Appendix 1

Appendix 1 - Additions for EVERY STUDY – UHL as Host/Site

Every study added to EDGE must have the following added irrespective of the type of study (except for Musketeer Memorandum studies & where Capacity & Capability Confirmation is not required (CCC) which are dealt with at the end)

Teams added: UHL R&I Team

Relevant Study support team for PI CMG (Which CMG employs the PI rather than the disease area of the study)

Individuals: Where you know for certain who the PI is, please add them ensuring that choose employing organisation as UHL on the RED LEVEL ONLY

****Where University of Leicester is Sponsor please add University Sponsor Team**

These teams must be added at BOTH the **GREEN** (Project Level) and **RED** (Site Level) – **please remember to tick Manage for each Team.**

Attributes to be added at **PROJECT LEVEL (GREEN):**

Contracts

Data Flows / GDPR*

Feasibility (Arrange)

Finance

HRA approval

Mandatory Category 1, 2, 3 & 4 (please complete Primary Clinical Management Area if known)

Software / Hardware Requirements

Communications

*This attribute must be added but it does not need to be fully completed prior to authorisation.

Workflows to be added **PROJECT LEVEL (GREEN):**

Archiving Arrangements

CMG Approval

Confirm Process Stage 3

Contracts Process WEF 01.04.2019

Final Contracts Pre-Sign Checks (HRA Studies Only)

Finance

Study Staff Added

When adding UHL as a site on the **RED LEVEL** ensure **Patient identifier type is set at Local Number**.

ADD TEMPLATE PROJECT FILES TO SITE LEVEL FILES (IN RED LEVEL)

All other attributes and workflows must be added where relevant in accordance with the excel spread sheets.

Teams or Users must be added as relevant to the CMG / Specialty or Support Department.

PHARMACY

Where it is identified that Pharmacy are involved with a study. Please add the following workflows:

On the Project Level **(GREEN)**

Pharmacy Approval (R&I Use)

On the Project Site Level (**RED**)

UHL Pharmacy Approval Workflow (Pharmacy Use)

In addition, please add Pharmacy Team to the **RED** Level

IMAGING

Where it has been identified that IMAGING are involved with a study. Please add the following workflows:

On the Project Level **(GREEN)**

For studies added up to and including 5th August 2016 workflow 'Imaging Services Approval (R&I Office Use Only)' may have been added to studies. If the workflow has been added then it must be completed, but from 5th August 2016 onwards the RED level imaging approvals are sufficient and this 'old' Workflow is now longer needed.

On the Project Site Level (**RED**)

Imaging Approval Workflow (Imaging Use Only)

Imaging Post Approval Check Workflow (Imaging Use Only)

Imaging Research Proposal Application Attribute

In addition, please add Imaging Team to the **RED** Level

MEDICAL DEVICES / EQUIPMENT

Where it has been identified that MEDICAL DEVICES / EQUIPMENT are involved with a study, please add the Medical Devices / Equipment Attribute to the **GREEN** Level

Then add the workflows relevant to the Study in the **RED** Level:

If the equipment to be used in the study does NOT have a CE Mark then add the Workflow 'Medical Devices Authorisation – NO CE MARK'

If the equipment to be used in the study DOES have a CE Mark then add the Workflow 'Medical Devices Authorisation – CE MARKED'

CARDIAC SERVICES

Where it has been identified that CARDIAC SERVICES are involved with a study. Please add the following workflows:

On the Project Level **(GREEN)**

For studies added up to and including 5th August 2016 workflow 'Cardiac Services Approval' may have been added to studies. If the workflow has been added then it must be completed, but from 5th August 2016 onwards the RED level approvals are sufficient and this 'old' Workflow is now longer needed.

On the Project Site Level (**RED**)

Cardiac Investigations Workflow

Cardiac Investigations Attribute

In addition, please add Cardiac Services Team to the **RED** Level

PATHLOLOGY

Where it has been identified that PATHOLOGY are involved with a study. Please add the following workflows:

On the Project Level **(GREEN)**

Add the Laboratory Services

On the Project Site Level (**RED**)

Laboratory Services approval (Pathology Services Only) Workflow

Pathology Services Approval Attribute

In addition, please add Laboratory Services Team to the **RED** Level

MUSKETEERS MEMORANDUM STUDIES

The Musketeers Memorandum is a special arrangement that has been agreed to allow Genetic studies to be approved very quickly for many rare diseases. UHL has signed up to the agreement and as such we undertake to approve studies within days of receipt. Many Musketeers studies do not follow the usual project information so it will be difficult to add in all the information for all those studies. Separate Attributes and Workflows have been built to accommodate these studies.

It is obvious when you receive a MM study. Each MM study needs the following only:

Musketeers Memorandum Attribute

Musketeers Memorandum Workflow

Mandatory Category 2 Attribute

Mandatory Category 4 Attribute.

Teams added: UHL R&I Team

Add all relevant Local PI and staff in the speciality.

NO REQUIREMENT FOR CONFIRMATION OF CAPACITY OR CAPABILITY STUDIES

These are studies where the HRA confirm that there is no expectation for a Trust to confirm their Capacity or Capability. They require minimal review and often the only activity is to provide a meeting room.

These studies must have the following attributes added on the **GREEN** Level:

- Mandatory Category 4
- HRA Approval
- Capacity/Capability Confirmation NOT REQUIRED
- Mandatory Category 1 (Primary Clinical Management Area)

The following Workflows must be added on the **GREEN** level:

- Capacity/Capability Confirmation NOT REQUIRED

All relevant staff and Points of Contact will be added to the study in the usual way.