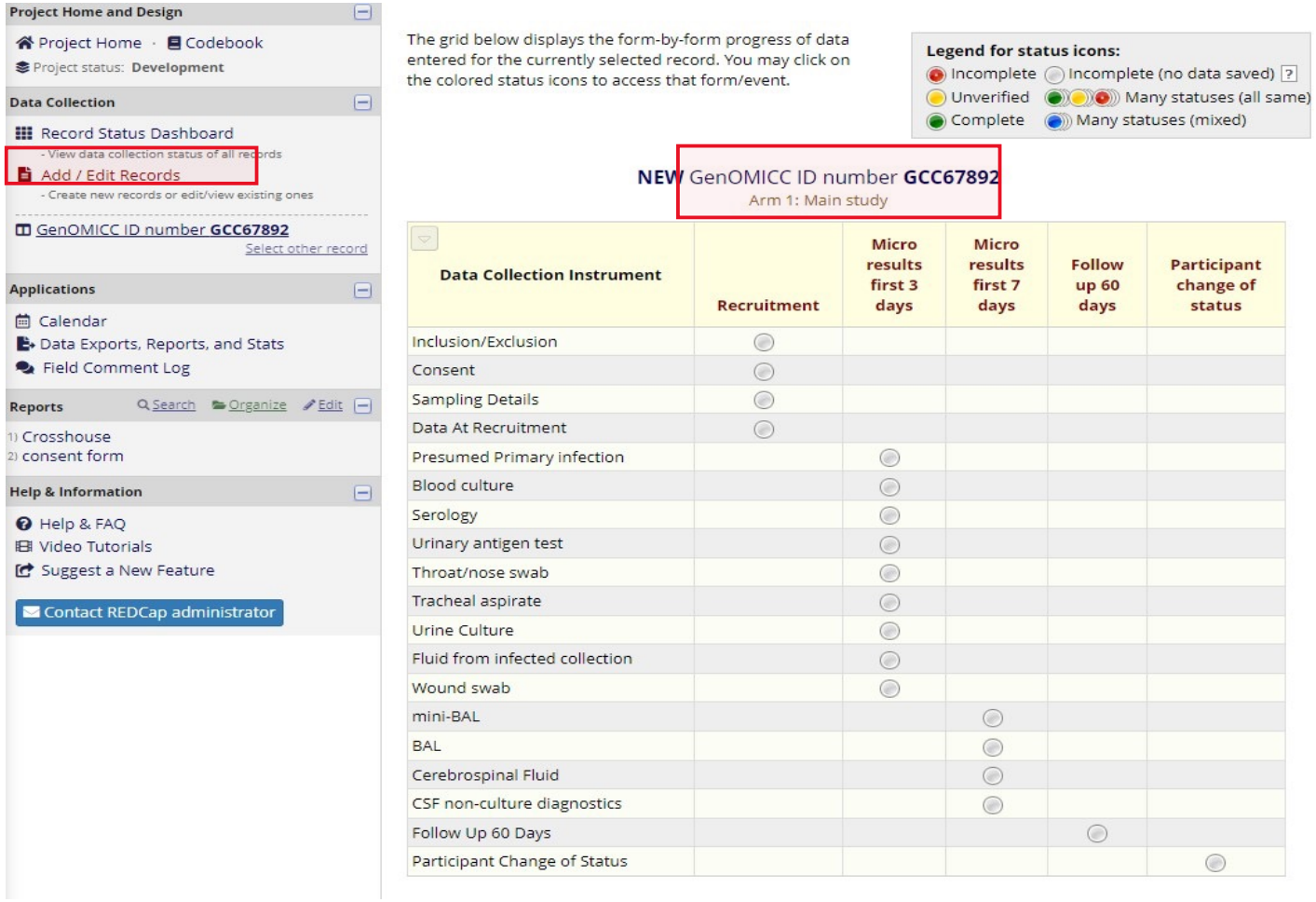
Before adding a new record to REDCap, read through this guide to see how eCRFs are created and completed

# Entering the patient ID

- The GenOMICC ID for each patient is the barcode number on the pre-printed stickers found inside each specimen kit.
- The ID number should always be entered into the eCRF exactly as it is shown on the label ‘GCCxxxxx’.
- This is GCC (uppercase) followed by 5 digits. Please don’t add in spaces or hyphens.
- If you do make a mistake entering the patient GCC_ID, please continue to enter the data and then let us know what the correct number should be. We can correct this for you without the need to add a new record.


It is important that the GCC_ID entered on the eCRF matches the sample GCC_ID.

# Creating or editing a record




Click ‘Add/Edit Records' to create a new record or alter an existing one.

