**TMPL\_023: Statement of Responsibilities for CTIMPs and Complex non-CTIMP Sponsored Studies**

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| **Study Title** |  |
| **R&D Reference Number** |  |

UHBW, as the Sponsor, takes responsibility for the quality and conduct of the research study. For CTIMPs, this includes the following areas of legal responsibility, as described in the Clinical Trials regulations:

* Authorisation for clinical trials and research ethics committee opinion
* GCP and the conduct of clinical trials
* Pharmacovigilance
* Manufacture and labelling of investigational medicinal products

Where UHBW is Sponsor of a study, it is expected that the Chief Investigator will maintain oversight as described in the UHBW Investigator Oversight SOP. Although certain roles and duties within the trial may be delegated (eg to trials units and research nurses), the CI must maintain oversight of the delivery of the trial. More generally, the CI is expected to demonstrate clinical leadership as champion of the study and to work closely with other investigators and staff and with their clinical trials unit (where applicable).

It is the responsibility of the Chief Investigator to comply with regulations (CTIMPs) and to conduct the study in accordance with:

* Medicines for Human Use (Clinical Trials) Regulations 2004 (SI031) and amendments (CTIMPs only)
* UK Policy Framework for Health and Social Care Research
* ICH GCP Guidelines – May 1996
* UHBW’s Research Policy (current version can be found on both the Trust DMS and R&D website)
* UHBW’s Research SOPs (current versions can be found on both the Trust DMS and R&D website)

As part of the sponsorship process, the CI and a Sponsor representative will attend an initial Risk Assessment meeting and will document identified risks and mitigations to address the risks. It is the shared responsibility of the Sponsor and the CI to identify and document the risks and mitigations to risks throughout the life-cycle of the study.

**Further information on CI responsibilities can be found in UHBW’s Investigator Oversight SOP.**

***By signing below, I am fully aware and understand my responsibilities as Chief Investigator. I agree to conduct the study in accordance with the applicable legislation UHBW’s Research Policy and UHBW’s Research SOPs.***

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| **Signed:** | ………………………………………………………………………………………………………………………………………………. |
| **Name:** | ………………………………………………………………………………………………………………………………………………. |
| **Date:** | ………………………………………………………………………………………………………………………………………………. |

**Acknowledgement of Sponsor Responsibilities *(as described in UHBW’s Sponsorship SOP)***

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| **Signed:** | ………………………………………………………………………………………………………………………………………………. |
| **Name:** | ………………………………………………………………………………………………………………………………………………. |
| **Date:** | ………………………………………………………………………………………………………………………………………………. |