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1. PURPOSE

To define the procedures related to generating and documenting the generation of participant randomisation schedules in clinical trials.

2. APPLICABILITY

This SOP applies to all clinical trials for which CEBU assumes primary responsibility for generating the schedule for randomised allocation of trial participants to intervention arms.

3. ROLES AND RESPONSIBILITIES

Person requesting randomisation: responsible for completing the randomisation request form for details of randomisation schedule.

Randomising Statistician (or designated CEBU staff member): responsible for producing randomisation schedule, documenting the procedure and distributing the schedule in the required format to the person(s) responsible for randomising patients (typically the trial manager/coordinator or in the case of a blinded drug trial the pharmacist responsible for dispensing the drugs). In general, this should not be the Trial Statistician, however in some open label trials, this may be carried out by the Trial Statistician.

Reviewing Statistician: responsible for conducting quality checks of the final randomisation schedule and programs used to generate the final schedule. This will not be the same person as the Randomising Statistician and again should not be the Trial Statistician with the exception as described above, or if the trial statistician reviews a version prior to using the final seed.

4. INTRODUCTION

The purpose of participant randomisation and allocation concealment is to reduce selection bias by eliminating any investigator influence (specifically by those recruiting) over which participants are entered into the trial, and which arm they are entered into (whether the intervention to be received is blinded or not). In a randomised trial, participants are assigned to an intervention group based on a predetermined sequence of random intervention assignments. Using concealed allocation means that the investigator, research staff and study participant do not know the order of the intervention group assignments and cannot predict a future intervention assignment. The Randomising Statistician is required to produce the sequence of assigned interventions in accordance with the trial protocol and this SOP.

5. BACKGROUND

The request for a randomisation will most likely come from a CEBU statistician who ideally should have been involved in writing the protocol to ensure that the method of randomisation and allocation of interventions is appropriate, but it may come for another statistician or a member of

the trial team (referred to as the Requesting Statistician). In writing the protocol, consideration will be given to the following details:

- Definition of any strata to be used in the randomisation to ensure balance of baseline prognostic and other confounding factors.
- Number of groups and number of participants to be randomised to each group (and each stratum if appropriate).
- Method of randomisation (e.g. simple randomisation, blocked randomisation, minimisation etc.). If block randomisation is used, details of the block sizes and whether fixed or variable should not in general be documented in the protocol, so that the clinical staff involved in the trial are unaware of the block sizes used and will find it harder to predict the next allocation.
- Method of implementation (e.g., sealed envelopes, web-based system, telephone based system etc.).
- Who is blinded in the trial (e.g., observer blind, patient blind, open label etc)?
- The circumstances for breaking the randomisation code if appropriate.

The Randomising Statistician should be comfortable with those sections of the protocol that describe the randomisation procedure, which should match the details provided in the request form.

Particular attention should be paid to the protocol if the request for randomisation has not come from a CEBU statistician and there is no indication that a statistician has been involved in the protocol. If necessary, amendments to the protocol should be suggested, which may need to be approved by Ethics prior to generation of the randomisation schedule.

Generation of randomisation schedules should be in accordance with the current version of the trial protocol as approved by Ethics.

When requesting the randomisation schedule, a randomisation request form should be filled in by the Requesting Statistician providing the details of the randomisation information. This is completed in REDCap via the Randomisation Schedule Request Form (screenshot in appendix 10.5.1). The Requesting Statistician will then change the ownership of the Randomisation Schedule Request Form to the Randomising Statistician (screenshot in appendix 10.5.2). The Requesting Statistician will not be able to access the REDCap entry after this. Any updates to the request after this change of ownership will need to be made by the Randomising Statistician.

When an additional randomisation schedule (e.g. an emergency list, extra randomisations needed) for a study is requested, the Requesting Statistician fills in a new randomisation request form. Each randomisation request is stored as a separate record in the REDCap database. Randomisation requests from the same study can be linked through their CEBU ToggI code which is captured in the REDCap database.