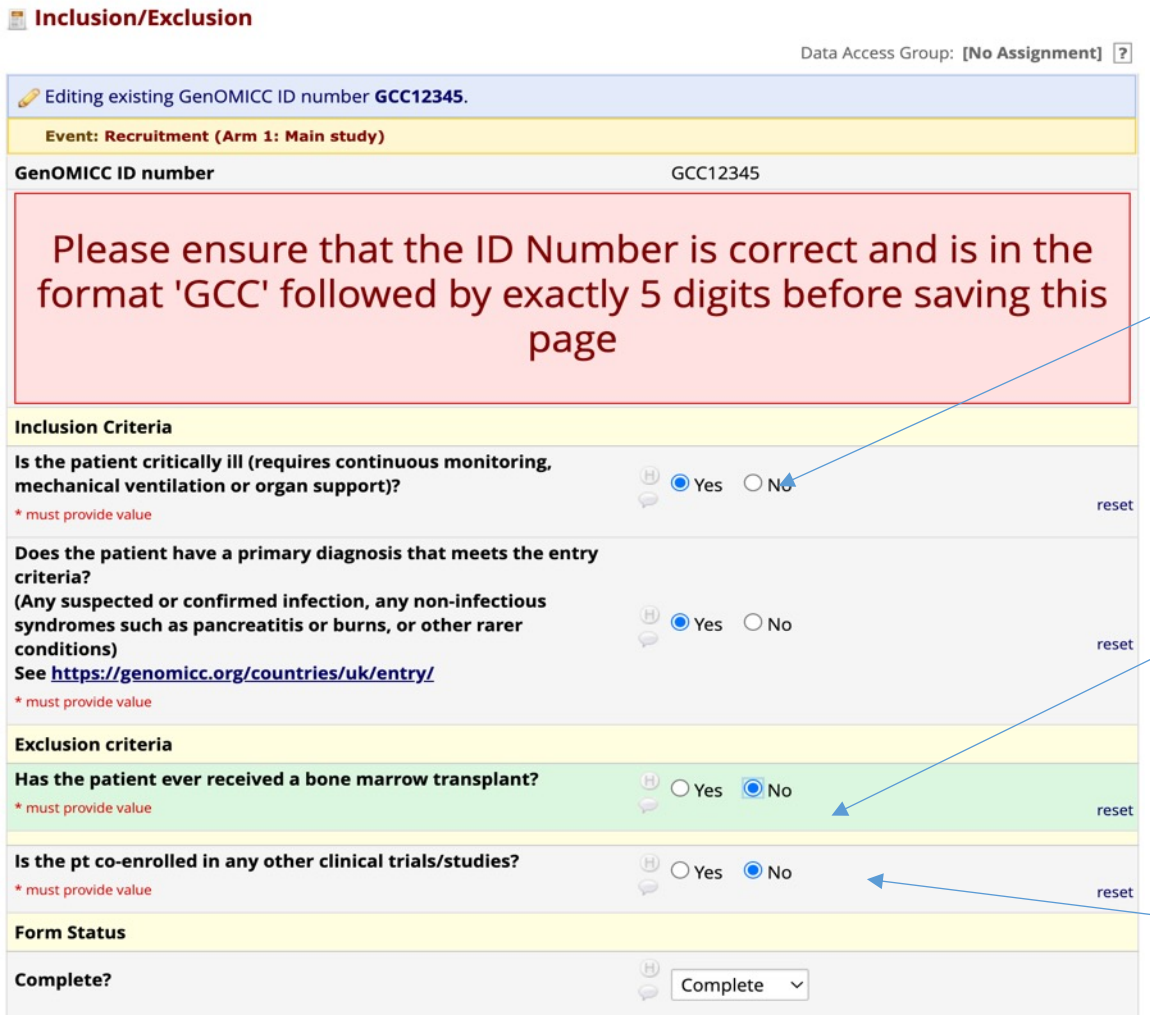
A box will pop up where a new (or existing) GCC_ID can be added.

Always add patient records into Arm 1: Main study.

The GCC_ID used to create the eCRF should match the sample ID for each patient.

Move through each page remembering to save.

# Inclusion/Exclusion

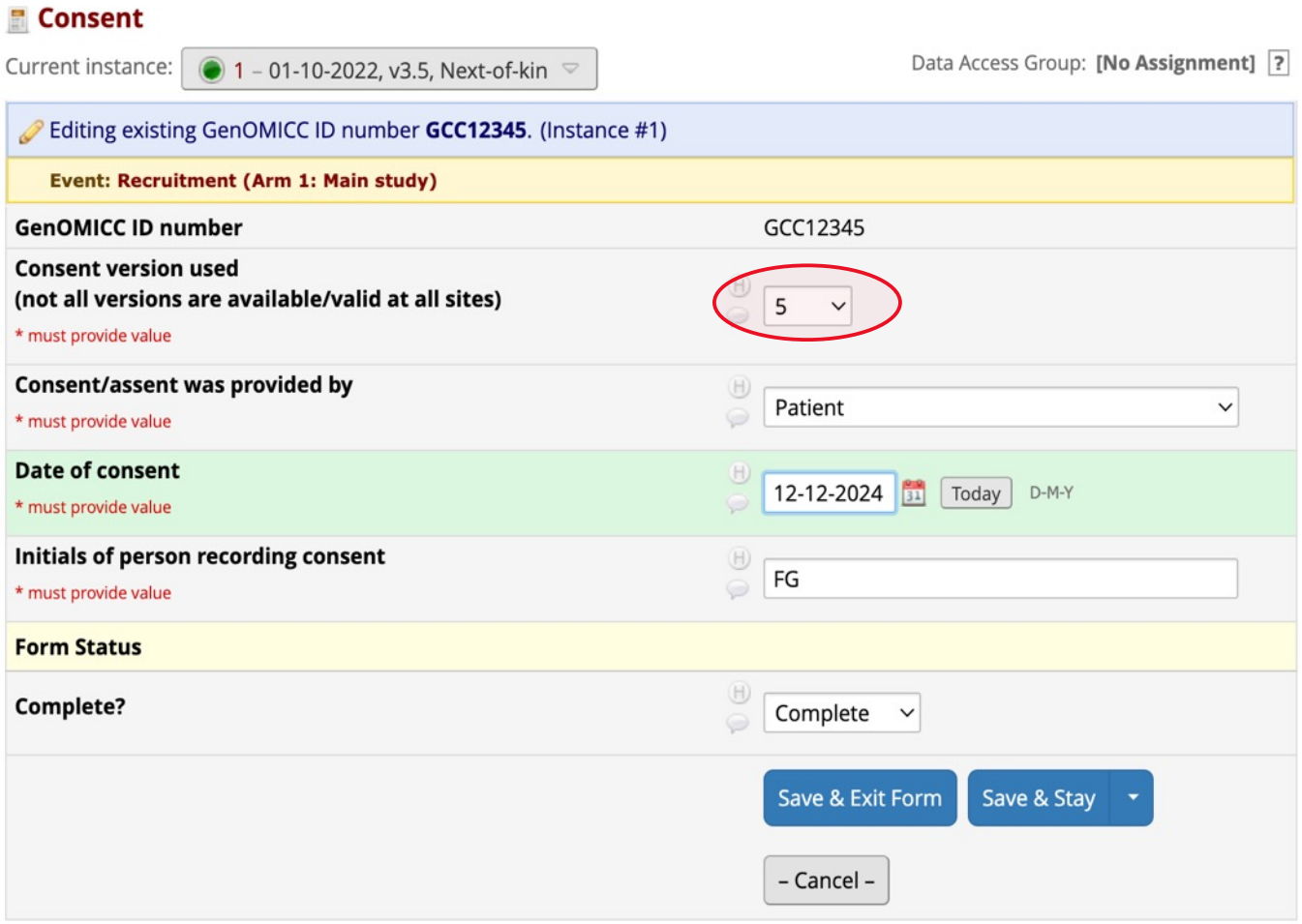



This should always be yes. Although, the patient does not need to be undergoing the monitoring at the actual time of recruitment. Once a patient is eligible for GenOMICC, they remain so for the rest of their lives.

