

Purpose

NSW EPCT specialty HRECs are required to extend an invitation to the Senior Executive (SE) from NSW PHO/LHD or speciality networks listed in an application; informing them when and by which HREC the application will be reviewed.

Definitions

EPCT: Early Phase Clinical Trial.

HREA: Human Research Ethics Application.

HREC: Human Research Ethics Committee.

NS: National Statement on Ethical Conduct in Human Research.

NSW Health Observer: Refers to an individual invited or nominated by an appropriate Site Executive to attend the HREC review of an EPCT application from the LHD or Institution listed in an application.

LHD: Local Health District.

PHO: Public Health Organisation.

SE: Site Executive.

Guidance

As an appointed HREC for the review of EPCT from NSW PHOs, Bellberry will extend an invitation to the Site Executive and Research Director of each PHO/LHD nominated in an application that has progressed to a full Bellberry HREC review, informing them when the specific application will be reviewed.

The Site Executive and Research Director for each PHO/LHD nominated in an application will concurrently be extended an invitation to attend as an NSW Health Observer, either in person or remotely, and can nominate whether they are able to attend, or delegate attendance to an appropriate nominee. Attendance is not mandatory, with one NSW Health observer invited/nominated per site listed on an application.

If an application from an NSW PHO(s) is received for a protocol that has previously undergone a full Bellberry HREC review, i.e. a multicenter application where an extension of HREC approval to include additional NSW PHO(s) is sought, the opportunity for an NSW Health Observer to attend will not be available.

An NSW Health Observer will only be permitted to observe during the review of the application for which their PHO/LHD is listed. Confirmation of attendance is requested 5 days prior to the meeting. A record of invitations and attendance will be provided to NSW Office of Health and Medical Research.

Prior to attendance an NSW Health Observer will be required to review the NSW EPCT Observer Attendance Guidance, Confidentiality Agreement and Conflict of Interest Declaration. An NSW Health Observer is required to maintain the confidentiality of Bellberry member names at all times, and should

declare any conflicts of interest, and acknowledge and return either the study specific or annual Confidentiality Agreement/Conflict of Interest Declaration prior to the HREC meeting. An NSW Health Observer will not be permitted to record, in any format, the HREC meeting.

During the meeting, the NSW Health Observer will be invited in at the beginning of their application review and can remain for the duration of the review of their Institutions application only and will not be able to contribute in any way to the review, discussion or decision of the HREC. Following the conclusion of the review of the specific application the NSW Health Observer will be informed when to exit the meeting.

Following the meeting the Observer will be contacted by the Early Phase Clinical Trials Manager or Bellberry Operations Manager to discuss any questions or feedback they may have regarding the process.

References

CMM NSW SOP7.1 EPCT Observer Process

CMM F7.1.3 NSW EPCT Observer CDA & COI Declaration – Study Specific

CMM F7.1.4 NSW EPCT Observer CDA & COI Declaration – Annual