**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 TMDA 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 TMDA 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:**