There is only one exclusion to recruitment and that's if a patient has had a bone marrow transplant.

If the patient is enrolled in other studies, select 'yes' – new fields will appear where we ask for the name of the study and ID number.

# Consent

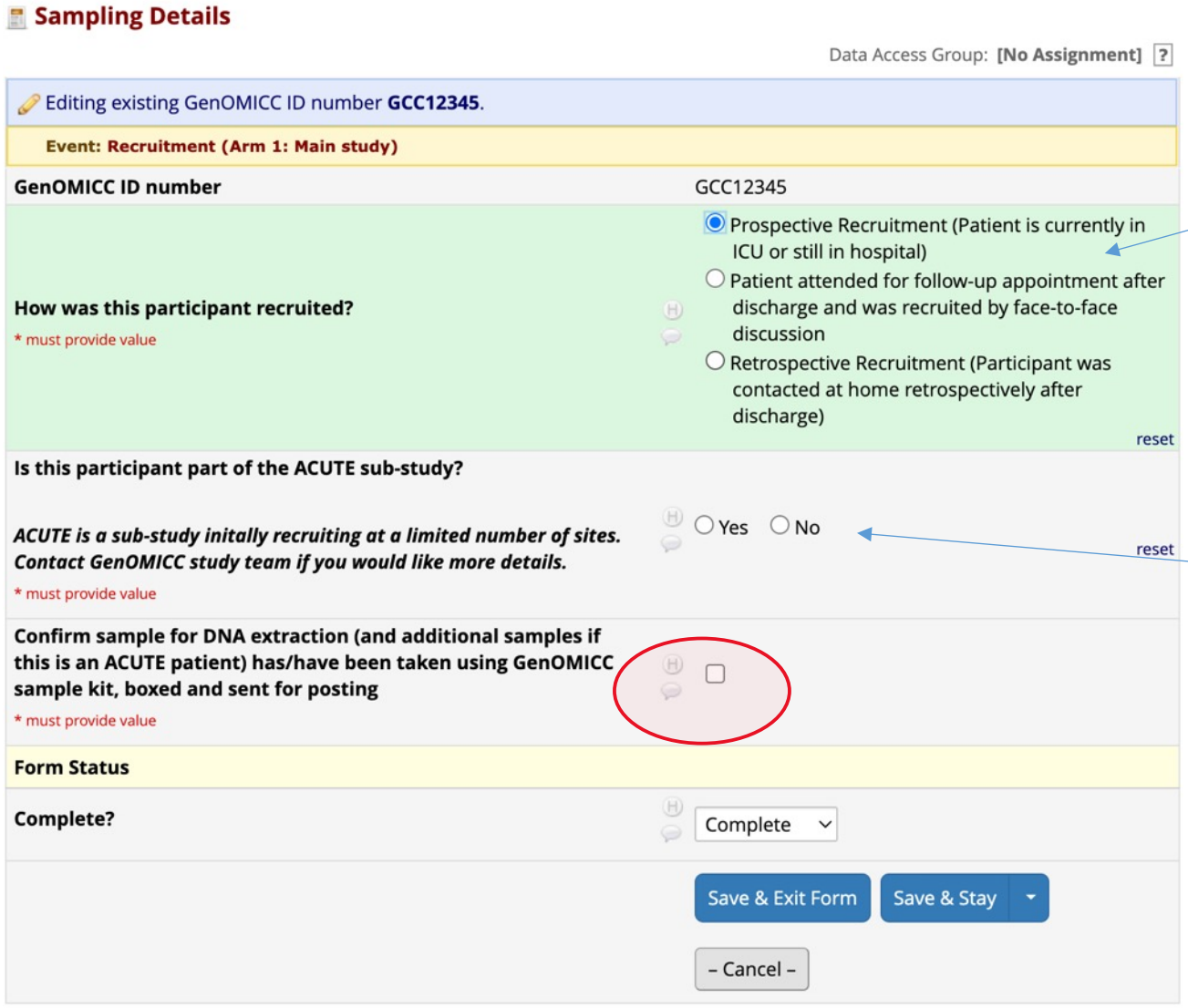



Select the correct version of the consent form from the dropdown menu – circled here in red.

Please add a new consent page, version, and date each time consent status has been updated.

A patient may be included in the study with consent from a relative or consultee (if they are unable to consent for themselves), then provide direct consent once they have regained capacity.

