

Locality Assessment by Locality Organisation

Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2009-v1).

Locality organisation sign off

Ethics committees review whether investigators have ensured their studies would meet established ethical standards if conducted at appropriate localities. Each locality organisation is asked to use the locality assessment form to check that the investigator has also made the appropriate local study arrangements.

Ethics approval for study conduct at each site is conditional on favourable locality assessment at that locality.

Please note that the locality organisation may have additional requirements to be met before a study may commence at that locality.

Part One: General

To be completed by the principal investigator for this locality.

Full project title:

Short project title:

Locality to be assessed:

Brief outline of study:

Principal investigator (for this locality):

Contact details:

Other local investigators (list all at this site):

Contact details:

Part Two: Locality Issues

To be completed by the principal investigator for this locality and signed by the authorised locality representative. (See the Guidelines (NAFG-2009-v1) (pages 13–15) for more information and examples.) Identify any local issues and specify how these issues will be addressed.

1. Suitability of local researcher

For example, are all roles for the investigator(s) at the local site appropriate (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?

Yes No

2. Suitability of the local research environment

a) Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? Is this site accessible for mobility-impaired people where necessary)?

Yes No

b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?

Yes No

3. Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed?

Yes No

4. Have the local investigator contact details and other important contact details been provided to the locality organisation for checking?

Yes No

Part Three: Declaration by locality organisation

I am authorised to complete locality approval on behalf of this locality organisation. I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.

(Questions 1–4 at Part Two above must be completed prior to signing.)

I confirm the organisation has sufficient indemnity insurance to compensate participants for harm that does not qualify for compensation under the Injury Prevention, Rehabilitation and Compensation Act 2001.

Signature: Date:

Name: Position:

Contact details: