STANDARD APPLICATION FORM

# ADAPTED VERSION 26 June 2023

For the Ethical Review of

Health-Related Research Studies, which are not subject to National Research Ethics Committee Review

DO NOT COMPLETE THIS APPLICATION FORM

IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT OR A CLINICAL INVESTIGATION OF A MEDICAL DEVICE

REQUIRING HPRA AUTHORISATION OR A POST-MARKETING FOLLOW-UP INVESTIGATION OF A MEDICAL DEVICE

# **Title of Study:** Assessing the impact of hygiene and motivation factors on job satisfaction among Anaesthesiology doctors in training in a large tertiary referral hospital

Application Version No: 3 Application Date: 9/4/2024



SECTION A GENERAL INFORMATION MANDATORY\*

SECTION B STUDY DESCRIPTORS MANDATORY\*

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This Application Form is divided into Sections.

\*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

**IMPORTANT NOTE:** Please refer to **Sections H and I** within the form before any attempt to complete the Standard Application Form. **Section H** is designed to assist applicants in ascertaining if their research study is in fact a clinical investigation of a medical device or a post-marketing follow-up investigation of a medical device. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

Please contact the Health Products Regulatory Authority, the National Research Ethics Committee for Clinical Trials (NREC-CT) or the National Research Ethics Committee for Medical Devices (NREC-MD) if in doubt.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

**PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.**

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

**A1 Title of the Research Study:**



**A2 (a) Is this a multi-site study?**

If you chose ‘yes’ please delete questions A2 (e) (f) and (g); If you chose ‘no’ please delete Questions A2 (b) (c) and (d)

**A2 (e) If no, please name the chief investigator with overall responsibility for the conduct of this single-site study.**

**Title: Name:** Criona Walshe

**Qualifications:** MB BCh BAO BMed Sci FFARCSI FJFICMI MD MSc Med Ed

**Position:** Consultant Anaesthesiologist

**Dept:** Anaesthesiology, Pain and Critical Care Medicine

**Organisation:** Beaumont Hospital

**Address:** Beaumont Road, Dublin 9

**Tel:** 01 809xxxx **E-mail:** xxxx[@beaumont.ie](mailto:crionawalshe@beaumont.ie)

**A2 (e) (i) Joint appointment / Dual affiliation applies:**

**A2 (f) For single-site studies, please name the only site where this study will take place.**



**A2 (g) For single-site studies, please provide details of the principal investigator at the site.**

**Title: Name:** Criona Walshe

**Qualifications:** MB BCh BAO BMed Sci FFARCSI FJFICMI MD MSc Med Ed

**Position:** Consultant Anaesthesiologist

**Dept:** Anaesthesiology, Pain and Critical Care Medicine

**Organisation:** Beaumont Hospital

**Address:** Beaumont Road, Dublin 9

**Tel:** 01 809xxxx **E-mail:** xxxx[@beaumont.ie](mailto:crionawalshe@beaumont.ie)

**A2 (g) (i) Joint appointment / Dual affiliation applies:**

**A3. Details of Co-investigators:**

**Name of site (if applicable):** Beaumont Hospital

**Title: Name:** Susan Duggan

**Qualifications:** BA MSc BL **Position:** Associate Faculty **Dept :** Academic

**Organisation:** Irish Management Institute

**Address:** Sandyford Rd Dublin 16

**Tel:** 01207xxxx **E-mail:** xxxxx[@ucc.ie](mailto:susan.duggan@ucc.ie)

**Role in Research e.g. statistical / data / laboratory analysis:** Idea development/conduct of research, data analysis and write-up

**Name of site (if applicable):** Beaumont Hospital

**Title: Name:** Paul O’Connor

**Qualifications:** BSc Psychology, MSc Research Methods Psychology, PhD Psychology

**Position:** Personal Professor

**Dept :** Academic Department of General Practice **Organisation:** National University of Ireland, Galway **Address:** a1 Distillery Rd, Newcastle, Galway, Irelan