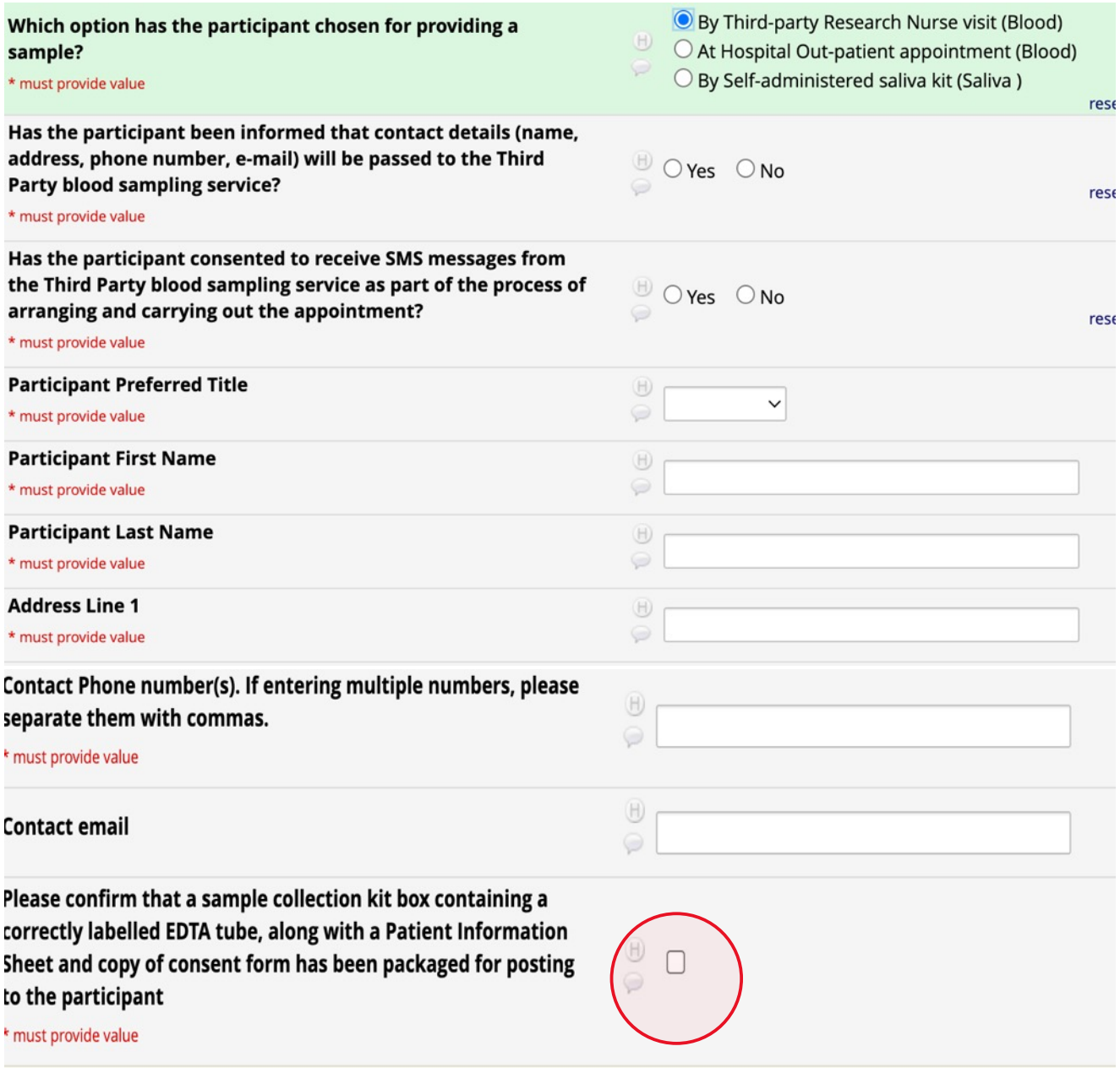
# Sampling details




Different pop-up boxes will will automatically appear, depending on the option selected for how the patient was recruited.

The ACUTE sub-study is only happening at a small number of sites, so in most cases the answer here is no. We have separate ACUTE guidance for the completion of REDCap.

Always confirm that samples have been taken and posted in the data field (as circled in red)




## Retrospective recruitment only

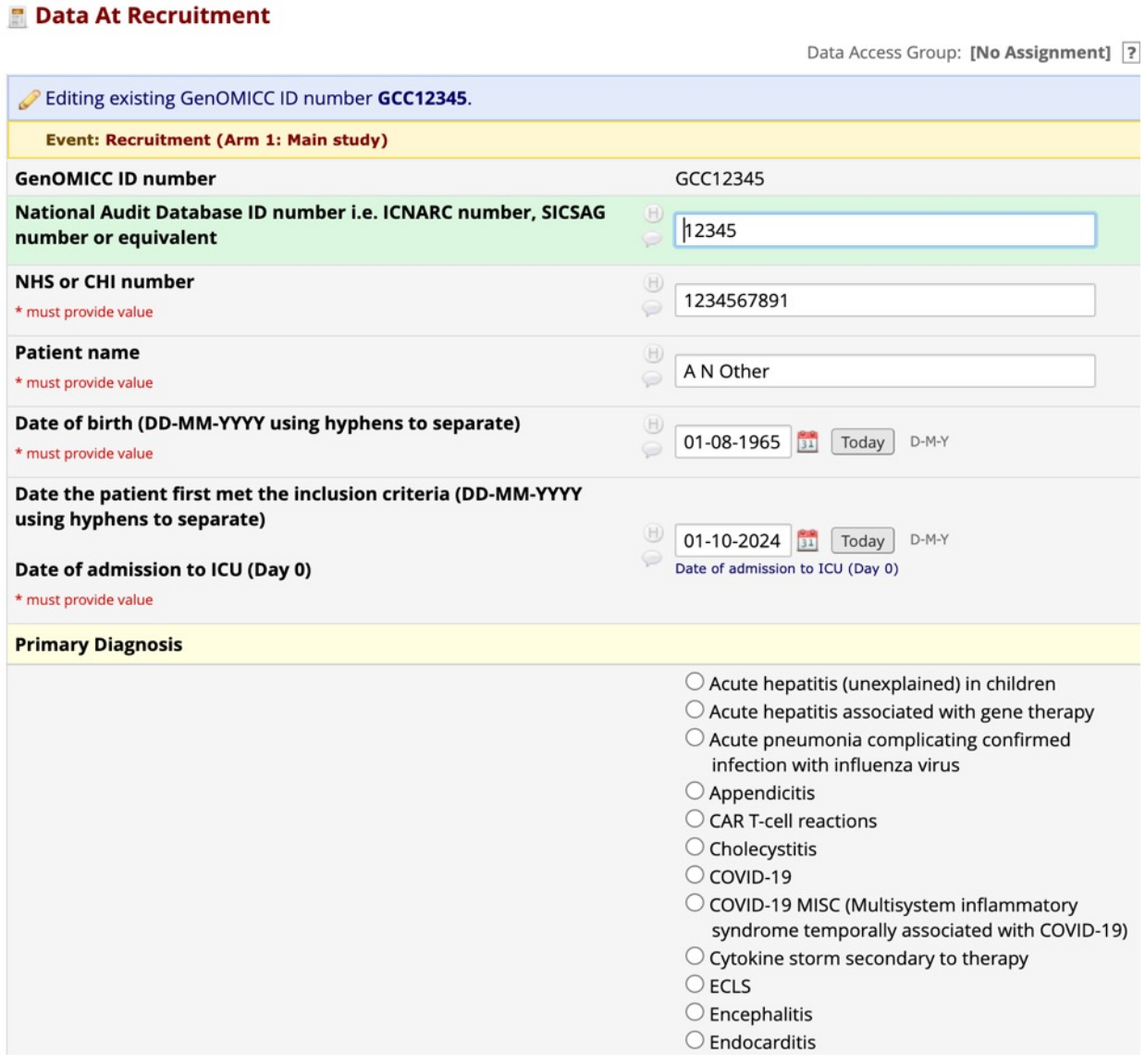
A series of data fields will appear for completion, if the 'third-party research nurse visit' sampling option has been selected.

