REMAP-CAP

Randomized, Embedded Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Consent Case Report Form

16th July 2024

Updates to the REMAP-CAP Consent CRF

Consent Case Report Form

- We have undertaken a thorough review of the REMAP-CAP CRF, and are in the process of updating both the eligibility module and eCRF.

- A number of limitations of the existing Consent CRF have been raised by various stakeholders, and this has led to a complete redesign of the Consent CRF.
  - Updates to this form have been prioritised ahead of changes to other forms in the eCRF

Consent Case Report Form

- These changes aim to:
  - More clearly document a range of consent discussions and scenarios
  - Accommodate region-specific consent requirements
  - More easily identify situations where appropriate consent may not have not been obtained
  - Avoid unnecessary or ambiguous questions

- The updated Consent CRF will apply to all participants randomised after 18th July, 2024. No changes are required for existing participants.

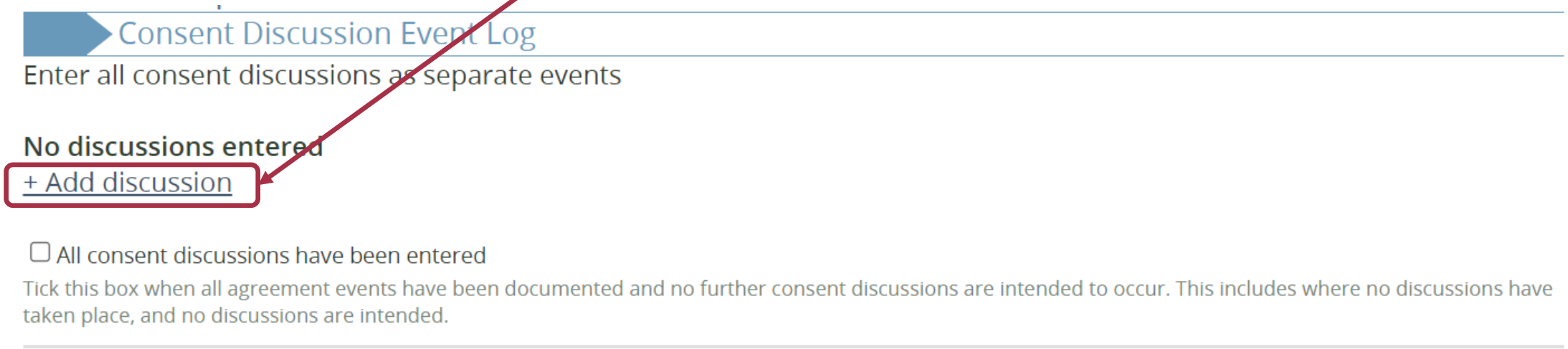
Completing the Consent CRF

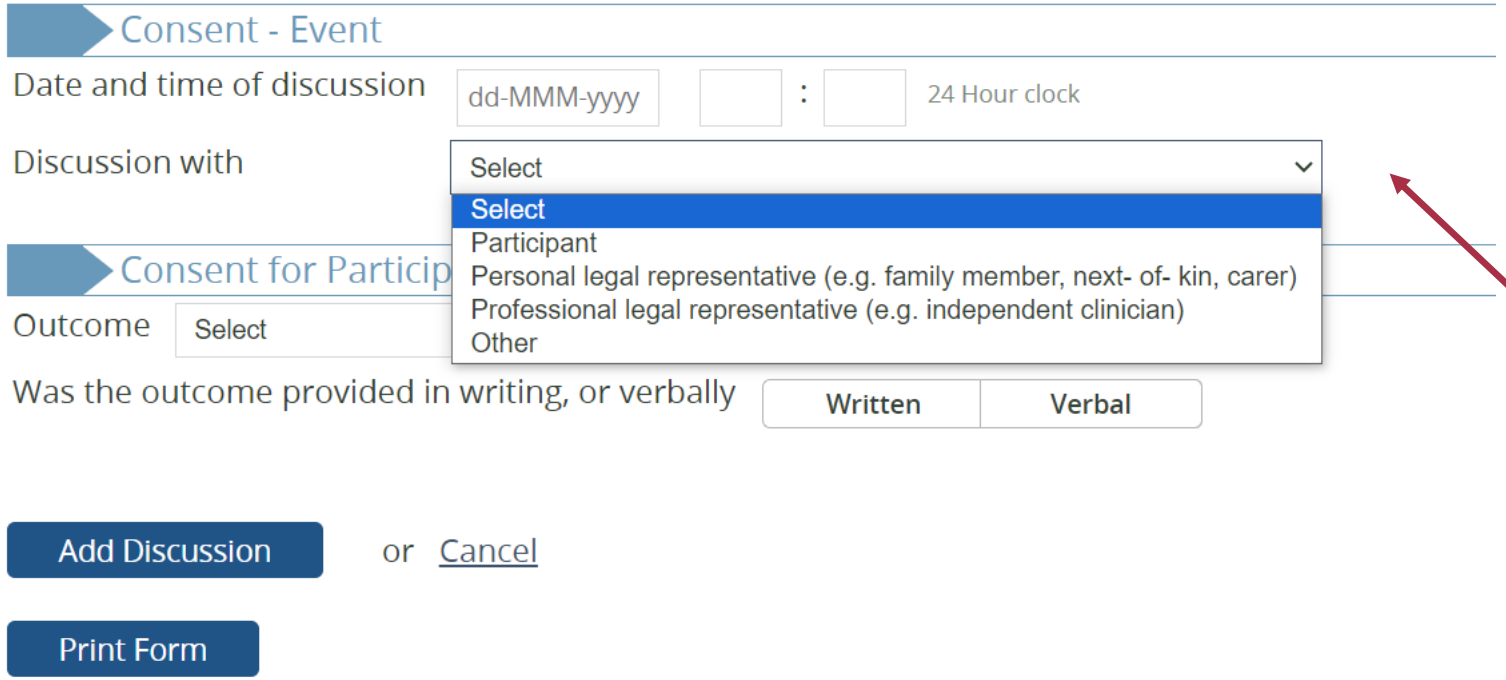
General guidance

- Enter all consent discussions that have occurred, including those with no decision / outcome
- Contact your regional coordinating centre if you are unsure how a particular question should be answered.
- If consent is not obtained in writing from the participant, you will be asked to provide a reason why it has not.
  - It is recognised that, while every attempt will be made to obtain consent in writing from the participant, this may not be possible or necessary in every instance.

To add a consent discussion / event, navigate to the participant's Consent CRF and click '*add discussion*'.

Each consent discussion or event should be added separately.





Enter the date and time of the discussion, and who the discussion was with.

Note that '*professional legal representative*' will only appear if this is permitted in your region.

