

**WHAT ARE THE DIFFERENCES BETWEEN  
VERSION 5.4 AND VERSION 5.5  
OF THE RESEARCH ETHICS COMMITTEE  
STANDARD APPLICATION FORM?**

Application Form Cover Sheet

- addition of 'Title of Study' in Version 5.5
- addition of 'Principal Investigator' in Version 5.5
- addition of 'Applicant's Signature' in Version 5.5
- addition of 'For Official Use Only – Date Stamp of Receipt by REC' in Version 5.5

Application Form Header

- addition of 'Office Use – REC Reference No' in Version 5.5

Application Form General

- formatting changes in Version 5.5

Application Form Last Page

- addition of 'Please ensure this application form is fully completed as incomplete submissions will not be received'

A2 – Principal Investigator

- addition of 'Address' in Version 5.5

A4 – Co-Investigators

- addition of 'Address' in Version 5.5

B8 (b) – How many research participants are to be recruited per treatment group (if applicable)?

- THIS QUESTION APPEARED IN VERSION 5.4 AND IS DELETED IN VERSION 5.5

B8 (c) – Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference)

-THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was: -  
“B8 (d) Please give a brief justification of sample size and details of the sample size calculation (including minimal clinically important difference)”

C1.1 – Names of Treatment Group / Insert Name of Group

-THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was: -  
C1.1 Names of Arms / Insert Name of Arm

C2.1 (d) – If yes, will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes/No

THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was: -  
C2.1 (d) – If yes, will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.

C2.1 (e) NEW QUESTION IN VERSION 5.5: **If no, please justify.**

C3.1 (d) NEW QUESTION IN VERSION 5.5: **What arrangements are in place for research participants who may regain capacity?**

C4.4 Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the study. Please elaborate **and provide copies.**

THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 did not include the phrase ‘and provide copies’

C4.7 NEW QUESTION IN VERSION 5.5: **Please explain your approach to reviewing assent where research participants reach the age of 18 during the course of the study.**

C5.16 Persons aged > 65

THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was ‘[Elderly / Aged Persons](#) > 65’

L1 Please identify any **particular additional** ethical issues which this project raises and discuss how you have addressed these issues.

THIS QUESTION IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 did not include the phrase ‘particular additional’

## WHAT ARE THE ADDITIONAL DIFFERENCES BETWEEN THE VERSION 5.4 AND VERSION 5.5 GUIDANCE MANUAL?

G1.3 Guidance Note: There are currently a small number of radiation oncology units in the Republic of Ireland e.g. [St. Luke's Radiation Oncology Network \(Rathgar, St. James's & Beaumont\)](#), the UPMC Beacon Hospital, the Hermitage Medical Clinic, Limerick Regional Hospital (Limerick Regional Hospital is a satellite unit of the Mater Private Hospital), the Mater Private Hospital, St. Vincent's Private Hospital, University College Hospital Galway, University College Hospital Cork and the UPMC Whitfield Cancer Centre.

THIS GUIDANCE NOTE IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was: -

There are currently a small number of radiation oncology units in the Republic of Ireland e.g. [St. Luke's Hospital](#), the UPMC Beacon Hospital, the Hermitage Medical Clinic, Limerick Regional Hospital (Limerick Regional Hospital is a satellite unit of the Mater Private Hospital), the Mater Private Hospital, St. Vincent's Private Hospital, University College Hospital Galway, University College Hospital Cork and the UPMC Whitfield Cancer Centre. [There are plans to build further units at Beaumont Hospital and St. James's Hospital.](#)

Section G2 Introductory Text: The Principal Investigator for Radiotherapy Trials involving patients must be a Radiation Oncologist. Please revisit your response to Question A2 if applicable. It is recognised however that rare exceptions will occur to the above rule, for example in a dermatology trial where radiotherapy is administered by a **radiation therapist** and overseen by a dermatologist, it may be inappropriate to name a radiation oncologist as the principal investigator...

THIS GUIDANCE NOTE IS REWORDED IN VERSION 5.5 – in Version 5.4 the term 'radiotherapist' was used as opposed to '**radiation therapist**'

L1 Guidance Note: It may be prudent to think carefully before replying 'none' in response to this question

THIS GUIDANCE NOTE IS REWORDED IN VERSION 5.5 – the wording in Version 5.4 was: -

[A number of committees are of the opinion that all applications to conduct research raise ethical issues. Hence](#), it may be prudent to think carefully before replying 'none' in response to this question.

### APPENDIX SEVEN – ACKNOWLEDGEMENTS

- addition of **St. Francis Hospital (Raheny)**
- addition of **St. Vincent's Hospital (Fairview)**

### APPENDIX SIX – WORKING GROUP MEMBERS

- addition of **Byrne, Ned – St. Vincent's Hospital (Fairview)**
- addition of **McQuillan, Regina – St. Francis Hospice (Raheny)**

