Template Agreement for Local Independent Safety Monitor for a Clinical Trials

Protocol Title:

Principal Investigator:

Sponsor:

Date:

Dear \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*name of ISM*)

You have kindly agreed to act as the local Independent safety monitor for the above trial. Your role is important to the conduct of the study and to independently assure the safety of the participants.

This roles requires that you review all adverse events and thoroughly investigate and serious and unexpected events. We shall therefore notify you via (*telephone/email - please describe*) of any SAE’s immediately the trial team becomes aware of any such event. Please then arrange with the trial team to review the case as soon as possible, and where appropriate examining the participant in question. Please produce a short report on each SAE.

Every (*week/month/ 6 months – as appropriate to the length and complexity of study*) we will give you a report of all the adverse events for your review. Please produce a short report on your review of these events.

Please let us know if you have any questions and we appreciate your help with this clinical trial.

Best wishes

(The PI and or sponsor)