Research Ethics and Ethical Research Plans

Anna Bogdan, Warsaw University of Technology

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Historical Violations of Research Ethics

The development of ethical guidelines for research involving humans was primarily driven by the need to protect participants from abuse and to ensure their dignity, safety, and autonomy. The main reasons include:

1. History of Abuses in Medical Research – Numerous cases of experiments conducted without informed consent, often in highly unethical conditions. Some of the most well-known examples include:

- **Nazi Experiments during World War II** – Conducted on concentration camp prisoners, these experiments were extremely brutal and inhumane (https://en.wikipedia.org/wiki/Nazi_human_experimentation).
- **The Tuskegee Syphilis Study (1932–1972)** – In the U.S., African American men with syphilis were studied without being informed of available treatment options (https://www.cdc.gov/tuskegee/about/index.html)
- **Psychological Experiments** – Such as Stanford Prison Experiment, which raised ethical concerns about psychological harm (https://en.wikipedia.org/wiki/Stanford_prison_experiment).

Funded by the European Union

Historical Violations of Research Ethics

2. The Need to Protect Participant Autonomy – Ensuring informed consent, meaning that participants are fully informed about the purpose, methods, possible risks, and benefits of a study, as well as their right to withdraw at any time.

3. Prevention of the Exploitation of Vulnerable Groups – Certain populations, such as children, the elderly, individuals with disabilities, and economically disadvantaged people, were often used in research without proper safeguards.

4. Standardization of Ethical Principles in Science – The creation of universal ethical standards to ensure that research is conducted responsibly and with respect for human rights.

Funded by
the European Union

Key Ethical Documents Regulating Research

The Nuremberg Code (1947) – The first major ethical document, established after the Nuremberg Trials, emphasizing the importance of voluntary consent.

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Source: https://en.wikipedia.org/wiki/Nuremberg_Code

Funded by the European Union

Key Ethical Documents Regulating Research

The Declaration of Helsinki (1964, with multiple revisions) – Introduced by the World Medical Association, setting fundamental ethical principles for biomedical research.

1. Physician's Duty: Physicians must prioritize and protect the health, well-being, and rights of patients, including those participating in medical research.
2. Ethical Standards: Medical research involving human participants should adhere to ethical standards that respect participants and safeguard their health and rights.
3. Informed Consent: Obtaining voluntary informed consent from research participants is essential, ensuring they are adequately informed about the study's aims, methods, potential risks, and benefits.
4. Risk Assessment: Researchers must assess and minimize potential risks to participants, ensuring that the anticipated benefits justify any possible
5. Vulnerable Groups: Special protection is required for vulnerable populations who may have limited capacity to provide informed consent or are susceptible to coercion
6. Research Protocols: Studies should be based on sound scientific knowledge and be conducted by qualified individuals. Research protocols must undergo independent ethical review and approval.
7. Transparency and Dissemination: Researchers have an obligation to make research results publicly available and ensure the accuracy and completeness of their reports.
8. Study Provisions: Participants should have access to interventions identified as beneficial in the study, and researchers must ensure that provisions are made for this access.

Source: *https://www.wma.net/policies-post/wma-declaration-of-helsinki/*

Funded by the European Union

Key Ethical Documents Regulating Research

The Belmont Report (1979) – Defined three core ethical principles: respect for persons, beneficence, and justice.

1. Respect for Persons – Individuals should be treated as autonomous agents, and those with diminished autonomy (e.g., children, individuals with disabilities) must be protected.
2. Beneficence – Researchers must maximize possible benefits and minimize potential harm to participants.
3. Justice – The selection of research subjects must be fair, ensuring that no group unfairly bears the risks or reaps the benefits of research.
4. Application to Research:
   - Informed Consent – Participants must voluntarily agree to take part in research after being fully informed about its purpose, risks, and benefits.
   - Assessment of Risks and Benefits – Researchers must conduct a thorough risk-benefit analysis to ensure ethical justification.
   - Selection of Subjects – The process of choosing participants should be equitable and free from exploitation.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Funded by the European Union

Key Ethical Documents Regulating Research

The CIOMS International Ethical Guidelines (Council for International Organizations of Medical Sciences) – Expanding on the principles of the Declaration of Helsinki, particularly for research in developing countries.

