Pro-forma for MEMO

v3.8 05.FEB.2024

R&D Number:       Date of Discussion:

*Sections A and B of this form should be completed and submitted to MDSO@uhbw.nhs.uk*

**Section A**

|  |
| --- |
| **Study Title:**  |
| **Principal Investigator (PI) at UHBW:**      Tel:       | **Point of Contact (PoC) at UHBW:**      Tel:       |
| **Sponsor:**       | **Funding organisation:**       |
| Is this a commercially sponsored study? | [ ]  Yes | [ ]  No | How will any costs outlined below be met?       |
| Estimated study start date (at this site):      /     /      | Projected study end of recruitment date:      /     /     Projected end of support department involvement date:      /     /      |
|  |  |  | Estimated number of participants:       |

**Section B**

|  |  |
| --- | --- |
| **Study medical device 1:** |       |
| Supplier: |       |
| Is the use of the device? | Part of standard clinical care | [ ]  | Over and above standard clinical care | [ ]  |
| Has the device been tested and accepted by MEMO? | Yes | [ ]  | No | [ ]  | NA | [ ]  | **If yes**, MEMO number?  |       |
| Does the device have a CE mark?**If yes**, what does the CE mark cover?       | Yes | [ ]  | No | [ ]  | NA | [ ]  | **If device has a CE mark and is being used within its intended CE mark MEMO pro-forma is not required** |
| Is the device being used ‘off-label’ i.e. is it being used in a different way to that which it was intended? | Yes | [ ]  | No | [ ]  | NA | [ ]  |
|  |  |  |  |  |  |  |  |
| Any Additional Information:  |       |

|  |  |
| --- | --- |
| **Study medical device 2:** |       |
| Supplier: |       |
| Is the use of the device? | Part of standard clinical care | [ ]  | Over and above standard clinical care | [ ]  |
| Has the device been tested and accepted by MEMO? | Yes | [ ]  | No | [ ]  | NA | [ ]  | **If yes**, MEMO number?  |       |
| Does the device have a CE mark?**If yes**, what does the CE mark cover?       | Yes | [ ]  | No | [ ]  | NA | [ ]  | **If device has a CE mark and is being used within its intended CE mark MEMO pro-forma is not required** |
|  |  |
| Is the device being used ‘off-label’ i.e. is it being used in a different way to that which it was intended? | Yes | [ ]  | No | [ ]  | NA | [ ]  |
|  |  |  |  |  |  |  |  |
| Any Additional Information |       |

|  |
| --- |
| **Resource Authorisation**To be completed by Brett Cohen or Azzam Taktak. The form may either be signed or returned via email from the signatory’s UHBW email account |
| Are there any there any resource implications or costs to MEMO associated with supporting this study? | Yes | [ ]  | No | [ ]  | NA | [ ]  |
| If **Yes** Please detail |  |
| **Capacity & Capability statement:** MEMO will support this study based on the information outlined above |
| **Name:** | **Signature:** | **Date:      /     /** |