6. PROCEDURE FOR GENERATING THE RANDOMISATION SCHEDULE

6.1 Generation of a randomisation schedule

- Generation of the randomisation schedule using a single Stata do-file that:

- Includes the Stata version number. The random numbers generated are not consistent across different versions of Stata. They will vary from one version to another, even when the `seed` option of the `ralloc` command is used (Section 10.1.1). Including the version number in the do-file will ensure random numbers are generated using the same version of Stata every time the do-file is run, thereby ensuring reproducibility of the randomisation schedule.
- Sets the block sizes. This should be a mix of block sizes to ensure that clinical staff involved in the trial cannot guess subsequent randomisations. Variable block sizes should always be used unless specified otherwise.
- Sets the strata as defined in the protocol.
- Uses the (pseudo) random number generator to assign the order of randomisations within each stratum (either by individual or by block as appropriate). The “seed” for the random number generator should be set to the date and time that the randomisations are being generated in the form MMDDHHMM, where MMDD is month and date and single digit months do not have a leading 0, and HHMM is hours and minutes in a 24-hour clock format. For example, randomisations generated on the 9th of March 2020 at 2pm should use the seed 3091400 (3=march, 09= 9th, 2pm= 14:00).
- Outputs sequential lists of patient randomisations within each stratum.
- The Randomising Statistician will then change the ownership of the Study Randomisation schedule to the Reviewing Statistician. The do-file and randomisation schedule will be checked by the Reviewing Statistician. Any feedback will be incorporated by the Randomising Statistician and re-circulated to the Reviewing Statistician.
- Once both the Reviewing and Randomising Statistician are happy with the final code/ output, the Reviewing Statistician will be required to sign off on the completed randomisation schedule, using the sign off form in REDCap (screenshot in appendix 10.5.3). After that, the ownership of the Randomisation sign off form will need to be transferred back to the Randomising Statistician.
- The randomisation schedule will be disseminated as required by the protocol.
 - In the context of a drug trial, the randomisation schedule will be passed to the pharmacist responsible for preparing the study drugs.
 - Where opaque envelopes are required for randomisations (e.g. in an open-label or patient-blinded trial), the randomisation schedule will be outputted in text format which will then be mail-merged in Word into two documents. The first document is to be printed on envelopes and should display the trial name, the sequential ID number and the stratum. The second document will produce inserts which will be either letters or labels, as required, with the same information plus the treatment allocation according to the randomisation schedule. Again, this process and the merged documents will be checked and approved by the Reviewing Statistician prior to the randomisation schedule sign off. The inserts detailing the random allocation will then be placed in the opaque envelopes by a person independent of the project under the supervision of the Randomising Statistician. The set of sealed envelopes, ordered according to the sequential ID number and separated by strata, will then be given to the person involved in recruiting, along with a set of instructions on the opening of the envelopes (see Section 6.3). Note this may be multiple people in the case of a multicentre trial.

- For web-based randomisations, the randomisation schedule will be provided to the person developing the web-based randomisation program. If there is a post-processing do file for the web-based schedule, the Randomising Statistician or Reviewing Statistician will be asked to check this file (more details are available in section 10.6 at the end of the document)
- Once the randomisation is complete all of the required files will be uploaded onto the REDCap “CEBU Randomisation Lists Database” (https://redcap.mcri.edu.au/redcap_v10.1.2/index.php?pid=6) maintained within the REDCap system **after which all files stored on local hard drives or share drives should be deleted** (see Section 6.2). It is the responsibility of the Randomising Statistician to ensure that this data is uploaded once randomisations have been complete.

6.2 Documentation of procedures

Accurate documentation of all procedures used in the generation of the randomisation schedule will be kept on the REDCap “CEBU Randomisation Lists Database”. This will be generated by the Randomising Statistician who is the only person who will have access to these files. However, all users of the REDCap “CEBU Randomisation Lists Database” can access the list of all randomisations. The database will include:

- Study name, name of the Principal Investigator (PI) and name of the study coordinator (if different to the PI).
- The version number and the date of the protocol followed in generating the schedule. The protocol may also be uploaded into the database where available.
- The date the randomisation schedule was generated.
- Details of the persons responsible for preparing and checking the schedule.
- Contact details of person(s) to whom the randomisations are handed and who will be responsible for the implementation and use of the schedule.
- Details of distribution of electronic and paper copies of the schedule including storage and access control methods as required in the protocol.
- A copy of the guidelines regarding the use of the randomisations handed to user(s) of the schedule (see Section 6.3).

The randomisation entry will also have (1) the randomisation request form and (2) the sign-off form linked to the entry.

