 

**HSE Reference Research Ethics Committee Annual Report Template**

**Research & Development, HSE**

|  |  |
| --- | --- |
| Version: | 2 |
| Date: | 14th April 2022 |

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| --- | --- | --- | --- |
| Version | Date | Change | Author |
| V0.1 | 23.02.22 | * First draft | VMM |
| V0.2 | 14.04.22 | * Amended following consultation with working group | VMM |
| V0.3 | 27.05.22 | * Further amendments following consultation | VMM |

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# Glossary of key terms

# Abbreviations

# 1. General Information

**Name of the HSE Reference Research Ethics Committee**:

**Contact details:**

**HSE Reference Research Ethics Committee Manager:**

**HSE Reference Research Ethics Committee Chairperson:**

**Reporting period:**

## 1.1 Description of the HSE Reference Research Ethics Committee

This section should provide a short overview of the Reference REC, the area it covers, and the service it provides, and to whom it provides the service.

## 1.2 Changes to the Standard Operating Procedures in the Reporting Period

This section should outline any changes to the SOPS that have taken place in the reporting period.

# 2. Chairpersons Introduction

This section is for the Chairperson to give a brief report of the committee’s functions over the previous year and to provide their reflections on how the committee has operated

# 3. Committee membership

## 3.1 Members of the Committee

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member’s name** | **Area of Expertise** | **Expert or Lay** | **Date of Appointment** | **Date Left** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## 3.2 Declaration of Interest

This section should include any details of any potential conflicts of interest e.g. membership of another REC, supervising students who may submit applications, consultancy, or shareholding in companies engaged in research.

|  |  |
| --- | --- |
| **Name** | **Declaration of Interest** |
|  |  |
|  |  |
|  |  |

## 3.3 Training

This section should record any training undertaken by committee members during the reporting period.

|  |  |
| --- | --- |
| **Date of training** | **Training attended** |
|  |  |
|  |  |
|  |  |
|  |  |

# 4. Report of Committee Activity

## 4.1 Summary of Meetings Held

**Meetings for Full Ethical Review** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
| **Month** | **Date of meeting** | **Number of REC members present** |
|  |  |  |
|  |  |  |
|  |  |  |

**Proportionate Review Sub Committee Meetings** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
| **Month** | **Date of meeting** | **Number of REC members present** |
|  |  |  |
|  |  |  |
|  |  |  |

**Number of inquorate meetings:**

## 4.2 Summary of Committee Attendance

This section should report on the number of meetings held and the attendance of committee members at each meeting.

**Attendance of Members at Full Committee Meetings** *(add date of reporting period)*

|  |  |
| --- | --- |
| **Name** | **Number of meetings attended** |
|  |  |
|  |  |
|  |  |

**Attendance of Members at Proportionate Review Sub-committee Meetings** *(add date of reporting period)*

|  |  |
| --- | --- |
| **Name** | **Number of meetings attended** |
|  |  |
|  |  |
|  |  |

## 4.3 Reference Research Ethics Committee Activity During the Reporting Period

**Management Information**

|  |  |
| --- | --- |
| Average number of applications reviewed per meeting |  |
| Number of completed applications allocated for full review |  |
| Number of applications reviewed within the time line of x days |  |
| Number of applications that were not reviewed within the time line of x days |  |
| Number of completed proportionate review applications reviewed |  |
| Number of substantial amendments reviewed |  |
| Number of non-substantial amendments reviewed |  |
| Number of patient safety incident reports received[[1]](#footnote-1) |  |
| Number of serious adverse event reports received[[2]](#footnote-2) |  |
| Number of appeals against the committee decision |  |
| Number of complaints received |  |
| Number of compliments received |  |
| Number of projects completed or terminated during the reporting period |  |
| Number of annual update reports received |  |
| Number of final/end of study reports received |  |

## 4.4 Summary of Applications

**Assignment of Applications to Full Committee Meeting** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
|  | **No** | **%** |
| Number of applications rejected on basis of incompleteness or not meeting the criteria |  |  |
| Number of applications withdrawn prior to the committee meeting |  |  |
| Number of student applications reviewed |  |  |
| Number of applications from HSE staff reviewed |  |  |
| Number of applications from academic institutions (excluding students) reviewed |  |  |
| Number of applications from any other organisation reviewed |  |  |
| Total |  |  |

**Applications for Full Ethical Review by Type** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
|  | **No** | **%** |
| Child or maternal health |  |  |
| Community |  |  |
| Diagnostics |  |  |
| Disease management |  |  |
| Efficacy study |  |  |
| Exploratory |  |  |
| Health services research |  |  |
| Mental health |  |  |
| Interventional clinical trial |  |  |
| Prevention |  |  |
| Public health |  |  |
| Qualitative study |  |  |
| Treatment evaluation |  |  |
| Other |  |  |

**Decisions taken at Meetings** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
| **Decision taken at meetings following review** | **No** | **%** |
| Favourable opinion |  |  |
| Provisional or conditional favourable opinion |  |  |
| No opinion – request for further information, changes, or re-submission |  |  |
| Unfavourable opinion |  |  |

**Applications Assigned to a Proportionate Review Sub-committee by Type** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
|  | **No** | **%** |
| Child or maternal health |  |  |
| Community |  |  |
| Diagnostics |  |  |
| Disease management |  |  |
| Efficacy study |  |  |
| Exploratory |  |  |
| Health services research |  |  |
| Mental health |  |  |
| Interventional clinical trial |  |  |
| Prevention |  |  |
| Public health |  |  |
| Qualitative study |  |  |
| Treatment evaluation |  |  |
| Other |  |  |

**Decisions taken at Meetings** *(add date of reporting period)*

|  |  |  |
| --- | --- | --- |
| **Decision taken at meetings following review** | **No** | **%** |
| Favourable opinion |  |  |
| Provisional or conditional favourable opinion |  |  |
| No opinion – request for further information, changes, or re-submission |  |  |
| Unfavourable opinion |  |  |

**5. Declarations**

**Declaration by the Chairperson**

**I declare that the information within this report is a true representation of the *name of Reference REC* activity for the reporting period.**

**Name**

**Signature Date**

**Declaration by the Organisational Leads**

**On behalf of the affiliated organisations for the *name of Reference REC,* I confirm that the information within this report meets the reporting requirements.**

**Name**

**Signature Date**

**Name**

**Signature Date**

**Name**

**Signature Date**

**Name**

**Signature Date**

# Appendix A.

Please add any additional information that you wish to report. This might include a list of projects completed or terminated during the year.

# References

1. Patient safety incidents should be disclosed in accordance with the requirements of the HSE Open Disclosure Policy. The incident should be reported either by completion of the appropriate National Incident Report Form or direct entry to National Incident Management System. [↑](#footnote-ref-1)
2. Serious adverse event reports may include Serious Adverse Reactions related to drugs/interventions/procedures; Suspected Unexpected Serious Adverse Reactions; Unforeseen events. [↑](#footnote-ref-2)