If '*other*' is selected, you will be asked to specify who the discussion was with. Enter the relationship of the individual to the participant, or their position. Do not enter the name of the individual.

If more than one individual was present during the discussion, select the individual who provided the decision (either to agree to or decline participation) in writing or verbally.

If no decision was made at the time of the discussion, select *participant* if the participant was actively involved in the discussion.

Consent - Event

Date and time of discussion: dd-MMM-yyyy : 24 Hour clock

Discussion with: Personal legal representative (e.g. family member, next- of- kin, carer)

Consent for Participation

Outcome: Information provided, no decision made

Add Discussion or Cancel

Print Form

Select the outcome of the discussion.

If no decision was made (e.g. if the participant or their proxy wanted more time to consider participation) select '*information provided, no decision made*'. Then click '*add discussion*' to save the event.

If / when a decision has been made, this should be entered as a separate event.

Consent - Event

Date and time of discussion: dd-MMM-yyyy : 24 Hour clock

Discussion with: Personal legal representative (e.g. family member, next- of- kin, carer)

Consent for Participation

Outcome: Agreed to participation in one or more domains

Was the outcome provided in writing, or verbally: Written | Verbal

Which domains did they agree to participate in

Influenza Antiviral Domain (I) Outcome	Agreed	Declined	No Outcome
Endothelial Domain (E) Outcome	Agreed	Declined	No Outcome
Ventilation Domain (V) Outcome	Agreed	Declined	No Outcome

Add Discussion or Cancel

Print Form

Select the outcome of the discussion.

If the participant or an appropriate proxy has agreed to participate in at least one domain, select '*agreed to participation in one or more domains*'.