The patient must be informed their personal information will be passed onto Inuvi, the third-party research organisation, for the purposes of arranging the sampling appointment. (We will delete the participant's contact information after the sampling appointment has taken place).

We will automatically collect this information each day from REDCap and send it to Inuvi where they will contact the patient directly to arrange an appointment. Nurses at site do not need to do anything except ensure that a sample kit has been promptly dispatched with the correct postage.

Please check the box circled in red to confirm the kit has been sent to the patient. It is important the kit is sent without delay as it will be required by the Inuvi nurse attending the patient for sampling.

# Data at recruitment




The ICNARC or SICSAG number is not a compulsory field, so please leave this blank if there is no number available.

Please enter 10 zeros ‘0000000000’ if there is no NHS/CHI number available.

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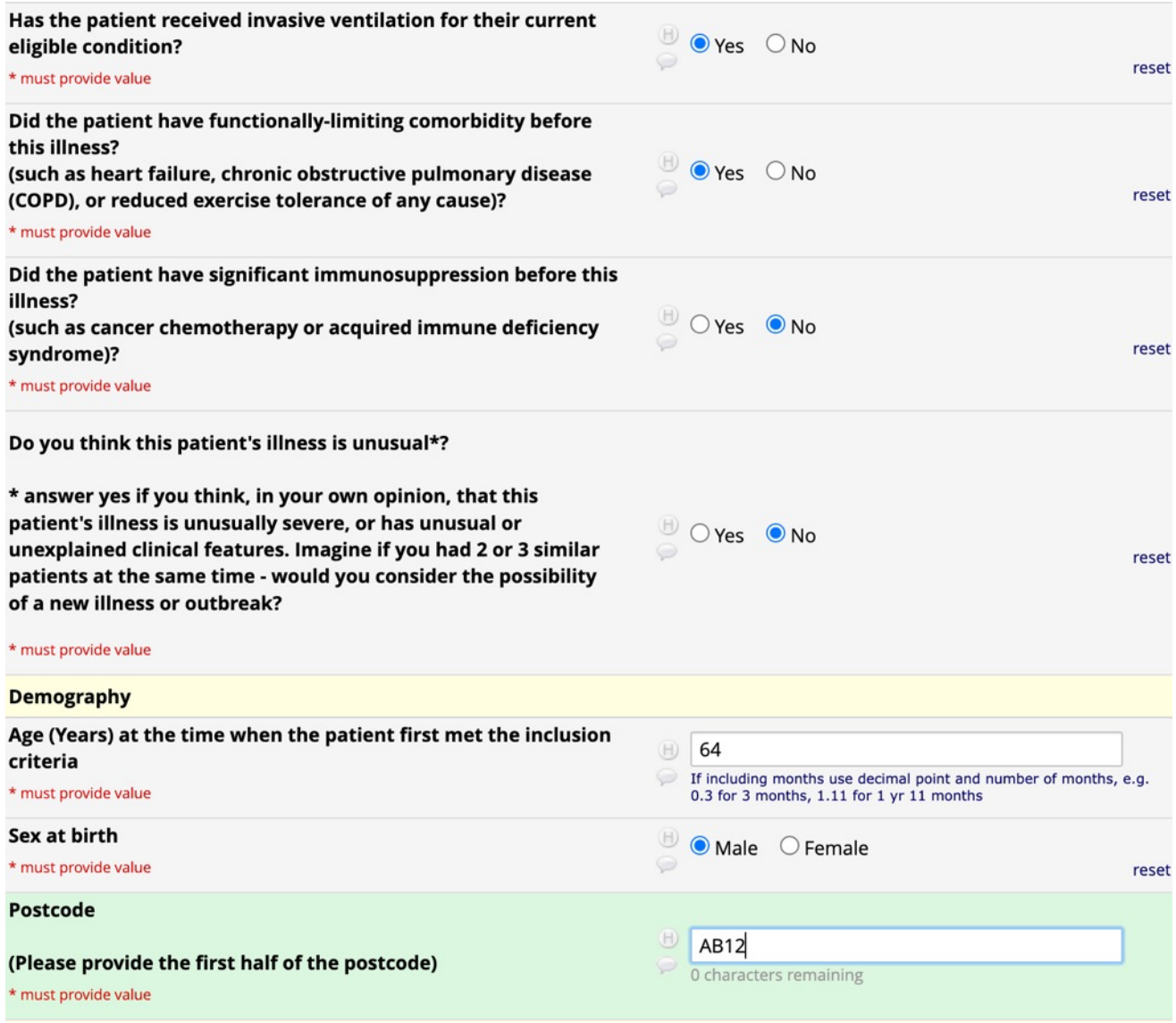
There is a long list of diagnoses to choose from.

Depending on which diagnosis is selected, other dropdown choices may appear, such as an ALT results box for hepatitis patients.

# Data at recruitment continued..



| | |
|---|---|
| **Has the patient received invasive ventilation for their current eligible condition?**<br>* must provide value | (H) ◉ Yes ○ No reset |
| **Did the patient have functionally-limiting comorbidity before this illness?**<br>**(such as heart failure, chronic obstructive pulmonary disease (COPD), or reduced exercise tolerance of any cause)?**<br>* must provide value | (H) ◉ Yes ○ No reset |
| **Did the patient have significant immunosuppression before this illness?**<br>**(such as cancer chemotherapy or acquired immune deficiency syndrome)?**<br>* must provide value | (H) ○ Yes ◉ No reset |
| **Do you think this patient's illness is unusual*?**<br>*** answer yes if you think, in your own opinion, that this patient's illness is unusually severe, or has unusual or unexplained clinical features. Imagine if you had 2 or 3 similar patients at the same time - would you consider the possibility of a new illness or outbreak?**<br>* must provide value | (H) ○ Yes ◉ No reset |
| **Demography** | |
| **Age (Years) at the time when the patient first met the inclusion criteria**<br>* must provide value | (H) 64<br>If including months use decimal point and number of months, e.g. 0.3 for 3 months, 1.11 for 1 yr 11 months |
| **Sex at birth**<br>* must provide value | (H) ◉ Male ○ Female reset |
| **Postcode**<br>**(Please provide the first half of the postcode)**<br>* must provide value | (H) AB12<br>0 characters remaining |

The additional fields here give us some information on the severity of the patient's illness.

