REQUEST FOR SIGNATURE DOCUMENT FOR RESEARCH PURPOSES

A fully completed hard copy of this form, plus supporting sign-off documentation, must be forwarded to the Quality & Patient Safety Department for review prior to CEO sign off & commencement of your research study.

1. PRINCIPAL INVESTIGATOR – BEAUMONT HOSPITAL EMPLOYEE:

Name: _____

Position / Department: _____

Telephone No:_____ E-Mail: _____

2. SECOND ON-SITE CONTACT PERSON:

Name: _____

Position / Department: _____

Telephone No:_____ E-Mail: _____

3. WHAT TYPE OF RESEARCH DOES YOUR REQUEST RELATE TO:

TITLE OF RESEARCH STUDY: _____

_____

_____

Is this a Clinical Trial of a Medicinal Product under the EU Clinical Trial Regulations?

Yes ☐ No ☐

If yes, please confirm HPRA approval (include supporting documentation)

Is this a Clinical Investigation of a Medical Device under the EU Medical Devices Regulations? **Yes ☐ No ☐**

If yes, please confirm HPRA approval (include supporting documentation)

Does this study involve additional exposure to ionising radiation? **Yes ☐ No ☐**

If yes, and the medical exposure is proposed to take place in Beaumont Hospital, please confirm notification to the Beaumont Hospital Radiation Safety Committee:
(include supporting documentation)

Does this study require a health research consent declaration? **Yes ☐ No ☐**

If yes, please confirm HRCDC has granted the declaration:
(include supporting documentation)

4. ETHICS:

Please state name of Ethics Committee which has provided ethical approval:

_____

DATE OF ETHICS APPROVAL: _____
(include supporting documentation)

5. DATA PRIVACY IMPACT ASSESSMENT:

Has a Data Privacy Impact Assessment been completed and reviewed by the DPO?
(include supporting documentation) **Yes ☐ No ☐**

Have all recommendations from the DPO been taken into account and changes incorporated into relevant documents? **Yes ☐ No ☐**

6. LEGAL REVIEW - CONTRACTS / AGREEMENTS:

Name of Sponsor: _____

Please state type of agreement (CTA/DSA/MTA/OTHER) _____

Date the contract/agreements above was legally approved _____
(include supporting documentation)

7. INSURANCE / INDEMNITY:

Please confirm the study and its insurance / indemnity implications have been approved by the Hospital.

(include supporting documentation) **Yes ☐ No ☐**

Date of insurance approval: _____

8. FINANCE REVIEW:

Please confirm the study has been approved by the Finance Department.

Date of approval by Director of Finance _____

(include confirmation memo from Finance) **Yes ☐ No ☐**

9. DECLARATION OF PRINCIPAL INVESTIGATOR

I confirm that the details provided are accurate and that there are adequate facilities, resources and personnel in place to allow this research study to be conducted on the premises. Furthermore, I agree to inform the Chief Executive Officer if this changes during the course of the study.

Standard Clinical Trial Indemnity Form

I confirm that the Standard Clinical Trial Indemnity Form has not been altered in any respect; and no changes to the main content or text of this document have been made such as to invalidate it.

I confirm that I am aware of my role in compliance with General Data Protection Regulation as they pertain to this study.

_____ _____

Signature of Principal Study Investigator **Date**

_____

NAME (BLOCK CAPITALS) of Principal Investigator

10. HOSPITAL APPROVAL:

I confirm that all appropriate approvals are in place:

Title of Study: _____

_____

_____

_____ _____

On behalf of the Quality and Patient Safety Dept. **Date:**

Quality & Patient Safety Directors Office contact number: **01 809 3926**