You will be asked whether their agreement to participate was provided in writing, or only communicated verbally.

Indicate which domains the participant or their proxy has agreed to.

A participant or their proxy may agree to participate in one or more domains, while declining participation in others. In some cases, they may also make a decision about some domains, while requiring more time to consider participation in others.

Agreement for domain participation

- Participants or their proxies may choose to agree or decline participation in each domain for which they have received an allocation.
  - This decision relates to participation in the domain, and is distinct from agreement to the use of their data (covered on following slides).

- You are able to select “agreed”, “declined”, or “no outcome” for each domain the participant has received an allocation in.

Agreement for domain participation

- If the participant or their proxy declines to participate in one or more domains, their treatment with respect to any allocated interventions in those domains is a clinical decision and is at the discretion of the treating clinician.

Agreement for domain participation

- In some cases, a participant or their proxy may agree to participate in some domains, but may require more time to consider participation in other domains

- In such instances, allocated interventions should be continued as per protocol while the participant or their proxy is given the opportunity to make a decision about their participation
  - The treating clinician may pause or discontinue an allocated intervention at any time, if they believe that doing so is in the best interests of the participant.

Agreement for domain participation

- Complete a separate entry for each consent discussion.

- If there is ‘no outcome’ for one or more domains, save the entry and complete a new entry if / when the participant or their proxy has made a decision about their participation in those domains.
  - You will also be asked to confirm any previous decisions to agree to or decline participation in all other domains.

Consent - Event

Date and time of discussion: dd-MMM-yyyy : 24 Hour clock

Discussion with: Personal legal representative (e.g. family member, next- of- kin, carer)

Consent for Participation

Outcome: Declined / withdrew consent for participation in all domains

Was the outcome provided in writing, or verbally: Written | Verbal

Consent for use of data

Can data collected to the point of withdrawal be used: Yes | No

Select 'no' only where the participant or their representative has clearly expressed that they do not want any of their data to be used. The default in this trial is to use data collected to the point of withdrawal, unless otherwise specified.

Can data available from medical records be used to continue to collect data, where available: Yes | No

Can the participant be contacted to collect follow-up information at Day 90 and Day 180: Yes | No

Was there agreement for the storage and use of data for

Other research studies that are closely related to this research project: Yes | No

Any future research: Yes | No

Add Discussion or Cancel

Select the outcome of the discussion.

If the participant or an appropriate proxy has declined to participate in all domains, select '*declined / withdrew consent for participation in all domains*'.

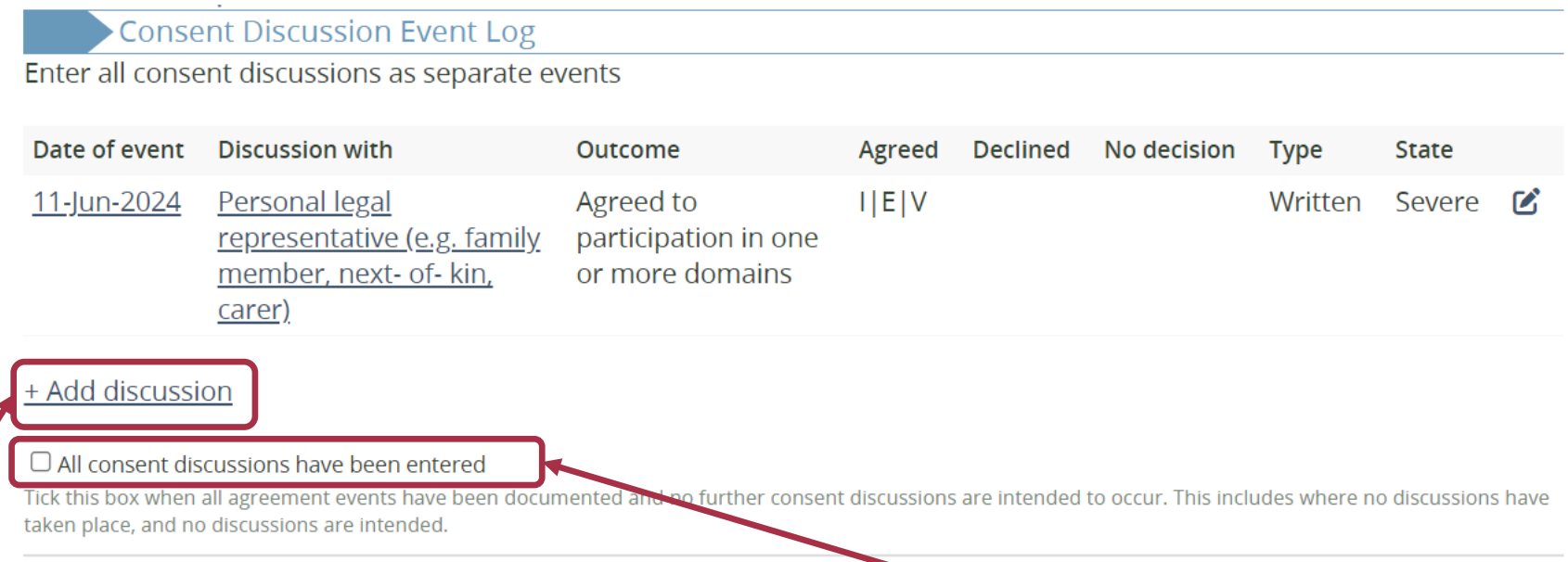
You will then be asked to confirm consent for the use of the participant's data.