We also use this information to understand more about how well the patient was before they became eligible for GenOMICC.

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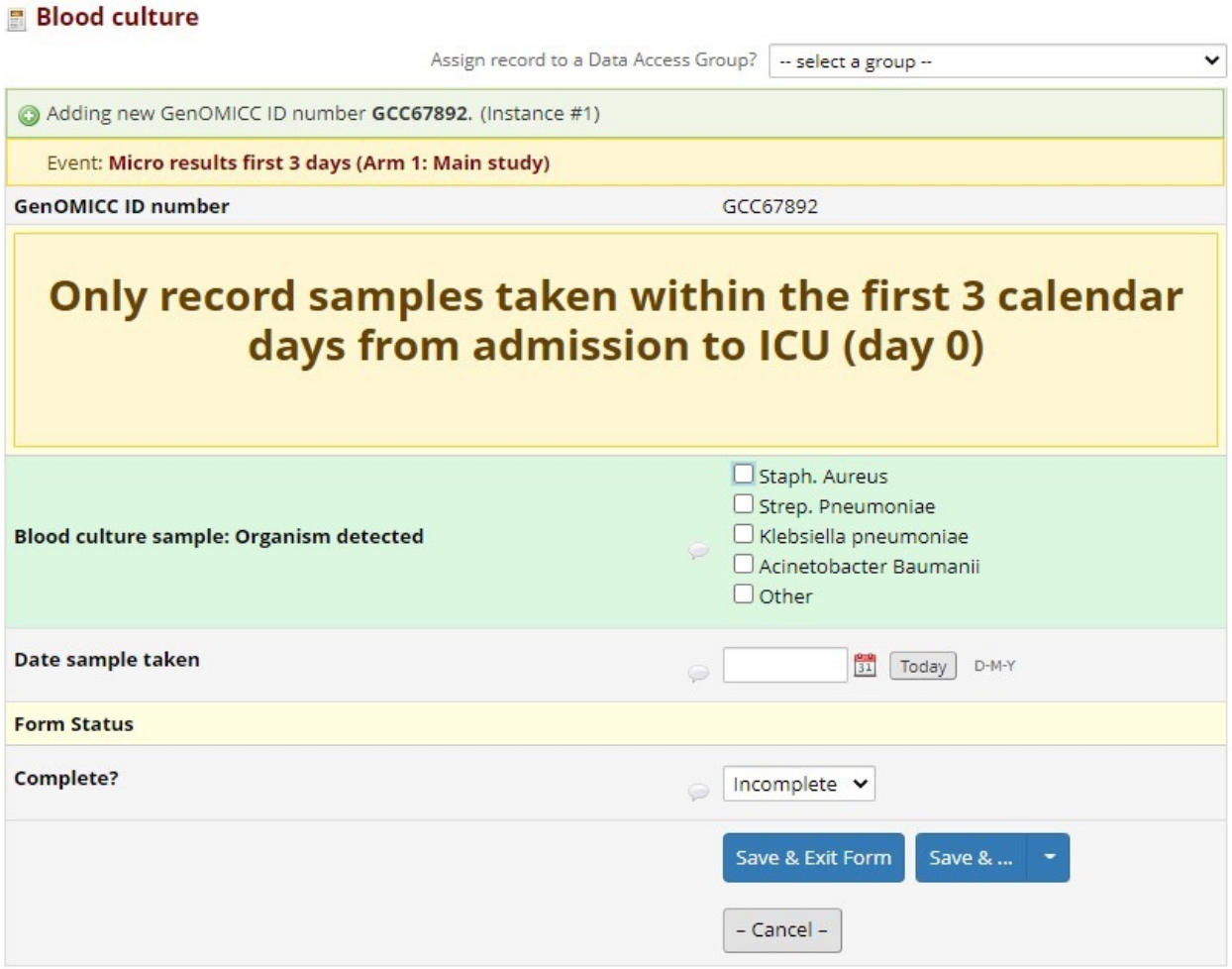
We require age in years and months, as at the date the patient was eligible for the study (date of admission to ICU).

Please only enter the first half of the postcode on this page. If there is no postcode available, please simply add **XX99** (such as in the event of an overseas participant).