**Tel:** 085xxxxxx **E-mail:** xxxxx[@universityofgalway.ie](mailto:paul.oconnor@universityofgalway.ie)

**Role in Research e.g. statistical / data / laboratory analysis:** Statistical advice for data analysis

**A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.**

**Name:** Dr Criona Walshe

**Position:** Consultant Anaesthesiologist

**Organisation:** Beaumont Hospital

**Address for Correspondence:** Beaumont Road, Dublin 9

**Tel (work):** 01 809xxxx **Tel (mob.):** 086xxxxxx  **E-mail:**

[crionawalshe@beaumont.ie](mailto:crionawalshe@beaumont.ie)

**A5 (a) Is this study being undertaken as part of an academic qualification?**



If answer is No, please delete remaining questions in Section A

**A5 (b) If yes, please complete the following:**

**Student Name(s):** Dr Criona Walshe

**Academic Course:** MSc in Leadership in Healthcare

**Academic Institution:** Irish Management Institute and University College Cork

**A5 (c) Academic Supervisor(s):**

**Title: Name:** Susan Duggan

**Qualifications:** BA MSc BL **Position:** Associate Faculty **Dept :** Academic

**Organisation:** Irish Management Institute

**Address:** Sandyford Rd Dublin 16

**Tel:** 01207xxxx **E-mail:** xxxx[@ucc.ie](mailto:susan.duggan@ucc.ie)

## SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

**B1. What is the anticipated start date of this study?**



**B2. What is the anticipated duration of this study?**



**B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.**



**B4. Provide brief information on the study background.**



Both hygiene and motivation factors are critical to motivation, however, they are mutually exclusive, such that hygiene factors do not motivate but are required to prevent dissatisfaction. Motivation factors are the elements required to promote satisfaction and motivation among employees. Measurement of hygiene factors may help identify sources of dissatisfaction as potential areas for improvement. Addressing these causes of dissatisfaction address is necessary as these elements must be addressed before workers can become motivated.

Anaesthesia doctors in training in Beaumont Hospital in recent years have regularly reported difficulties which fall under “hygiene” factors as defined by Herzberg, and this may be impacting levels of job satisfaction. This feedback generated the original idea to undertake this study.

Following comprehensive review of the literature, there is evidence of a link between employee engagement and job performance3. Engagement has been defined as the degree of involvement, satisfaction and enthusiasm an employee has for their work4. There is evidence that motivation and job satisfaction among doctors is associated with higher levels of patient care and experience5. There is a paucity of research examining job satisfaction among doctors, indeed hygiene and motivation factors have not been assessed among doctors in the Irish context, which makes this worthwhile area for further study in our context.

**References**

1. Herzberg F, Mausner B, Bloch Snyderman, B The motivation to work. Wiley 1959
2. Alrawahi S, Sellgren SF, Altouby S, Alwahaibi N, Brommels M. The application of Herzberg's two-factor theory of motivation to job satisfaction in clinical laboratories in Omani hospitals. Heliyon. 2020 Sep 6;6(9):e04829
3. Kang JY, Lee MK, Fairchild EM, Caubet SL, Peters DE, Beliles GR, Matti LK. Relationships Among Organizational Values, Employee Engagement, and Patient Satisfaction in an Academic Medical Center. Mayo Clin Proc Innov Qual Outcomes. 2019 Oct 22;4(1):8-20
4. Harter JK, Schmidt FL, Hayes TL. Business-unit-level relationship between employee satisfaction, employee engagement, and business outcomes: a meta-analysis. J Appl Psychol. 2002; 87(2):268-279.s
5. Halawani LA, Halawani MA, Beyari GM. Job satisfaction among Saudi healthcare workers and its impact on the quality of health services. J Family Med Prim Care. 2021 May;10(5):1873-1881.

