

Appendix 9.6 – Observer Affirmation

Please read the definitions overleaf before signing this affirmation

I....., of,

acting as an observer of the NHMRC on-site assessment of ethical review processes a

.....('the institution') on/...../20.....

affirm that I understand that my role as Observer allows me to attend, watch and listen to meetings between, and the actions of, the Assessment Team and representatives of the institution and the institution's Human Research Ethics Committee but does not allow me to participate or intervene in those meetings or actions;

And agree:

- 1) That I will not interfere with, or seek to influence, the Assessment Team's assessment of the institution's ethical review processes, whether before, during or after the on-site assessment visit;
- 2) That I will not communicate or disclose Confidential Information to any person other than the authorised representative of the institution or members of the Assessment Team, without prior approval in writing from the Lead Assessor or CEO of the NHMRC (and with the agreement of the Head of the institution), except as required by law;
- 3) That I will not publish or communicate my opinion or observations on the assessment process to any person other than the authorised representative of the institution or members of the Assessment Team, without prior approval in writing from the Lead Assessor or CEO of the NHMRC (and with the agreement of the Head of the institution), except as required by law.

I understand that if I breach any of the above conditions the NHMRC may take into consideration in its decisions related to its certification processes my actions and any intended or unintended consequence of my actions. I understand that I may also be liable to civil or criminal proceedings as a result of my breach.

I also acknowledge that while the NHMRC will maintain my personal information in a manner consistent with the *Privacy Act 1988* (Cth) it may disclose information about me, to any person:

- a) to the extent required by law or by a lawful requirement of any government or governmental body, authority or agency;
- b) if required in connection with legal proceedings;
- c) for public accountability reasons, including a request for information by parliament or a parliamentary committee or a Commonwealth Minister;
- d) for any other requirements of the Commonwealth.

Signed:

.....

Date:/...../20.....

Definitions

Assessment Team includes those of the Chair or Acting Chair of the Certification Assessor Panel and representatives of a nominating institution/HREC, present during the on-site assessment; but does not include a member of the Certification Assessor Panel not present during the on-site assessment.

Certification Assessor Panel means the Certification Assessor Panel Working Committee, appointed under section 41 of the *National Health and Medical Research Council Act 1992* (Cth), or a member of the Certification Assessor Panel.

Confidential Information – means all information made available to the Observer by the institution or their servants or agents, the Lead Assessor, NHMRC or the Commonwealth for the purposes of the NHMRC, whether orally or in writing, or by any other means whatsoever, and includes information that:

- 1) is by its nature confidential
 - or
- 2) is designated by the NHMRC or the Commonwealth as confidential
 - or
- 3) the Observer knows or ought to know is confidential;
 - but does not include information which:
- 4) is or becomes public knowledge other than by breach of this Deed or by any other unlawful means;
- 5) is in the possession of the Observer without restriction in relation to disclosure before the date of receipt from the NHMRC or the Commonwealth
 - or
- 6) has been independently developed or acquired by the Observer.

Interest – includes a direct pecuniary interest, indirect pecuniary interest or non-pecuniary interest, for example, an appointment to, or employment or consultancy or other involvement with the institution, another organisation or body that is in some way involved with the NHMRC.

For the avoidance of doubt, an *interest* also arises where an Observer has a relationship, whether professional or personal, with a person who may benefit from a decision of the NHMRC to which the Observer contributes.

Lead Assessor – means the Chair or Acting Chair of the Certification Assessor Panel who is present during the on-site assessment visit.