If you want to view the log of all randomisation schedules that have been generated within CEBU, you can access it from REDCap “CEBU Randomisation Lists Database” via the Project Bookmarks (see appendix 10.6).

6.3 Randomisation guidelines

Where necessary guidelines will be written for the user(s) of the randomisation schedule, in accordance with the study protocol. A copy of these guidelines will be given to the person

responsible for recruiting and an electronic copy will be stored in the CEBU Randomisation Lists Database. Guidelines will include details on:

- Where to store the envelopes/randomisation schedule
- Procedures for opening the envelopes where applicable
- Details of what happens if an envelope/drug allocation is misplaced.
- In some cases, details on where and how to document allocations.

Producing and disseminating these guidelines may be the responsibility of the person(s) producing the randomisation schedule, or more likely the requesting statistician and/or PI. See Appendix for a template for guidelines for envelopes (Section 10.3) and randomisation schedules for a drug trial (Section 10.4).

The randomisation schedule should remain confidential until the end of the study as defined in the protocol.

7. TIMING OF GENERATION OF THE RANDOMISATION SCHEDULE

The randomisation schedule will be produced and implemented once approval for the trial has been granted by the relevant authorities and prior to participant recruitment.

8. KEEPING A LOG OF ANY ACCESS TO THE RANDOMISATION SCHEDULE

The Randomising Statistician is the only person who can access the randomisation schedule stored in REDCap once it has been finalised. The Randomising Statistician may be asked to access the randomisation schedule and share the schedule (for example for a Data Safety Monitoring Board report). **If the Randomising statistician is asked for a copy of the randomisation schedule for any reason, approval should be obtained from the project PI before providing any unblinded data.**

If a randomisation schedule is requested and shared, the Randomising Statistician will need to complete an unblinding form associated with the randomisation schedule in REDCap to record why, when, and whom the schedule was shared with and record that the PI has agreed to this access. In the notes section of the log the Randomising Statistician can record extra information such as whether the provision of the scheduled was masked (e.g. treatment A & treatment B) or unmasked (e.g. control vs intervention). A new unblinding form should be completed for each request. A copy of the unblinding form is given in appendix 10.7.

9. When an existing project adds a new site that needs a randomisation schedule

A project may add another data collection site (e.g. hospital) after the trial has commenced. This is a new randomisation and therefore needs to be entered into the randomisation database as a new entry. Therefore, the randomisation needs a new request, do file, and review.

The REDCap randomisation database is for randomisations, not projects, so each new randomisation needs a new entry.

10. APPENDICES

10.1 Generating the master randomisation schedule

10.1.1 The ralloc command

The generation of randomisation schedules uses the `ralloc` command in Stata which provides a sequence of treatments randomly permuted in blocks of constant or varying size. If not constant, the size and order of the blocks are also random. Allocation may be stratified by one or more variables. The `ralloc` command can be installed from within Stata by typing “`ssc install ralloc`”. The latest version is “`sxd1_4`”. A typical use of `ralloc` is in a randomised controlled clinical trial (RCT), and, in particular, in a multicentre trial where balance in treatment allocations may be desirable within centre and other defined strata. The syntax for this command is:

```
ralloc <Block ID varname> <Block Size varname> <Treatment varname stub>, ntreat(#)
strata(#) osize(#) nsubj(#) seed(#) trtlab(<label1> <label2> ...) sav(<filename>)
```

`ralloc` only allows allocation ratios 1:1, 1:2, or 1:3 (see the text from the help file below). It does not allow more complex allocation ratios. For example a 3-arm trial with an allocation ratio 2:2:1 would require you to enter 5 treatment arms to ensure correct allocation ratio.

ratio(#) specifies allocation ratio (1:#) in a 2 treatment trial. # is 1, 2, or 3

Options

ntreat(#)	Specifies the number of treatment arms
strata(y#)	Specifies the number of strata (the default is 1)
osize(#)	Specifies the number of different block sizes
nsubj(#)	Specifies the number of subjects per stratum
seed(#)	Specifies the random number seed
trtlab(<label1> <label2> ...)	Specifies the labels for each treatment arm
sav(<filename>)	Specifies the name of the file to which data are saved

The generation of more randomisation numbers than specified in the protocol is recommended since occasionally extra randomisations are required once the trial is running (for example to account for drop-out). Having already generated additional randomisation numbers enables quick provision of extra envelopes. Both the randomisation numbers generated for each stratum and those for which envelopes have been produced must be documented.