**B5. List the study aims and objectives.**



**B6. List the study endpoints / measurable outcomes (if applicable).**







**B7. Provide information on the study design.**



**B8. Provide information on the study methodology.**

The research paradigm will be positivist, each variable under scrutiny is suitable for quantitative approach to measurement and analysis. All doctors in training in the department of anaesthesia at the time of the study will be included and invited to participate.

There are three clear steps required. Extensive research of the literature has yielded several studies that have validated questionnaires to measure hygiene and motivation factors. The questionnaire by Tan1 explores hygiene has been adapted to suit the study context, and will be piloted to ascertain ease of comprehension by study subjects. Job satisfaction will be measured using the Minnesota short questionnaire(MSQ)2 which collects data on intrinsic, extrinsic and general satisfaction. The MSQ has been used in the healthcare context3,4.

Included with this application are the study questionnaire that will be utilised, in addition to the participant information leaflet. Participation is entirely voluntary, completion of the questionnaire will require checking a box consenting to the processing of submitted data. Participants may choose not to respond (rather not say option) to the demographic data section, or leave any of the questions blank, or exit at any time. Incomplete questionnaires will be discarded and deleted.

1. Tan, TH, Waheed A Herzberg’s Motivation-Hygiene Theory and Job Satisfaction in the Malaysian Retail Sector: Mediating Effect of Love of Money Asian Academy of Management Journal 2011 Vol. 16 Pages 73-94
2. Weiss DJ, Dawis, R. V., & England, G. W Manual for the Minnesota Satisfaction Questionnaire 1967
3. *Sonmez LO, Gul M. Occupational burnout, job satisfaction and anxiety among emergency medicine doctors in Turkey. Pak J Med Sci. 2021;37(3):757-763.*
4. Walkowiak, Dariusz & Staszewski, Rafal. (2019). Nurses' Job Satisfaction -the Factor Structure of the Minnesota Satisfaction Questionnaire.

**B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.**



**B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).**



**B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.**



**B11. How many research participants are to be recruited in total?**



**B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).**



**B12 (b) Please provide details on the method of randomisation (where applicable).**



**B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.**



## SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

## C1 PARTICIPANTS – SELECTION AND RECRUITMENT

**C1.1 How will the participants in the study be selected?**



**C1.2 How will the participants in the study be recruited?**



**C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)**



**C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)**



**C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project?**



Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section E1 for explicit consent for data processing)

**C2.1 (a) Will informed consent to take part in the research be obtained?**

**C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained. Please note explicit consent to process personal data for research purposes is mandatory under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations unless the data is anonymous or a ‘consent declaration’ has been obtained or an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations**

**2021 applies.**



**C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)**



**C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?**

**C2.2 (b) If no, please justify.**



**C2.3 (a) Will there be a time interval between giving information and seeking consent?**

**C2.3 (b) If yes, please elaborate.**



**C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.**



Note: The Assisted Decision-Making Capacity (Amendment) Act 2022 took effect on the 26th April 2023.

Note: Refer to the HSE National Consent Policy for Health and Social Care Research – search “capacity” and / or “emergency”

**C3.1 (a) Will all adult research participants have the capacity to give informed consent?**

If answer is Yes, please delete remaining questions in Section C3



**C4.1 (a) Will any research participants be under the age of 18 i.e. Children?**



If answer is No, please delete remaining questions in Section C4



**C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity.**

**Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.**

1. **Healthy Volunteers**
2. **Patients**
   * **Unconscious patients**
   * **Current psychiatric in-patients**
   * **Patients in an emergency medical setting**
3. **Relatives / Carers of patients**
4. **Persons in dependent or unequal relationships**
   * **Students**
   * **Employees / staff members**
   * **Persons in residential care**
   * **Persons highly dependent on medical care**
5. **Intellectually impaired persons**
6. **Persons with a life-limiting condition**

(Please refer to guidance manual for definition)

