**REQUEST FOR SIGNATURE DOCUMENT**

**FOR RESEARCH PURPOSES**

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

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**USEFUL CONTACT DETAILS**

Director of Quality & Patient Safety 01 809 3921

Finance Department: 01 809 2107 / 2904

Insurance Department: 01 809 2611 / 3250

Head of FOI/Legal Review 01 797 7330

AON Healthcare: 01 266 6432 ([www.aon.ie](http://www.aon.ie))

Beaumont Ethics (Medical) Research 01 797 4711/01 8092680

**1. (a)PRINCIPAL STUDY INVESTIGATOR –BEAUMONT HOSPITAL EMPLOYEE**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position / Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. (b) SECOND ON-SITE CONTACT PERSON (IF AVAILABLE)**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Beaumont Hospital / Smurfit Building Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Beaumont Hospital / Smurfit Building extension no: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Beaumont Hospital / RCSI e-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. (c) NATIONAL LEAD (MULTI-SITE STUDIES) – IF DIFFERENT FROM 1(a)**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. 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) **Yes □ No □**

**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) **Yes □ No □**

**Does this study include whole genome sequencing involving a commercial third party?**

If yes, please provide details of commercial third party: **Yes □ No □**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

If yes, please confirm approval by Beaumont Hospital Radiation Safety Committee:

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

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

If yes, please confirm HRCDC has granted the declaration:

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

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATE OF ETHICS APPROVAL**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Include supporting documentation)

PROPOSED START DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ PROPOSED END DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Protocol No: \_\_\_\_\_\_\_\_\_\_\_ EudraCT No: \_\_\_\_\_\_\_\_\_\_\_\_ REC. REF. NO: \_\_\_\_\_\_\_\_\_

**3. DATA PRIVACY IMPACT ASSESSMENT**

Has a Data Privacy Impact Assessment been completed and reviewed by the DPO?

(Include supporting documentation) **Yes □ No □**

Date of review by Beaumont Hospital DPO: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**4. INSURANCE / INDEMNITY**

Please confirm the study and its insurance / indemnity implications (Standard

Clinical Trial Indemnity Form and Certificate of Insurance form Sponsor if relevant)

has been approved by the Hospital Insurance Department[[3]](#footnote-3)? **Yes □ No □**

Date of approval by Hospital Insurance Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please include supporting documentation i.e. Standard Clinical Trial Indemnity Form

and letter of notification from AON Healthcare)

**5. LEGAL REVIEW - CONTRACTS / AGREEMENTS**

**Name of Sponsor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this study covered under a master agreement? **Yes □ No □**

If yes, please provide details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is there a contract / CTA for this study? **Yes □ No □**

Is there a Data Sharing Agreement? **Yes □ No □**

If there a Material Transfer Agreement? **Yes □ No □**

Other agreement? **Yes □ No □**

Please state type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has the contract/agreements above been reviewed by the Hospital Legal Advisor[[4]](#footnote-4)?

 **Yes □ No □**

DATE OF REVIEW BY HOSPITAL LEGAL ADVISOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please include supporting documentation from Hospital Legal Advisor)

**6. FINANCE REVIEW**

Has the study and its financial implications been discussed and approved by the

Director of Finance? **Yes □ No □**

Date of approval by Director of Finance[[5]](#footnote-5) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please include supporting documentation)

**7. VALIDATED AND SIGNATURE DOCUMENTS INCLUDED IN PACK:**

|  |  |  |  |
| --- | --- | --- | --- |
| **VALIDATED DOCUMENTS** |  | **DOCUMENTS FOR SIGNATURE** |  |
| *Health Products Regulatory Board (HPRA) Approval letter(if required)* |  | *Standard Clinical Trial Indemnity Form*  |  |
| *Approval of Radiation Safety Committee (if required)* |  | *Clinical Trial Agreement (CTA)*  |  |
| *Ethics Approval letter received* |  | *Data Transfer / Sharing Agreement*  |  |
| *Data Protection Impact Assessment (DPIA) review* |  | *Materials Transfer Agreement* |  |
| *Insurance Department validation memo from AON* *re: Indemnity received.* |  | *Other (please specify)* |  |
| *Sponsor insurance certificate* |  |  |  |
| *Legal Review:**-Clinical Trial Agreement**-Materials Transfer Agreement**-Data Transfer/ Sharing Agreement**-Other*  |  |  |  |
| *Finance Validation memo received* |  |  |  |

**8. DECLARATION OF PRINCIPAL INVESTIGATOR**

**Site Specific Assessment Form**

I confirm that the details provided in the Site Specific Assessment Form are accurate and I concur with the declaration therein 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 ([www.stateclaimsagency.ie](http://www.stateclaimsagency.ie))

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**

**9. HOSPITAL APPROVAL**

**I confirm that all appropriate approvals are in place:**

**Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sharon Dwyer Date:**

**Director of Quality and Patient Safety**

**A fully completed copy of this document plus a scanned copy of original signed contracts/agreements must be sent to Legal Services. (legalservices@beaumont.ie)**

1. Principal study investigator must be a Beaumont Hospital employed healthcare professional [↑](#footnote-ref-1)
2. This may be a research nurse or research assistant [↑](#footnote-ref-2)
3. lynneherbert@beaumont.ie / 01 809 2611 [↑](#footnote-ref-3)
4. legalservices@beaumont.ie – submissions for legal review is by e-form link below:

<http://eforms/administration/requestforclinicaltriallegalreview/lists/forms/newform.aspx?FlowId=1&IsDlg=1&src=http://my.beaumont.ie> [↑](#footnote-ref-4)
5. kennethruigrok@beaumont.ie@beaumont.ie [↑](#footnote-ref-5)