

Changes to recruitment status options on the ANZCTR

As of Thursday 23rd June 2016, the options available for selection in the 'Recruitment status' field in Step 7 of the ANZCTR registration form will be updated to bring ANZCTR data further in line with other WHO primary registries and with Clinicaltrials.gov. The changes are summarised below.

1. Amendments to status definitions and options.

Recruitment status	Previous definition	Change	New definition
Not yet recruiting	Participants are not yet being recruited	No change	-
Recruiting	Open for recruitment and the first participant has been enrolled	No change	-
Enrolling by invitation	Participants were/are being/will be invited to participate from a predetermined population	Removed	-
Active, not recruiting	Study is ongoing (i.e. participants are being treated or examined), but participants are not currently being recruited or enrolled	Amended	Closed to recruitment and participants are being treated or examined
Closed: follow-up continuing	Closed to recruitment of participants and follow-up is still continuing	Removed	-
Closed: follow-up complete	Closed to recruitment of participants and follow-up is complete	Removed	-
Completed	Closed to recruitment of participants and data analysis complete	Amended	The study has concluded normally; participants are no longer being treated or examined (i.e. follow-up and data collection are complete)
Withdrawn	Study halted prematurely, prior to enrolment of first participant	No change	-
Suspended	There is a temporary halt in recruitment and enrolment but potentially will resume	No change	-
Stopped early	Recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being recruited	Amended name only (previously 'Terminated')	-

Please note that in line with the updated definitions:

Trials currently listed as 'Enrolling by invitation' will be changed to 'Recruiting'.

Trials currently listed as 'Closed: follow-up continuing' will be changed to 'Active, not recruiting'.

Trials currently listed as 'Closed: follow-up complete' will be changed to 'Completed'.

- When 'Stopped early' is selected, registrants are required to indicate the stage of data analysis (select one) as a new mandatory sub-field:
 - * **No data analysis planned**
 - * **Data collected is being analysed**
 - * **Data analysis is complete**
- When 'Withdrawn' or 'Stopped early' is selected, registrants are required to select all reasons which apply for early stopping/withdrawal as a new mandatory sub-field:
 - * **Lack of funding/staff/facilities**
 - * **Participant recruitment difficulties**
 - * **Safety concerns**
 - * **Other reasons/comments (please specify)**

Any registrants with questions relating to these changes should contact the ANZCTR team at info@actr.org.au or +61 2 9562 5333.