1. **Persons with an acquired brain injury**

**C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).**



**C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.**



## SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

**D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?**



**D1 (b) What other activities (if any) are taking place for the purposes of this research study e.g. chart review, sample analysis etc?**



**D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.**



**D3. What is the potential benefit that may occur as a result of this study?**



**D4 (a) Will the study involve the withholding of treatment?**



**D4 (b) Will there be any harms that could result from withholding treatment**



**D4 (c) If yes, please elaborate.**



**D5 (a) How will the health of participants be monitored during the study, and who will be responsible for this?**



**D5 (b) How will the health of participants be monitored after the study, and who will be responsible for this?**



**D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?**

**D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?**



**D7 Please comment on how individual results will be managed.**

Note: refer to the HSE National Consent Policy for Health and Social Care Research – search “findings”



**D8. Please comment on how aggregated study results will be made available.**



**D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)?**



**D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)?**



## SECTION E DATA PROTECTION

SECTION E IS MANDATORY

## E1 DATA PROCESSING - CONSENT

Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section C2 for informed consent to take part)

**E1.1 (a) Will explicit consent be sought for the processing of data?**

**E1.1 (c) If yes, please confirm that a copy of the ‘explicit consent’ will be provided to the data subject prior to the commencement of the health research. This is mandatory requirement under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021.**





YOU MUST ANSWER ALL QUESTIONS IN THIS SECTION AS THEIR FULFILLMENT IS A MANDATORY REQUIREMENT UNDER THE DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018

**E2.1 Please specify which arrangements are in place to ensure that personal data will be processed as is necessary; a) to achieve the objective of the health research and; b) to ensure that shall not be processed in such a way that damage or distress to the data subject?**

| Personal data collected includes participant gender and whether on the training | |  | |
| --- | --- | --- | --- |
| scheme or not. These data will be processed in order to ascertain whether there is | | | |
| any association or impact from these factors on job satisfaction. There will be no | | |  |
| distress to participants as the option “prefer not to say” is provided. |  | | |

**E2.2 Please specify the data controller**\*1**; joint data controllers (if applicable) and any data processors**\*2 **involved in the research.**

| **Name of** | **Name of Organisations** | | | **Name of Organisations which** |
| --- | --- | --- | --- | --- |
| **Organisation** | **which are the Joint Data** | | | **are data processors acting on** |
| **which is the sole** | **Controllers for this** | | | **behalf of / and under the** |
| **Data Controller** | **research study (where** | | | **instruction of the sole data** |
| **for this research study** | **applicable)** | | | **controller or joint data controllers (if any)** |
| Beaumont Hospital |  | Non-applicable |  |  |
|  | **Please note contracts will apply** | | | |

**E2.3 Please specify any person or organisation who provides funding for, or otherwise supports, the project.**



**E2.4 Please specify any person other than employees of the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.**

| Anonymised survey data will be shared with academic supervisor in the IMI and to | |
| --- | --- |
| statistician in NUI Galway. They will provide advice on statistical analysis and assist | |
| with data analysis. |  |



1 ‘The data controller for a research study is the organisation that determines the purpose and the manner by which personal data are processed for the research study (i.e. ‘Whom’, ‘Why’, ‘How’).’ **– HSE RGMS Framework, Sept ‘21** 2 ‘A data processor is defined as the organisation that processes personal data on behalf of, and under the

instruction of, the data controller (i.e. two distinct organisations).’ **– HSE RGMS Framework, Sept ‘21**

**E2.5 The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legal requirement. Please specify the provision of training.**



**E2.6 Has a “risk assessment” and/or “data protection impact assessment” been carried out, taking in to account local policy and/or legal requirements?**



**E2.7 Please specify the measures in place that demonstrate compliance with the data minimisation principle (Is it adequate, relevant and limited to what is necessary?)**



