DECLARATION BY MONITOR

Name:

Title of the study:

Protocol number:

Site:

I, the undersigned, declare that:

1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH - GCP) and understand the responsibilities and obligations of the clinical trial monitor within the context of this study.

2. I have notified TFDA of any aspects of the above with which I do not/am unable to, comply. (If applicable, this may be attached to this declaration.)

3. I will carry out my responsibilities as specified in the trial protocol and in accordance with TFDA requirements and ICH–GCP.

4. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in monitoring this clinical trial.

5. I have*/have not (delete as applicable) previously been the monitor at a site which has been closed due to failure to comply with GCP. (*Attach details.).

6. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices. (*Attach details).

7. I will submit all required reports when needed.

Signature: **Date:**

Witness: **Date:**