10.1.2 Template for creating a basic randomisation schedule with 1 stratum

```
version ##.#

set seed MMDDHHMM // Note this should correspond to the date and time the //
randomisations were generated detailed at the top of the // do-file

ralloc bid bsz trt, ntreat(#) osize(#) nsubj(#) seed(#) ///
trtlab(<label1> <label2> ...) sav(<filename>)

gen id=_n
keep id trt
order id trt

sort id
export delimited using <filename>.txt, replace noquote
```

10.1.3 Template for creating a randomisation schedule with at least 2 strata

```
version ##.#

set seed MMDDHHMM // Note this should correspond to the date and time the //
randomisations were generated detailed at the top of the // do-file

ralloc bid bsz trt, ntreat(#) strata(#) osize(#) nsubj(#) seed(#) ///
trtlab(<label1> <label2> ...) sav(<filename>)

gen x=_n
bysort StratID (x): gen strata_x=_n

*Keeping # records per stratum.
drop if strata_x>#

*Creating a unique id number.
gen id=1000*StratID+strata_x
label define stratalbl 1 "xyz" 2 "abc"
label values StratID stratalbl

keep id StratID trt
order id StratID trt
sort id

export delimited using <filename>.txt, replace noquote
```

10.1.4 Alternative way to label treatments and stratum

In the example below the labels for the 3 treatments are long and therefore label define is used as opposed to the trtlab option of ralloc

```
ralloc bid bsz trt, ntreat(3) strata(2) osize(1) nsubj(50) ///
seed(MMDDHHMM) ///
sav(Rand_pilot_dvex)

label define trtlab 1 "Stoss Vitamin D + Daily Placebo" ///
                  2 "Stoss Placebo + Daily Vitamin D" ///
                  3 "Stoss Placebo + Daily Placebo"

label values trt trtlab
```

```

gen x=_n
bysort StratID (x): gen strata_x=_n

*Keeping # records per stratum.
drop if strata_x>#

*Creating a unique id number.
gen id=1000*StratID+strata_x
label define stratalbl 1 "xyz" 2 "abc"
label values StratID stratalbl

keep id StratID trt
order id StratID trt
sort id

export delimited using <filename>.txt, replace noquote

```

10.1.5 Template for creating a randomisation schedule for 3-arm trial with an allocation ratio 2:2:1

```

version ##.##

set seed MMDDHHMM // Note this should correspond to the date and time the //
randomisations were generated detailed at the top of the // do-file

ralloc bid bsz trt, ntreat(5) strata(2) osize(1) nsubj(50) ///
seed(MMDDHHMM) ///
sav(Rand_pilot_dvex)

label define trtlab      1 "Placebo" ///
                        2 "drug A"  ///
                        3 "drug A"  ///
4 "drug B" ///
                        5 "drug B"

label values trt trtlab

gen x=_n
bysort StratID (x): gen strata_x=_n

*Keeping # records per stratum.
drop if strata_x>#

*Creating a unique id number.
gen id=1000*StratID+strata_x
label define stratalbl 1 "xyz" 2 "abc"
label values StratID stratalbl

keep id StratID trt
order id StratID trt
sort id

export delimited using <filename>.txt, replace noquote

```

10.1.6 Example for exporting randomisation to Excel

Some randomisation schedules are required by Pharmacy, e.g. for a blinded drug study, so that pharmacy can prepare the drugs and can label each drug with the correct ID number. In this case the schedule should be exported to Excel via Stata's `export excel` command:

```
export excel using pilot_example_pharmacy.xlsx, replace firstrow(varlabels)
```

In this case, additional blank columns are required as part of the export so that the pharmacy can enter the patient details to link the patient to the randomisation number, namely Patient Name and UR Number. The following Stata script creates blank columns with these headings:

```
gen patient_name = .  
label var patient_name "Patient Name"  
gen ur_number = .  
label var ur_number "UR Number"  
gen screening_number = .  
label var id "Randomisation Number"  
label var trt "Randomisation Treatment"
```

```
order patient_name ur_number id trt  
keep patient_name ur_number id trt
```