**E2.8 Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.**



**E2.9 Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased.**



**E2.10 Please specify measures to protect the security of the personal data concerned.**



**E2.11 Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed.**



**E2.12 Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.**



**E2.13 Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner.**



**E3.1 What media of data will be collected?**



**E3.2 (a) Would you class the data collected in this study as anonymous, pseudonymised or identifiable data?**



**E3.2 (b) If ‘PSEUDONYMISED’, please confirm who will retain the ‘key’ to re- identify the data?**



**E3.3 Where will data which is collected be stored?**



**E3.4 (a) Will data collected be at any stage leaving the site (s) or organisation (s) of origin? Please note contracts may apply**



**E3.4 (b) If yes, please elaborate.**



**E3.5 Where will data analysis take place and who will perform data analysis (if known)? Please note contracts may apply**

| Data will analysed locally using SPSS by lead researcher, Dr Criona Walshe as lead | | | |
| --- | --- | --- | --- |
| investigator. | Anonymised survey data will be shared with academic supervisor in the | |  |
| IMI and to statistician in NUI Galway. They will provide advice on statistical analysis | | |  |
| and assist with data analysis. | |  | |
|  | | | |

**E3.6 (a) After data analysis has taken place, will data be retained?**



**E3.6 (b) If yes, for how long, for what purpose, and where will it be retained? [Note – if retention for future research purposes applies, please specify]**

Note: refer to the HSE National Consent Policy for Health and Social Care Research – search “broad” and “secondary”



**E3.7 Please comment on the confidentiality of collected data.**



**E3.8 Will any of the interview data collected consist of audio recordings / video recordings?**

**E3.9 (a) Will any of the study data collected consist of photographs/ video recordings?**



**E4.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?**

If answer is No, please delete remaining questions in Section E4



### F1 1 (a) Does this study involve human biological material?

If the answer is No, please delete Section F



Note: A National Research Ethics Committee to review research studies which involve exposure to medical ionising radiation is under negotiation.

Pending set up of a National REC, studies which involve exposure to medical ionising radiation may only be reviewed by a research ethics committee which has been recognised to give a single national opinion under S.I. No. 29/2023

### G1.1 (a) Does this study/trial involve exposure to radiation?

If answer is No, please delete remaining questions in Section G



Note: A National Research Ethics Committee to review clinical investigations of medical devices, and post-marketing follow up investigations of medical devices was set up in May 2021.

### H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device?

If answer is No, please delete remaining questions in Section H.



Note: A National Research Ethics Committee

to review clinical trials of medicines was set up May 2021.



### I1.1 (a) Does this study involve a medicinal product?No

If the answer is No, please delete remaining questions in subsection I1



### I2.1 (a) Does this study involve a cosmetic?

If the answer is No, please delete remaining questions in subsection I2



### I3.1 (a) Does this study involve food or food supplements?

If the answer is No, please delete remaining questions in subsection I3



SECTION J IS MANDATORY

**J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.**



**J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.**



**J3.1 Please give the name and address of the sponsor for this clinical trial (or the legally responsible entity or entities for research other than clinical trials)** 3

**J3.2 Please specify if the sponsor or legally responsible entity / entities is/are pharmaceutical companies, medical device companies, academic institutions, registered charities or other.**



**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place by the above-named sponsor, legally responsible entity or entities in respect of this research study.**



## SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

## K1 COST AND RESOURCE IMPLICATIONS

**K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)**



3 Refer to HSE RGMS Framework, Sept ’21 for more information - https://hseresearch.ie/governance- framework/





### K2.1 (a) Is funding in place to conduct this study?



**K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.**



**K2.1(d) Please provide additional details in relation to management of funds.**



**K2.1(e) Is the study funded by a ‘for profit’ organisation?**

**K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding?**



**K3.1 (a) Will any payments (monetary or otherwise) be made to investigators?**





**K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants?**

## SECTION L ADDITIONAL ETHICAL ISSUES

### L1 (a) Does this project raise any additional ethical issues?

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.