A Sponsor's Guide to the TUH Clinical Trial Feasibility Process

Here at Tallaght University Hospital (TUH), we endeavour to facilitate all clinical trials. We have developed a streamlined online feasibility process for clinical trials that are approved or currently undergoing approval under the EU Clinical Trials Regulation (EU-CTR). Applications are made via an online platform which connects TUH department leads. A member of staff is available to complete this form on behalf of sponsors. As a sponsor, we ask that you provide us with as much relevant information as possible so that we can help our department leads make a prompt and informed decision in order to deem the trial feasible. The application is reviewed by Pharmacy, Radiology and the Meath Foundation Research Laboratory, depending on which resources are required. For other services, including neurophysiology, echo-cardiology and spirometry, we make contact with these departments outside of the online platform.

1.0 Required Documents

1.1 The latest version of the trial protocol or synopsis. Our study coordinators require this information to determine which TUH resources are needed to conduct the trial. This document is not shared with other departments or staff

outside of the trial team. We will act in accordance **with non-disclosure agreements and/or confidentiality agreements where appropriate.**

1.2 **The latest version of the IMP Pharmacy Manual;** if use of the pharmacy department is required.

1.3 **The latest version of the Imaging Guide;** if radiological imaging is required.

1.4 **The latest version of the Laboratory Guide; if sample preparation and storage is required.**

Our online feasibility form enables us to assess a department's ability to facilitate trial activities at TUH. A department's inability to facilitate a trial does not preclude the trial from being conducted at TUH, as certain services may be outsourced to third-party vendors.

2.0 What we do with this information

We treat all manuals, protocols and sponsor information in accordance with Non-Disclosure Agreements, Confidentiality Agreements and General Data Protection Regulations, to which all EU sites are subject. We only share pertinent information with TUH department leads in order to respond to our sponsors promptly.

2.1 **As part of the application we inform the Department Leads of the following information.**

2.1.1 Target enrollment number of participants.

2.1.2 Projected Start Date

2.2 Pharmacy Specific

2.2.1 List of all IMPs and their route(s),

2.2.2 Storage condition,

2.2.3 Schedule for initial supply,

2.2.4 If specific equipment is needed like IV pumps and giving sets,

2.2.5 Anticipated start date,

2.2.6 If there is a standard of care arm/comparator or supplementary products and whether these are supplied by the sponsor.

2.3 **Radiology Specific**:

2.3.1 What services/scans are required,

2.3.2 If contrast is required,

2.3.3 Target patients,

2.3.4 How many the trial will run for,

2.3.5 How often scans are required,

2.3.6 If images are to be read/sent off-site, to where and how it will be transferred,

2.4 **Meath Foundation Research Laboratory (MFRL) specific**:

2.4.1 Source of funding to pay lab fees,

2.4.2 Type of sample,

2.4.3 Number of samples per week,

2.4.4 Estimated total number of samples,

2.4.5 Expected weekly lab use,

2.4.6 Equipment and storage requirements,

2.4.7 Shipping requirements,

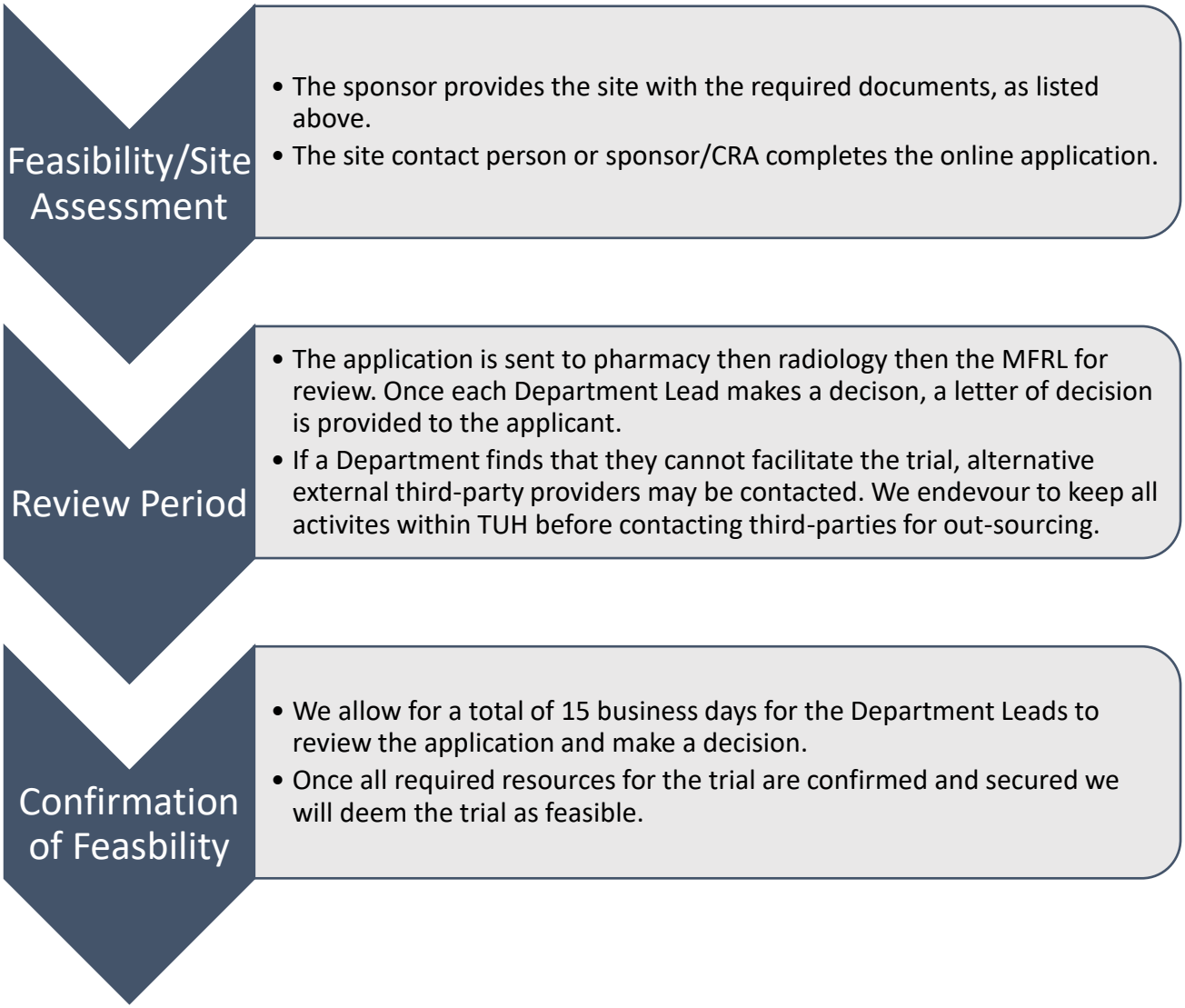
2.4.8 Estimated duration of lab access in weeks,

2.4.9 Number of staff who need lab access, and their roles,

2.4.10 If staff need IATA training/lab safety training.,

2.4.11 Biosafety/hazard classification,

2.4.12 If infectious samples will be processed.



Further Information:

If you would like to complete, or you would like a member of our staff to complete the online Clinical Trial Feasibility application, please contact ResearchEthics@tuh.ie and your email will be forwarded to the applicable person.