CTIMP – Non-CTIMP Co-Enrolment Checklist

This checklist must be completed by the CI and reviewed by the Sponsor Representative(s) for all instances where participants are intended to enrol in a CTIMP whilst also receiving an intervention from a non-CTIMP. Either, or both studies, must be sponsored by UoE and/or NHSL.

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| --- | --- |
| **CTIMP** | **Non-CTIMP** |
| **Trial Name:** |  | **Study Name:** |  |
| **Registry Number:** |  | **Registry Number:** |  |
| **REC Number:** |  | **REC Number:** |  |
| **Chief Investigator:** |  | **Chief Investigator:** |  |
| **Sponsor:** |  | **Sponsor:** |  |
| **Action** | **Completed** | **Comment** *(if N/A, provide justification)* |
| 1 | [CTIMP] Chief Investigator (CI) has been informed of the plan to co-enrol with [Non-CTIMP] and has provided written agreement for this to take place. *If the non-CTIMP will be in an interventional phase, the CTIMP CI must be prompted to consider the potential impact on trial endpoints and consult the [CTIMP] TMG or TSC and statistician where appropriate. if UoE-NHSL are co-sponsors. Otherwise, it is the responsibility of the CI to inform their Sponsor (if required) of the intention to co-enrol and to comply with their relevant sponsor processes* | ☐ Yes |  |
| 2 | [Non-CTIMP] CI has been informed of the plan to co-enrol with [CTIMP] and has provided written agreement for this to take place.*It is the responsibility of the [Trial B] CI to inform their Sponsor (if required) of the intention to co-enrol and to comply with their relevant sponsor processes. The Non-CTIMP CI, if the study will be in an interventional phase, must be prompted to consider the potential impact on trial endpoints and, if deemed necessary by the sponsor, consult the [Non-CTIMP] TMG or TSC and statistician.*  | ☐ Yes |  |
| 3 | A Clinical Pharmacologist has been consulted regarding the co-enrolment and has confirmed in writing that there are no safety concerns prohibiting the co-enrolment. *Where there is potential for drug interactions, the protocols and IMP (and NIMP if applicable) information (i.e. SPCs/IBs) should be sent to the clinical pharmacologist for review.*  | ☐ Yes☐ N/A |  |
| 4 | [CTIMP] CI will be advised by Sponsor Representative that co-enrolment should be documented in all co-enrolled participants medical notes when providing the completed checklist. | ☐ Yes☐ N/A |  |
| 5 | ACCORD Risk Assessment has been appraised and signed off.*Please select N/A if proposed co-enrolment is compatible with the co-enrolment rules described in the current risk assessment tool and protocol for the UoE/NHSL sponsored project(s).* | ☐ Yes☐ N/A |  |
| **Approvals** |
| Action points 1-5 must be completed and evidenced prior to sign-off by the co-Sponsors. The co-enrolment cannot take place until this checklist has been completed and the Sponsor has provided written authorisation for the co-enrolment to proceed. |
| **Sponsor Representative Sign-Off**  |
|  |  |  |  |  |  |  |
|  | **Sponsor Representative Signature** |  | **Position** |  | **Date** |  |