1. Respect for Persons – Emphasizes informed consent, privacy, and confidentiality for research participants.
2. Beneficence and Non-Maleficence – Research should aim to maximize benefits and minimize harm.
3. Justice – Fair distribution of research burdens and benefits, with special attention to vulnerable populations.
4. Scientific and Social Value – Research should be scientifically valid and address important health issues.
5. Independent Review – Ethical review committees must evaluate research proposals to ensure compliance with ethical standards.
6. Informed Consent – Participants must be fully informed about the study and voluntarily agree to participate.
7. Confidentiality – Personal data and medical records should be protected.
8. Use of Placebo – Ethical considerations should guide the use of placebos, especially when effective treatments exist.
9. Public Engagement – Community involvement is encouraged to ensure research relevance and ethical appropriateness.
10. Post-Research Access – Participants should have access to interventions proven effective in the study.

Source: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Funded by the European Union

Why is Research Ethics Important?

- Prevents exploitation of research participants
- Ensures high-quality, credible scientific results
- Upholds public trust in research and academia
- Ensure uniform standards in research
- Establish accountability for misconduct

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary of common issues in ethical research involving humans

Research ethics ensure scientific credibility and protect research participants.

Key issues to be considered in the research plan:

- .....
- .....
- .....
- ......
- ......

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

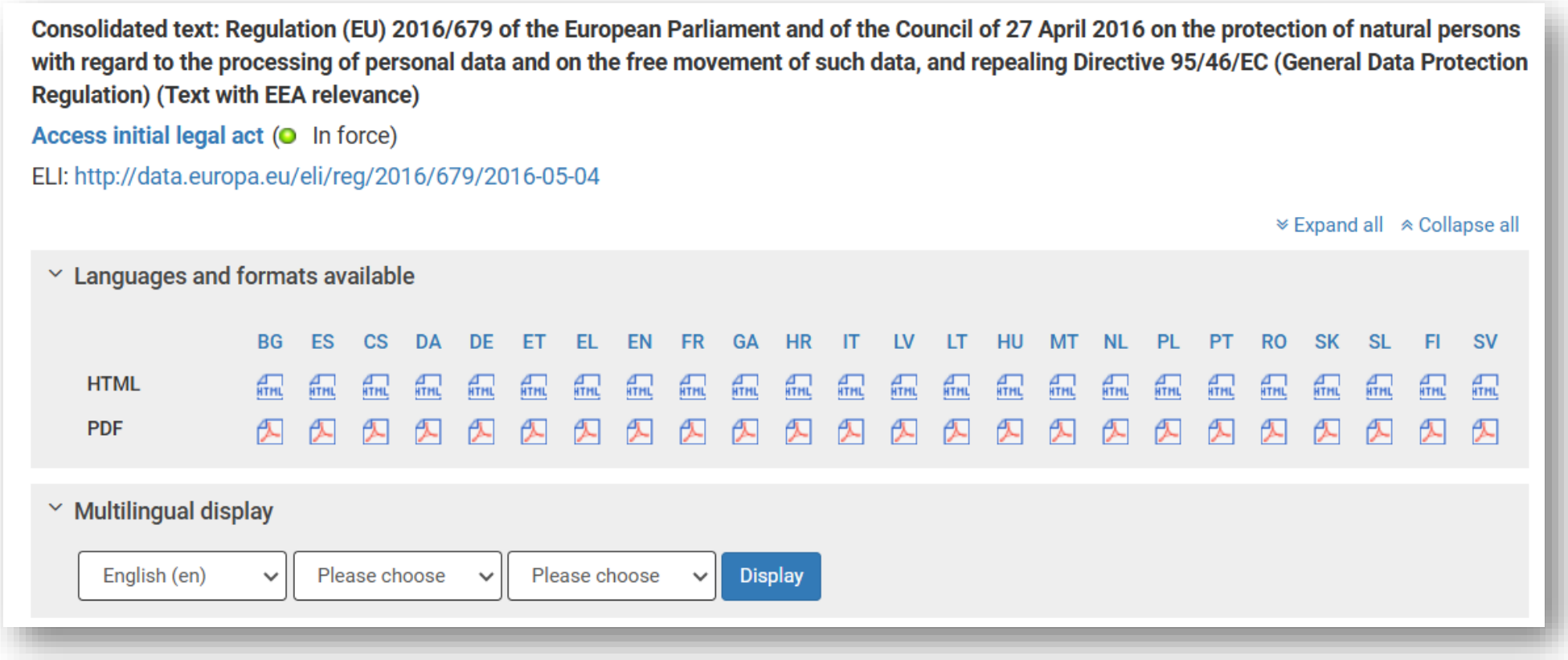
EU Regulations on Research Ethics

- GDPR (General Data Protection Regulation) – governs data privacy in research.
- Horizon Europe – EU's research framework program with strict ethical guidelines.
- The European Code of Conduct for Research Integrity.
- Ethical review process through national and institutional ethics committees.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

