**Appendix 2 – Multi Centre Checklist**

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| **Item Number:** | **Description of Sponsor Responsibility** | **Delegated to:** | **Included in contract:** |
|  | Who are the main points of contact between Sponsor and 3rd Party? The main topics to be considered: |  |  |
| Governance arrangements |  |  |
| EDGE |  |  |
| Contracts |  |  |
| Finance |  |  |
| Authorisations and sign off during trial sponsor Decision making. |  |  |
|  | Confirmation of whether existing EDGE Attributes / workflows to be used or study specific to be developed. Clear instruction is required for who will complete each attribute / workflow before the study commences. |  |  |
|  | Confirmation of which procedures are to be followed. Will sites follow Sponsor SOPs or will they be included in a Trial Specific procedure document |  |  |
|  | Who will be responsible for ensuring Training (GCP and Consent) is provided to all sites and appropriately documented. How will it be documented and where. Will training records be uploaded to EDGE for each site? |  |  |
|  | Site Feasibility – Confirmation of which documentation will be used for site feasibility – UHL Sponsor or 3rd Party form. (to include Pharmacy / support departments) |  |  |
|  | Site Feasibility – confirmation of which organisation will complete the RED Level of EDGE to confirm appropriate feasibility undertaken. (to include Pharmacy / support departments) |  |  |
|  | Who will be responsible for sending sites the Study Information Pack, answering queries and assisting with study set up. |  |  |
|  | Who will be responsible for sending sites the Study Information Pack following amendments, answering queries and assisting with amendment set up. |  |  |
|  | Site Initiation – Confirmation of which organisation will conduct site initiation. Which documentation will be used for initiation – UHL Sponsor or 3rd party form. |  |  |
|  | Site Initiation – confirmation of which organisation will complete the RED level of EDGE to confirm site initiation undertaken |  |  |
|  | Confirmation of Green Light -which organisation generates Sponsor green light for approval and communicates with the sites |  |  |
|  | Which organisation completes the RED Level of EDGE and uploads documents to confirm Sponsor Green Light for each site |  |  |
|  | Confirmation of Contracts / SOECAT process – who liaises with the sites. Who makes the decision on site contract amendments. Who signs the contract on behalf of the sponsor. |  |  |
|  | Confirmation of the Contracts / SOECAT amendments process – who liaises with the sties. Who makes the decision on site contract amendments. Who signs the contract on behalf of the sponsor. |  |  |
|  | Confirmation of Green Light for Amendments – which organisation generates Sponsor Green Light for approval and communicates with the sites |  |  |
|  | Which organisation completes the RED Level of EDGE and uploads documents to confirm Sponsor Green Light for each site |  |  |
|  | Who will be responsible for recruitment upload to CPMS and EDGE for the whole trial and chasing sites / verifying information from sites |  |  |
|  | How will SAE’s / SUSARS be reported to the Sponsor, how frequently, by which means and to who. Who will follow up on all safety reporting and ensure all SAEs/SUSARS are closed off appropriately at each site. |  |  |
|  | Who will conduct monitoring at sites. Who will chase monitoring visit reports to ensure completion. When and how will monitoring reports be submitted to the Sponsor. Will the sponsor be notified of the dates of monitoring visits. How soon after a monitoring visit will the sponsor receive the reports. |  |  |
|  | How will protocol deviations / serious breaches / Urgent safety measure be managed. Who will be responsible and how will communication with the sponsor take place and how frequently. Who will ensure all CAPAs are completed, finalised and signed off. |  |  |
|  | How will archiving be managed and achieved at the end of the study. Who will be responsible for ensuring sites archive appropriately. Who will archive the TMF and electronic data as per sponsor SOP? |  |  |
|  | Who will manage and ensure site closure is completed, EDGE updated and appropriate checks documented and signed off |  |  |
|  | Who will lead communication with the sites on trial specific information, study newsletters etc. |  |  |
|  | Who will be main point of contact between sites and 3rd party. How will the sponsor be engaged where necessary. |  |  |
|  | What regular reporting will be in place between 3rd party and sponsor on conduct and progress etc. TMG’s / TSC’s |  |  |
|  | Clear lines of communication in cases of urgent situations – i.e. Pandemic planning etc. |  |  |