|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Author | *Hélène François* | Reviewer(s) | *Christian Melot* | Approved by | *Michel Toungouz* |
| Public | *🞏 All 🗹 Investigators 🗹 Study Nurse 🗹 Study coordinator 🗹 Paramedics 🞏 Admin Staff*  |
| Document revision history / Changes-Revision Comment |  |

# General information

|  |  |
| --- | --- |
| Complainant’s name(*Thick and fill the right box*) |  ……………………………………………………………….. I would like to remain anonymous |
| Contact information |  |
| *Address* |  |
| *Phone number* |  |
| *@* |  |
| Research protocol |  |
| EC number |  |
| Name Principal Investigator |  |
| ComplaintConcernSuggestion(*Thick the right box*) |  |

# Other required information

|  |  |
| --- | --- |
| Which incident type best describes the issue ?(*Thick the right box*) |  Accounting and financial concerns(control issue, fraud, gifts, improper supplier or contractor activity, tax issues, falsification, …) |
|  |  Health care-participant confidentiality and privacy (any issue related to privacy rights guaranteed by the Belgian law that concern a participant’s medical records or personal health information) |
|  |  Health care-participant safety and care (any issue related to the quality of medical care provided to a participant at Hôpital Erasme) |
|  |  Health care - Other (bias in informed consent process, patient billing issues, sponsored research issues …) |
|  |  Human Resources and employees relations - disruptive and threatening behavior(any conduct that significantly interferes with the effective operation of Hôpital Erasme or poses a threat to personnel, students, or patient care) |
|  |  Human Resources and employees relations - other (harassment, use of retribution, bias in decision making, employee misconduct, inappropriate language or communications …) |
|  |  Information Technology, records and confidentiality (data privacy or security violations, inappropriate use of Hospital records, breach of confidentiality or privacy (non-healthcare) or other similar concerns) |
|  |  Research (inappropriate use of treatment, research grant misconduct, misappropriation of costs, other similar concerns) |
|  |  Safety (safety issues) |
|  |  Other (regulatory concern, issue that does not seem to fit any of the above categories) |
| Notified member management(*Thick the right box*) |  Yes No |
| *If yes* |  Investigator Research staff MAO EC Other (specify) : ………………………………………………. |
| Anyone else involved or aware of the incident ? |  Yes No |
| Please describe the incident |
| Do you know if this will occur again in the next 24 hours? |  Yes No |
| Would you like assistance ? |  Yes No |
| Suggestion |

This form can be mailed to *Hôpital Erasme*

*Service de la Recherche Biomédicale*

*Medical and Accreditation Office*

 *808 route de Lennik, 1070 Bruxelles*

Or

Sent by e-mail to MAO

**MAO.Rech-biomed@erasme.ulb.ac.be**