GDPR (General Data Protection Regulation)



Consolidated text: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)

Access initial legal act (In force)

ELI: http://data.europa.eu/eli/reg/2016/679/2016-05-04

Expand all Collapse all

Languages and formats available

	BG	ES	CS	DA	DE	ET	EL	EN	FR	GA	HR	IT	LV	LT	HU	MT	NL	PL	PT	RO	SK	SL	FI	SV
HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML
PDF																								

Multilingual display

English (en) | Please choose | Please choose | Display

https://eur-lex.europa.eu/eli/reg/2016/679

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

GDPR (General Data Protection Regulation)

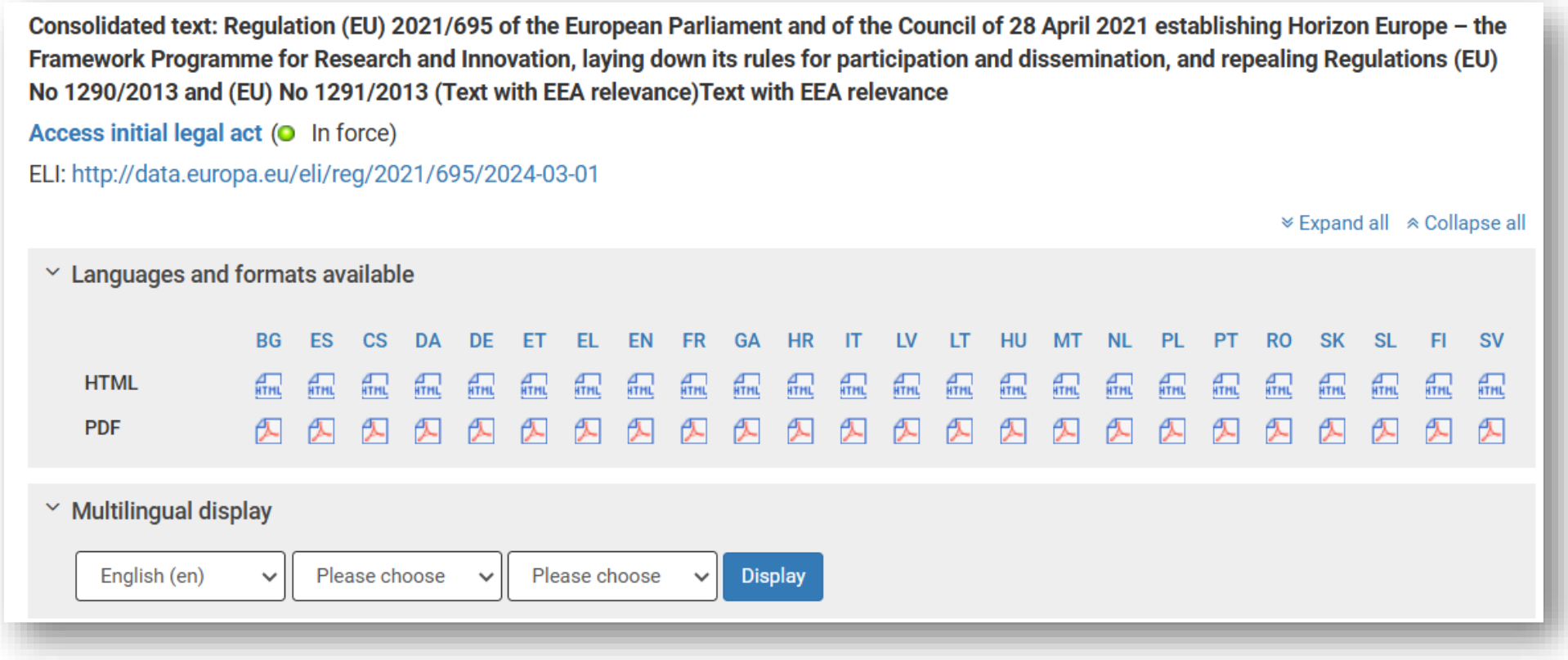
Key Principles of GDPR:

