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**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  | |
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| Any Additional Information: | |  | | | | | | | | | | | | | | |

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| **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 | |  | | | | | | | | | | | | | | |

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| **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:      /     /** | | | | | | |