Where there is more than one stratum, the randomisation schedule for each stratum should be exported to a separate worksheet:

```
preserve  
keep if id<=1500  
export excel using "pilot_example_pharmacy.xlsx",  
sheet("Stratum_1_condition xyz") sheetmodify firstrow(varlabels)  
  
restore, preserve  
keep if id>=201  
export excel using "pilot_example_pharmacy.xlsx", sheet("Stratum_2  
condition abc") sheetmodify firstrow(varlabels)  
restore
```

10.2 Instructions for mail-merging text file output from Stata into envelopes and inserts

10.2.1 Mail merging onto an A4 page

1. Create a text file containing the fields you require, e.g stratum, randomisation id and study arm. Open Word.
2. Start a new document.
3. Select the **Mailings** menu.
4. Click **Start Mail Merge -> Letters**.
5. Click **Select Recipients -> Use Existing List**.
6. Select the text file containing the fields you want to merge.
7. Click **Open**.
8. Write the generic text for the letter and insert the merge fields. Centre the text vertically and horizontally and select your desired font. An example is:
- 9.

XXX Trial

Stratum: XXXXXX

Randomisation ID: XXXX

Arm: **XXXXXXX**

10. To insert the merge fields:
 - a. Place the cursor where you want the merge field to appear.
 - b. Select **Insert Merge Field**.
 - c. Click on the field you want to insert.
 - d. Repeat steps a-c for all merge fields.
11. Click **Finish & Merge -> Edit Individual Documents**.
12. Select the records you want to merge. "All" is the default, and what you will usually want to select.
13. Click **OK**.
14. Save the newly created Word document.

Tips:

- Best practice is to print one randomisation per A4 sheet, which is then folded into 3 when inserted into an envelope. This helps prevent people being able to see the allocation through the envelope.
- Ensure "Print One Sided" is selected when printing out the inserts.

10.2.2 Mail merging to envelopes

1. Create a text file containing the fields you require, e.g. stratum, randomisation id and study arm.
2. Open Word.
3. Start a new document.
4. Select the **Mailings** menu.
5. Click **Start Mail Merge -> Envelopes**.
6. Select envelope size. This will generally be DL, which is the common business envelope.
7. Click **OK**.
8. Click **Select Recipients -> Use Existing List**.
9. Select the text file containing the fields you want to merge.
10. Click **Open**.
11. Write the generic text for the envelope and insert the merge fields. **Remember NOT to include the study arm on the envelope**. Centre the text vertically and horizontally and select your desired font. An example is:

XXX Trial

Stratum: XXXXXX

Randomisation ID: XXXX

12. To insert the merge fields:
 - a. Place the cursor where you want the merge field to appear.
 - b. Select **Insert Merge Field**.
 - c. Click on the field you want to insert.
 - d. Repeat steps a-c for all merge fields.
13. Click **Finish & Merge -> Edit Individual Documents**.
14. Select the records you want to merge. "All" is the default, and what you will usually want to select.
15. Click **OK**.
16. Save the newly created Word document.
17. To print, place envelopes in tray 5 face side down with the sealed end facing down towards you.

10.2.3 Mail merging to labels

1. Create a text file containing the fields you require, e.g. stratum, randomisation id and study arm (see "Rand template dofile.doc").

2. Open Word.
 3. Start a new document.
 4. Select the **Mailings** menu
 5. Select **Start Mail Merge -> Labels**.
- For 8 x 3 (small label):
- a. Tray: Multi-purpose Tray
 - b. Label Vendors: Avery A4/A5
 - c. Product Number: J8159
6. Click **OK**.
 7. Click **Select recipients -> Use Existing List**.
 8. Select the text file containing the fields you want to merge.
 9. Click **OK**.
 10. Write the generic text for the label and insert the merge fields in the first label box of the template. Centre the text vertically and horizontally and select your desired font. An example is:
 - 11.

XXX Trial

Stratum: XXXXXX

Randomisation ID: XXXX

12. To insert the merge fields:
 - a. Place the cursor where you want the merge field to appear.
 - b. Select **Insert Merge Field**.
 - c. Click on the name of the field (the field name should be in the first row of the text file being merged) in the "Field name" box under "Field properties".
 - d. Click **Insert**.
 - e. Repeat steps a-e for all merge fields.
13. Select **Update labels**.
14. Select **Preview Results**.
15. Select **Finish & Merge**.
16. Click **Edit Individual Documents**.
17. Select the records you want to merge. "All" is the default, and what you will usually want to select.
18. Click **OK**.
19. Save the newly created Word document.
20. To print, place labels face side down in tray 5.