# Blood culture

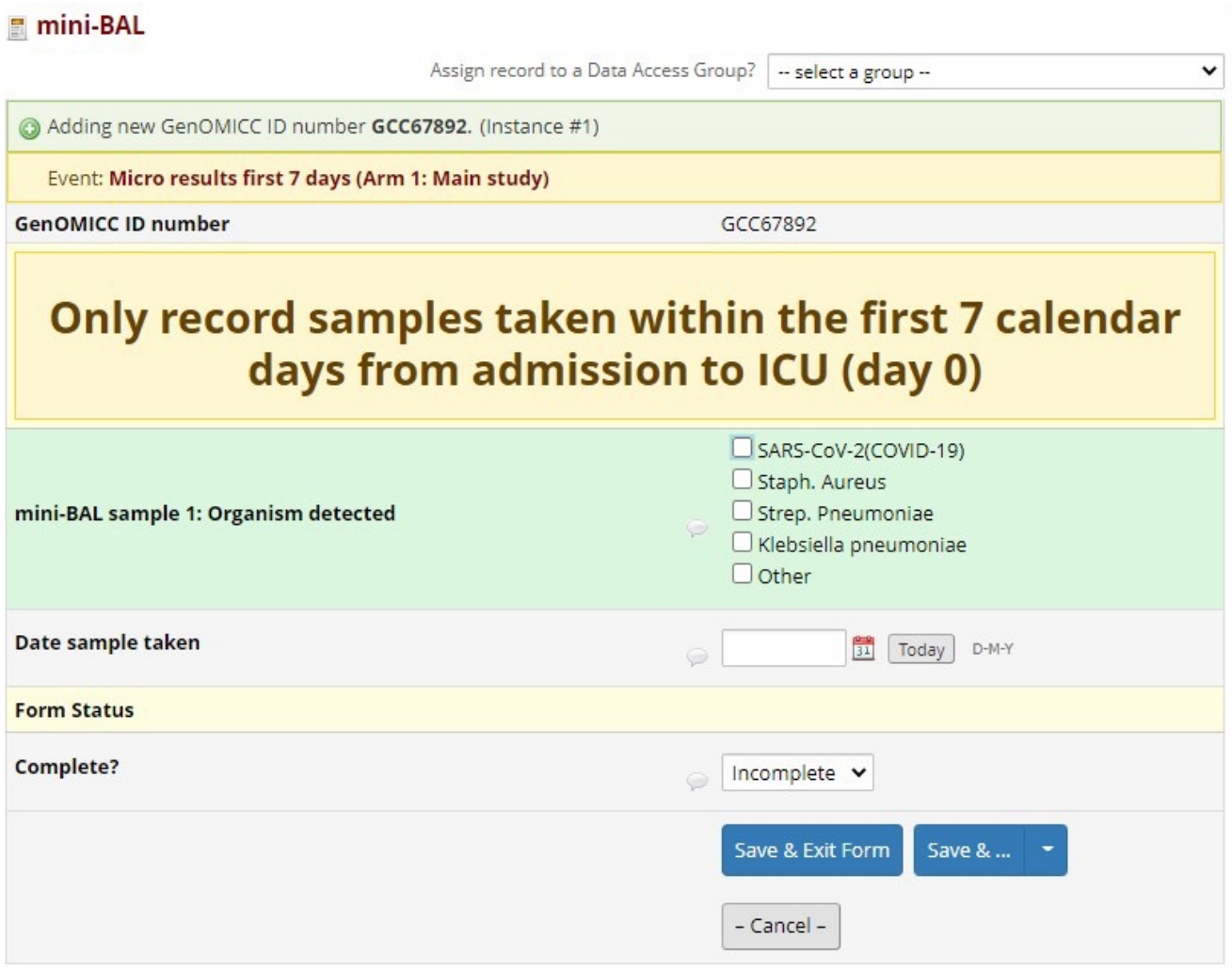



If a patient is admitted on a Monday (Day 0), then Thursday is Day 3 (i.e. third calendar day after admission – Tuesday is Day 1 after admission, Wednesday is Day 2 etc.). Any tests run on Monday, Tuesday, Wednesday, or Thursday can and should be entered in these sections.

If any lab tests show a result not listed, select 'other'. Another field will pop up for you to enter the details. If the result showed no growth or no specific organism, then leave the fields blank but mark the page as 'complete' so that we know the tests have been considered.

The same guidance applies to all microbiology pages (not shown in this guide) and include; **Serology, Urinary Antigen Test, Throat/Nose Swab, Tracheal Aspirate, Urine Culture, Fluid from Infected Collection and Wound Swab.**

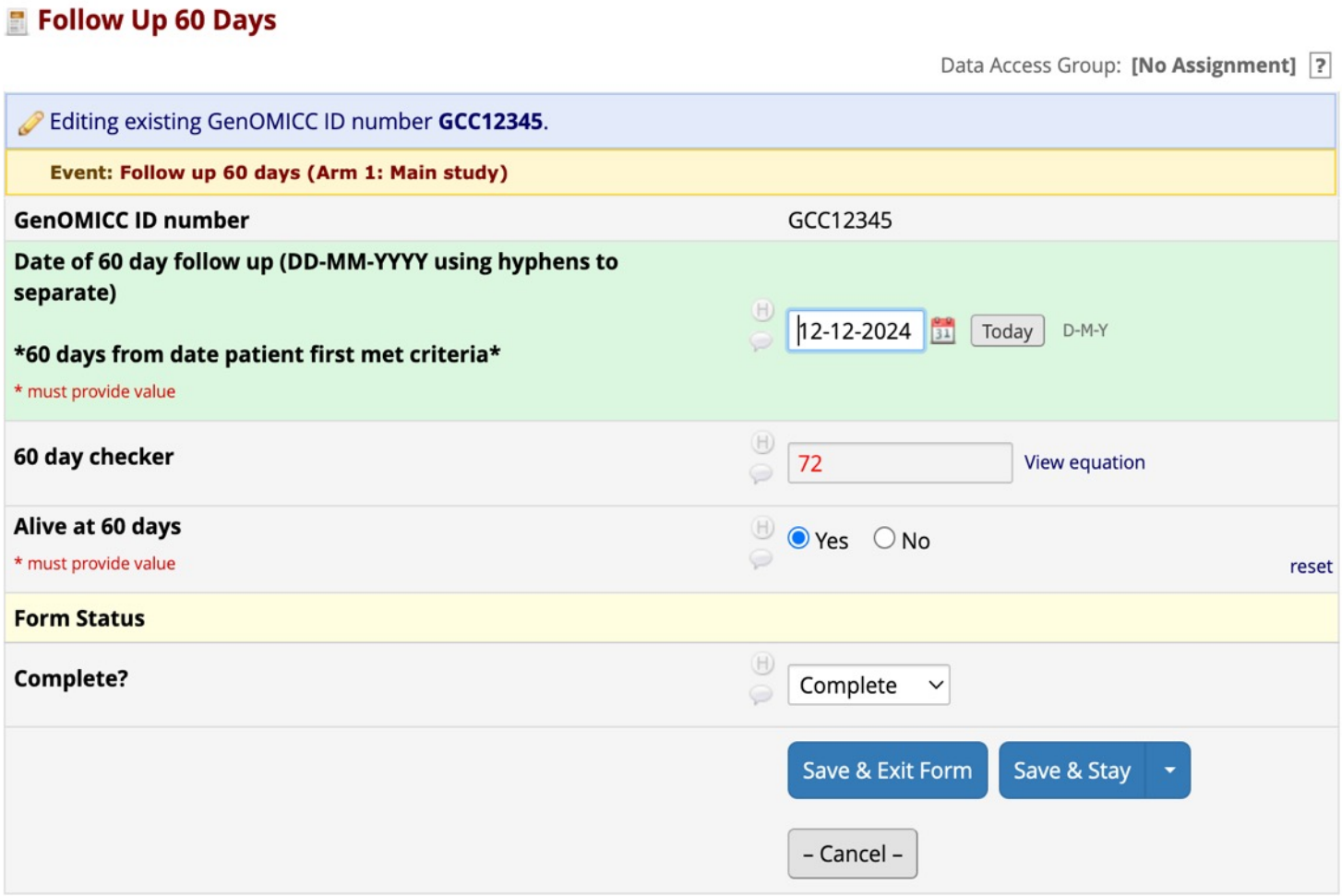
# Mini-BAL




The following test results may be included if taken within 7 days of admission to ICU (day 0).

