APPENDIX A: Chief Investigator Declaration

As Chief Investigator, I agree to abide by the following:

- ✓ The dignity, rights, safety and well-being of participants must be the primary consideration in any research study, in addition to reliable and accurate research data;
- ✓ I am familiar with my responsibilities as Chief Investigator under the UK Policy Framework for Health and Social Care and should I vacate the role, will organise a suitable replacement and gain the necessary approvals for this change;
- ✓ I will undertake the project in accordance with the UK Policy Framework for Health and Social Care, Good Clinical Practice (GCP) regulations, and, where applicable, the Medicines for Human Use (Clinical Trials) Regulations and R&KEO SOPs;
- ✓ The project will not commence until approval has been received from the Sponsor, the appropriate Research Ethics Committee, Health Research Authority, the Host Organisation (and, for Clinical Trials, the MHRA);
- ✓ Any amendments to the protocol or Trial design, including changes to start / end dates must be notified to the Sponsor, the appropriate Research Ethics Committee, Health Research Authority, and the Host Organisation;
- ✓ Each member of the research team is suitably qualified by education, training and experience to undertake the research;
- ✓ Each member of the research team will have access to adequate support, supervision and training;
- ✓ Any serious adverse events that occur during the research will be reported immediately to R&KEO. As PI I understand that I will be responsible for reporting such events to other appropriate bodies (Research Ethics Committees, Health Research Authority, Host Organisation, MHRA).
- ✓ Data will be processed and stored in accordance with the European General Data Protection Regulation and the Data Protection Act 2018;
- ✓ An adequate project master file will be maintained and made available for audit inspection;
- ✓ Full, accurate and legible records will be maintained in accordance with GCP guidelines and will be made available for audit inspection;
- ✓ Any adverse events or reactions as identified through GCP guidelines will be reported within the required timelines and a full record kept in the project master file;
- ✓ Make every reasonable effort to ensure that a peer-reviewed publication results from the research;

Project Title: | |

Signed: .....

(Must be signed by the Chief Investigator or in the case of student projects, by the project supervisor)

Name: (PLEASE PRINT) .....

Date: ...../...../..... (dd/mm/yy)