10.2.4 Printing a selection of letters or envelopes

There will be times when you want to produce letters and envelopes for a selection of the randomisation schedule, i.e. not print the entire document. A mail merge separates each page (whether letter, envelope or a page of labels) by section breaks, not page breaks. It sees the entire document as 1 page. Therefore trying to print envelopes from page 1 to page 20 will result in printing the entire document. In order to print only pages 1 to 20, the section breaks must be replaced with page breaks. The steps to do this are:

1. Select the **Home** menu
2. Click **Replace**.
3. Click on the **More** button.
4. Place the cursor in the **Find what:** space.
5. Click on the **Special** button and select **Section Break**.
6. Place the cursor in the **Replace with:** space.
7. Click on the **Special** button and select **Manual Page Break**.
8. Click on the **Replace All** button.
9. Now you can print the pages you want to.

10.3 Template for guidelines for use of envelopes

Participant IDs XX-YY are for patients in stratum 1, participant IDs XX-YY are for patients in stratum 2, The ID numbers within each stratum are to be assigned sequentially.

Randomisation process

When a participant has been assessed for eligibility and has consented to participate in the study the person responsible for carrying out the randomisation should take the next envelope available in the sequence for that stratum, e.g. envelope XX for the first participant to be randomised in stratum 1, followed by XX+1 for the second patient in this stratum etc...

The insert inside will contain details on whether the patient has been randomised to the “intervention” or “control” arm. If there is any blinding in this trial, the allocation for the patient should remain confidential.

It is important to record which trial arm the participant has been randomised to, and this will most likely be on a randomisation case report form (CRF). If this is the case, it is a good idea to staple the letter to or stick the label on this form as a reference.

10.4 Template for guidelines for use of randomisation list for a drug trial (see the randomisation plan template in a separate document)

The attached document is the randomisation schedule for the XXX trial. The randomisation for this trial is stratified by XXX.

Participant IDs XX-YY are for participants in stratum 1 (XXX), participant IDs XX-YY are for participants in stratum 2 (YYY), The ID numbers within each stratum are to be assigned sequentially.

Please note this schedule should remain confidential. Only XXX are allowed access to this form.

Randomisation process

Study drugs should be made up and labelled sequentially within each stratum as documented in this randomisation schedule. Labels should include:

- The name of the trial
- The sequential ID number
- The stratum
- The words “For Clinical Trial Use only”
- The expiry date


In the case of a recruiter-blind or participant-blind study, the label should not include details of the drug contained.


Once the drugs have been labelled, they should be stored in an appropriately secure place. When the next participant has been assessed for eligibility and has consented to be in the study, the pharmacist should dispense the next available drug allocation in that stratum.


The pharmacist should keep an electronic record of the trial drugs that are dispensed and should record the ID number, the stratum, the drug prescribed and the date the drug was dispensed.

10.5 REDCap forms

10.5.1 The Randomisation Schedule Request Form

 **Randomisation Schedule Request Form**

 Editing existing Study Name 1

Study Name	1
Study Information	
Toggl code	<input type="text"/>
Title or Short Title of RCT <small>* must provide value</small>	<input type="text" value="made up title to compare placebo and BCG"/>
Primary Investigator <small>* must provide value</small>	<input type="text" value="Dr Example"/>
Primary Investigator Contact Details	<input type="text"/>
Trial Coordinator (if different from PI)	<input type="text"/>
Department / Group	<input type="text"/>
Ethics Approval Number	<input type="text"/>
Protocol Version	<input type="text"/>
Protocol Version Date	<input type="text"/>  Today Y-M-D
Randomisation Schedule Information	
Number of groups & labels	<input type="text" value="2; placebo, BCG"/>
Randomisation allocation ratio	<input type="text" value="1:1"/>
Number of stratification factors	<input type="text" value="2"/>
Stratification factor 1 (enter one level per line)	<input type="text" value="sex: male"/> <input type="text" value="female"/> Expand
Stratification factor 2 (enter one level per line)	<input type="text" value="gestational age: <28weeks"/> <input type="text" value="≥28weeks"/> Expand
Number of participants and/or clusters to be randomised to each group (and each stratum if appropriate)	<input type="text" value="100 per treatment"/> Expand
What format does the randomisation number need to be in, if required? For example: id-strata-site (001-1-RCH); where id is 001-999, strata is 1 or 2, site is 3 letter code. Make sure you provide as much information as possible.	<input type="text" value="treatment_# example*"/> <input type="text" value="a_001 to a_999"/> <input type="text" value="b_001 to b_999"/> Expand
Method of randomisation (e.g. simple randomisation, blocked randomisation)	<input type="text" value="block 3 different sizes"/> Expand
Allocation Type Used <small>* must provide value</small>	<input type="text" value="Pharmacy list"/>