The same guidance applies to all the 7-day test result pages (not shown on this guide) if known and include: **BAL, Cerebrospinal Fluid (CSF) and CSF Non-Culture Diagnostics.**

# Follow-up at 60 days

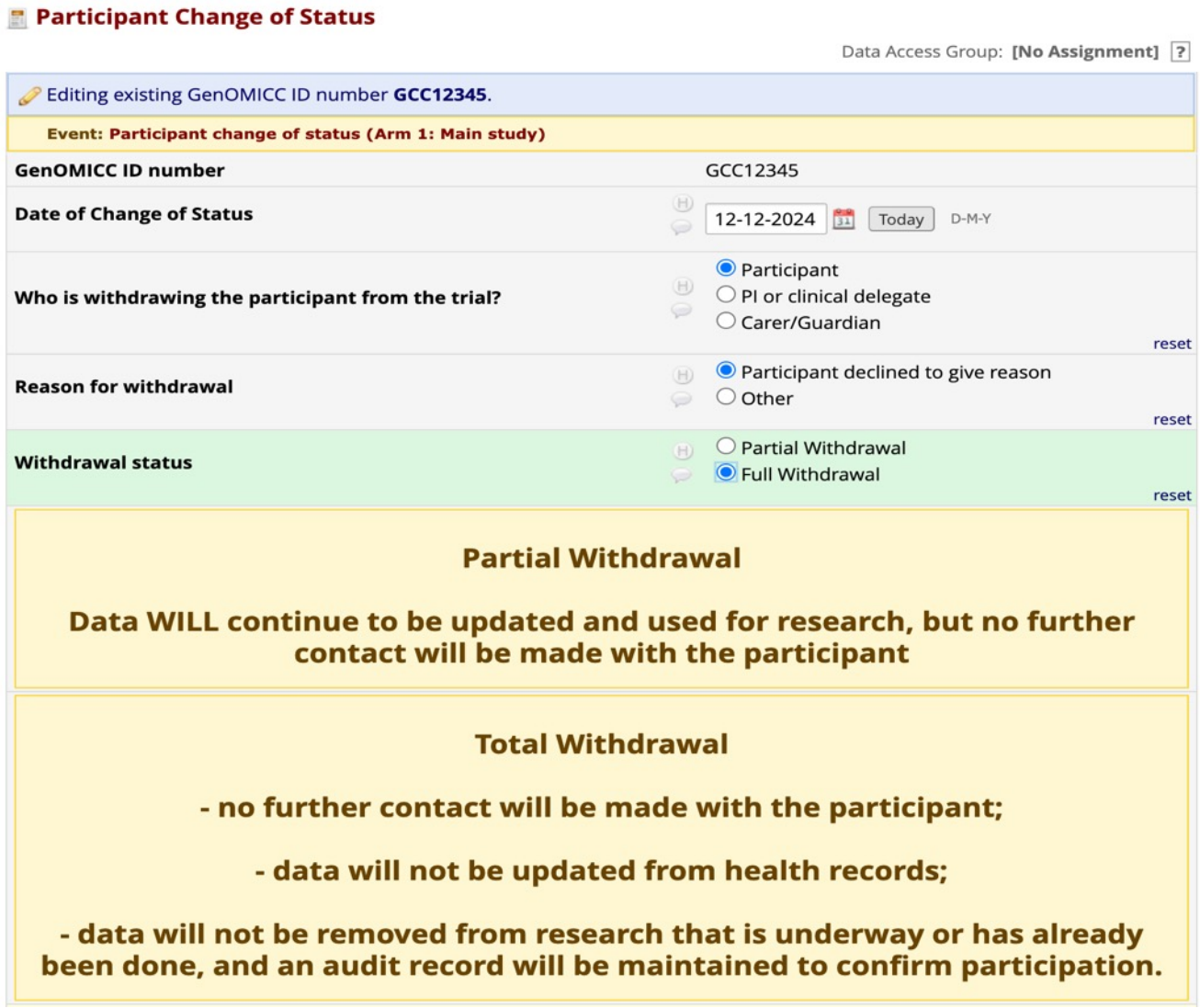



Please ensure at least 60 days have passed since Day 0 (admission to ICU when patient first became eligible) before this check is completed. (It does not matter if the check is carried out after 60 days).

We'll send a reminder if the follow up is not completed, after 60 days have passed.

This information can be obtained by checking electronic hospital records or the participant may be contacted at home if required.

# Participant change of status




Update status to ‘Partial Withdrawal’ if a participant wishes to remain in the study but receive **No future contact.**

Update status to ‘Full Withdrawal’ if the participant no longer wishes to participate in the study. Please also let the GenOMICC team know so we can destroy the patient's sample.

The participant change of status page is ONLY for patients who have withdrawn consent or do not wish to be contacted again in the future.

We will ensure anyone who fully withdraws is not included in further research however, they can’t be removed from research that has already taken place.

# Participant change of status

- The withdrawal section on the ‘participant change of status page’ does not need to be completed following death – deceased patients remain in the study.

- We may ask you to fully withdraw an eCRF if we have no sample for a patient – this means we are not trying to reconcile records with samples where there is no possibility of receiving one.

# Thank-you

Please don’t hesitate to contact us with any issues or questions

**E: genomicc@roslin.ed.ac.uk**

**T: 0300 365 7660**

It is helpful to us if your hospital name can be in the subject heading of any emails.