Note that the default in REMAP-CAP is to use all data collected to the point of withdrawal. Select '*no*' only if the participant or their proxy has explicitly stated that they do not want their data to be used.

If the participant or proxy agree to the use of data already collected, they may also chose whether or not to agree to the continued collection of data from existing medical records, and whether or not they would like to be contacted to participate in long-term follow-up.

In some regions, participants may be asked whether their data can be used for future research. These questions will not appear in all regions.

Once the details of the event have been entered and saved, you will be taken back to the Consent CRF landing page which displays a table summarising all consent discussions / events for the participant.



To add another discussion / event, click '*add discussion*'.

Once all consent discussions / events have been entered and no further discussions are intended, tick this box to mark the record as complete. This may include situations where no discussions have taken place and there is no intention to have any such discussions in future.

If any further discussions do occur, you can still come back and add these events as required.

Consent Discussion Event Log

Enter all consent discussions as separate events

Date of event	Discussion with	Outcome	Agreed	Declined	No decision	Type	State
11-Jun-2024	Personal legal representative (e.g. family member, next- of- kin, carer)	Agreed to participation in one or more domains	I|E|V			Written	Severe

+ Add discussion

☑ All consent discussions have been entered

Tick this box when all agreement events have been documented and no further consent discussions are intended to occur. This includes where no discussions have taken place, and no discussions are intended.

Your responses indicate that written consent has not been obtained from the participant. Please click the following button to indicate why written consent was not obtained from the participant. If written consent was obtained from the participant, add this event.

+Confirm no written consent obtained

If you have entered all consent discussions, and there is no record of consent being obtained in writing from the participant, you will see the highlighted message.

If this is not correct, add or update any consent events as necessary. If, however, no written consent was obtained from the participant (for any reason) click '*confirm no written consent obtained*'.

Select the reason why consent was not obtained in writing from the participant.
It is acknowledged that there may be situations where it is not possible or necessary to obtain written consent from the participant, but this question will help us to understand why it was not obtained.

No written consent obtained

What is the reason written agreement was not obtained

While it is expected that every attempt will be made to obtain consent in writing from the participant, it is acknowledged that this may not be possible or necessary in every instance. Please indicate why consent was not obtained in writing from this participant

Select

No written consent obtained

Can patient data be used without written consent from the participant according to local regulations and approvals

While it is expected that every attempt will be made to obtain consent in writing from the participant, it is acknowledged that this may not be possible or necessary in every instance. Please indicate why consent was not obtained in writing from this participant

Yes | No

Date of ethics committee / regulatory approval to use data in the absence of written consent

dd-MMM-yyyy

☐ Not applicable

Add No written consent obtained event or Cancel

Please indicate whether the participant's data can be used in the absence of written consent from the participant according to your local regulations, and the date of approval for this (if applicable).

If you are unsure of how to answer this, or have any questions, please contact your Regional Coordinators for assistance.