Specify the allocation type if choose "Other"	<input type="text"/>
Number of sites included with details	<div>1</div> <div>RWH</div> <div>Expand</div>
Number of person gets this randomisation list	<div>1</div>
Name of person list is going to_1	<div>pharmacist</div>
Email of person list is going to_1	<input type="text"/>
Is the person expecting the list?	<input checked="" type="radio"/> Yes <input type="radio"/> No <div>reset</div>
Please provide any specific instructions/ information about training that needs to go into the email the statistician sending the schedule needs to know:	<div></div> <div>Expand</div>
Who is blinded in the trial (e.g. observer blind, patient blind, open label etc.)?	<div>all participants and project staff</div> <div>Expand</div>
Does CEBU need to be involved in breaking the blind? And if so, what is the process for unblinding?	<div>no</div> <div>Expand</div>
	<input type="checkbox"/> Protocol attached <input type="checkbox"/> HREC approval letter attached
Attachment1	<div> Upload file</div>
Attachment2	<div> Upload file</div>
Requesting Statistician	<div><input type="text"/></div>
Randomisation List Creator	<div><input type="text"/></div> <div>* must provide value</div>
Date Requested	<div><input type="text"/></div> <div> Today Y-M-D</div>
Other comments	<div></div> <div>Expand</div>
Ownership Transfer	
Transfer to this person (randomisation statistician) NOTE: when you select complete, you will be locked out of this randomisation list record	<div><input type="text"/></div>
Form Status	
Complete?	<div>Incomplete</div>
<div>Save & Exit Form</div> <div>Save & Stay</div> <div>-- Cancel --</div>	

10.5.2 Ownership transfer completion message

Record Home Page

Record 1 belongs to another Data Access Group

You cannot access this project record because it is already being used by another Data Access Group within this project. You will have to use a different record if you wish to create a new project record.

[<< Go back to the previous page](#)

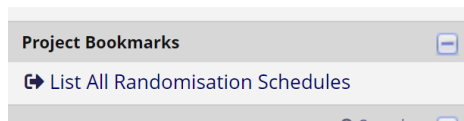
10.5.3 The Randomisation Sign off Form

Randomisation sign off form

Editing existing Study Name 1	
Study Name	1
Reviewing Statistician	<div><div>H</div><div>Kate Francis</div><div></div></div> <div>* must provide value</div>
Date Reviewed	<div><div>H</div><div>2021-04-14</div><div>Today</div><div>Y-M-D</div></div> <div>* must provide value</div>
Signature	<div><div>H</div><div></div><div>Add signature</div></div>
Any other comments?	<div><div>H</div><div></div><div>Expand</div></div>
Ownership Transfer	
<div>Transfer to this person - randomisation statistician. Make sure you completed all fields on the randomisation sign off before doing this. NOTE: when you select complete, you will be locked out of this randomisation record</div> <div><div>H</div><div></div><div></div></div>	
Form Status	
Complete?	<div><div>H</div><div>Incomplete</div><div></div></div>
<div><div>Save & Exit Form</div><div>Save & Stay</div><div>-- Cancel --</div></div>	

10.6 How to access the log of all randomisation schedules ever generated by CEBU

Look for the “List all Randomisation Schedules” option on the left hand side



Once you click on this you obtain a list like the shot below

CEBU Randomisation Lists Database PDF 6

Custom Reports

Choose a report: All Schedules

Download report as: CSV (Labelled) CSV (Raw)

Number of results returned: **155**
Total number of records queried: 155

All Schedules

Listing all randomisation list records irrespective of creator.

