Form 3

Site Specific Assessment
(SSA)

Notes: (1) **This form should be completed by the Investigator at each site in Ireland. In the case of a multi-centre clinical trial, the Site Specific Assessment form for each site must be submitted to the Recognised Ethics Committee (REC) by the Chief Investigator for his or her application to be valid.**

(2) Before a clinical trial can commence at a site, the CEO or person acting on his/her behalf at that site must have signed the declaration at the end of this form.

A.1 Trial and Site Identification

EudraCT no.:
Title of clinical trial:
REC reference no.:
Submission date:
Name of site:

A.2 Who is the Investigator for the research study at this site?

Name: Title: Address: Tel: Fax: E-mail:

A.3 Outline the qualifications and experience of investigators relevant to the current clinical trial.

A.4 Provide details of other named investigators on the local research team.

Name: Title: Position: Qualifications: Role in the research team:

Name: Title: Position: Qualifications: Role in the research team:

Name: Title: Position: Qualifications: Role in the research team:

A.5 Give a brief description of the recruitment of subjects, inclusion and exclusion criteria and the trial methods and design of the proposed research e.g. randomised, controlled. This should also include details of the duration of research participant involvement and exactly what procedures they will undergo.

A.6 Is indemnity in place for the conduct of this clinical trial at this site?

Yes No

If *yes* it is the responsibility of the Investigator to make a copy of the indemnification available to the CEO/ person acting on behalf of CEO.

A.7 Please outline the facilities and other departments that will be used for the purpose of conducting this clinical trial (e.g. laboratories, radiology, pharmacy etc.).

Declaration of Principal Investigator at Site

This declaration must be signed and submitted to the REC before the main application will be considered valid

- I am satisfied as to my suitability as principal investigator for the conduct of the research at this site and in respect of the supporting staff available to undertake the research at the site.
- I am satisfied that the facilities at this site are of such quality and adequacy as to conduct the research at this site
- I certify that the information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

Signature: .....

Print Name:

Date: (dd/mm/yyyy)

Declaration of CEO/ person acting on behalf of CEO

It is not necessary for this declaration to be submitted to the REC for the main application to be considered valid. However, the clinical trial cannot commence at the site until the declaration is signed.

I hereby declare that, having regard to the information contained in this form, I am satisfied that the clinical trial may be carried out at this site.

Signature: …….

Print Name: _____
Dated: (dd/mm/yyyy) _____