Search:

Study Name <small>(study_name)</small>	Department / Group <small>(dept_group)</small>	Primary Investigator <small>(study_pi)</small>	Requesting Statistician <small>(requestor)</small>	Randomisation List Creator <small>(creator)</small>	Date Created <small>(created_date)</small>
1718 - Working out dads	Murdoch Children's Research Institute	Rebecca Gallo	21 (Annelie Grobler)	30 (Cecilia Moore)	2021-04-14
1773 - Strengthening care for children	Murdoch Children's Research Institute	Harriet Hiscock	30 (Cecilia Moore)	30 (Cecilia Moore)	2021-04-06
ACE cessation trial	Heart Research	Vivek d'Udekem	23 (Diana Zannino)	8 (Suzanna Vidmar)	2018-03-20
Ambulant				12 (Charlotte Molesworth)	2015-08-07
Atopic Eczema	Dermatology Department	Elizabeth Lens		6 (Sarah Arnsperg)	2010-07-19
Baby Biotics	CCCH	Valerie Sung	1 (Fiona Mansah)	8 (Suzanna Vidmar)	2011-07-25
Baby DUCC Teleconference	Birth Centre / Operating Theatres of the Royal women's Hospital (RWH)	Dr Douglas Blank	7 (Susan Donath)	13 (Monsurul Hoo)	2018-06-22
Be Sweet To Babies - Preschoolers	Neonatal Unit	Denise Harrison		7 (Susan Donath)	2010-12-15
Be Sweet To Babies - Toddlers	Neonatal Unit	Denise Harrison		7 (Susan Donath)	2010-12-15
BEAR Study (Superseded by MIS BAIR)	Pediatrics	Nigel Curtis	7 (Susan Donath)	8 (Suzanna Vidmar)	2013-05-13
Bella Pally Study	Emergency	Franz Babi	5 (Katherine Lee)	8 (Suzanna Vidmar)	2015-05-19
BEST Trial	Infectious Diseases & Microbiology Group, MCRI/ICH	Dr Amanda Gree	21 (Annelie Grobler)	24 (Xiaofang Wang)	2021-05-12
BRACE - BCG vaccination to protect HCW from COVID-19	Infectious Diseases Group, MCRI	Prof Nigel Curtis	10 (Francesca Orsini)	10 (Francesca Orsini)	2020-03-23
BREL Study	Newborn Research, RWH	Jennifer Dawson	7 (Susan Donath)	8 (Suzanna Vidmar)	2013-02-21
Building Better Readers	Policy Equity and Translation Research Group	Dr Jon Quach	21 (Annelie Grobler)	10 (Francesca Orsini)	2017-04-21

10.7 Form in REDCap we use to record any instances of accessing the schedule/ unblinding

Study Name 1

Date of Unblinding Request Today Y-M-D

Participating Site Name

Participant ID#

Name and Role of Individual requesting the Unblinding (name, role, email) Expand

Reason for Unblinding ☐ Emergency Unblinding
☐ Unblinding upon DSMC request
☐ End of the study
☐ Other

Please specify the reason for unblinding if you choose "Other" Expand

Name of Unblinding Individual

Role of Unblinding Individual

Approval Date of Unblinding Today D-M-Y

To Whom the Unblinding Info was Passed

How the Unblinding Info was Passed Expand

Unblinding Request made by ☐ email (attached)
☐ online form

Attachment (original request email)

Form Status

Complete? Incomplete

Save & Exit Form Save & Add New Instance -- Cancel --

The randomisation schedule entry can have multiple forms with regard to unblinding, by adding a new instance (see red circle in image).

10.8 Instructions for Post-Processing Schedule for Import into REDCap

Randomisation schedules generated for projects utilising web-based randomisation (e.g. using REDCap) may require some post-processing to convert the schedule into a format suitable for upload into that system. Frequently the precise requirements of what the system will require are not known at the time the schedule is generated, and so this processing may be performed and documented separately, and possibly by a person other than the Requesting Statistician, the Randomising Statistician, or the Reviewing Statistician. The Randomising Statistician or the Reviewing Statistician will be asked to check the post processing do-file, and this do-file and the output (in CSV format) will be saved by the person that creates them to the schedule's record in the REDCap "CEBU Randomisation List Database".