- Lawfulness, Fairness, and Transparency: Personal data must be processed lawfully, fairly, and transparently to the data subject.
- Purpose Limitation: Data must be collected for specified, explicit, and legitimate purposes and not further processed in a manner that is incompatible with those purposes.
- Data Minimization: Only the necessary personal data should be collected for the intended purpose.
- Accuracy: Personal data must be accurate and kept up to date; inaccurate data must be corrected or deleted.
- Storage Limitation: Personal data should not be stored longer than necessary for the intended purpose.
- Integrity and Confidentiality (Security): Data must be processed in a way that ensures security, including protection against unauthorized or unlawful processing, accidental loss, destruction, or damage.
- Accountability: Organizations (data controllers) must be able to demonstrate compliance with GDPR principles.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe



Consolidated text: Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (Text with EEA relevance)Text with EEA relevance

Access initial legal act (In force)

ELI: http://data.europa.eu/eli/reg/2021/695/2024-03-01

Expand all Collapse all

Languages and formats available

	BG	ES	CS	DA	DE	ET	EL	EN	FR	GA	HR	IT	LV	LT	HU	MT	NL	PL	PT	RO	SK	SL	FI	SV
HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML	HTML
PDF																								

Multilingual display

English (en) | Please choose | Please choose | Display

https://eur-lex.europa.eu/eli/reg/2021/695

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe

Article 18

Eligible actions and ethical principles

1. Without prejudice to paragraph 2 of this Article, only actions implementing the objectives referred to in Article 3 shall be eligible for funding.

The following fields of research shall not be financed:

(a) activities aiming at human cloning for reproductive purposes;

(b) activities intended to modify the genetic heritage of human beings which could make such modifications heritable ([2]);

(c) activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

2. Research on human stem cells, both adult and embryonic, may be financed depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be provided within or outside the Union for research activities that are prohibited in all Member States. No funding shall be provided in a Member State for a research activity which is forbidden in that Member State.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe

Article 19

Ethics

1. Actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

Particular attention shall be paid to the principle of proportionality, to the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and to the need to ensure protection of the environment and high levels of human health protection.

2. Legal entities participating in an action shall provide:

(a) an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective, implementation and likely impact of the activities to be funded, including a confirmation of compliance with paragraph 1 and a description of how it will be ensured;

(b) a confirmation that the activities will comply with the European Code of Conduct for Research Integrity published by All European Academies and that no activities excluded from funding will be conducted;

(c) for activities carried out outside the Union, a confirmation that the same activities would have been allowed in a Member State; and

(d) for activities making use of human embryonic stem cells, as appropriate, details of licensing and control measures that shall be taken by the competent authorities of the Member States concerned as well as details of the ethics approvals that shall be obtained before the activities concerned start.

3. Proposals shall be systematically screened to identify actions which raise complex or serious ethics issues and submit them to an ethics assessment. The ethics assessment shall be carried out by the Commission unless it is delegated to the funding body. All actions involving the use of human embryonic stem cells or human embryos shall be subject to an ethics assessment. Ethics screenings and assessments shall be carried out with the support of ethics experts. The Commission and the funding bodies shall ensure the transparency of the ethics procedures without prejudice to the confidentiality of the content of those procedures.

4. Legal entities participating in an action shall obtain all approvals or other mandatory documents from the relevant national, local ethics committees or other bodies, such as data protection authorities, before the start of the relevant activities. Those documents shall be kept on file and provided to the Commission or the relevant funding body upon request.

5. If appropriate, ethics checks shall be carried out by the Commission or the relevant funding body. For serious or complex ethics issues, ethics checks shall be carried out by the Commission unless the Commission delegates this task to the funding body.

Ethics checks shall be carried out with the support of ethics experts.

6. Actions which do not fulfil the ethics requirements referred to in paragraphs 1 to 4 and are therefore not ethically acceptable, shall be rejected or terminated once the ethical unacceptability has been established.

Funded by
the European Union

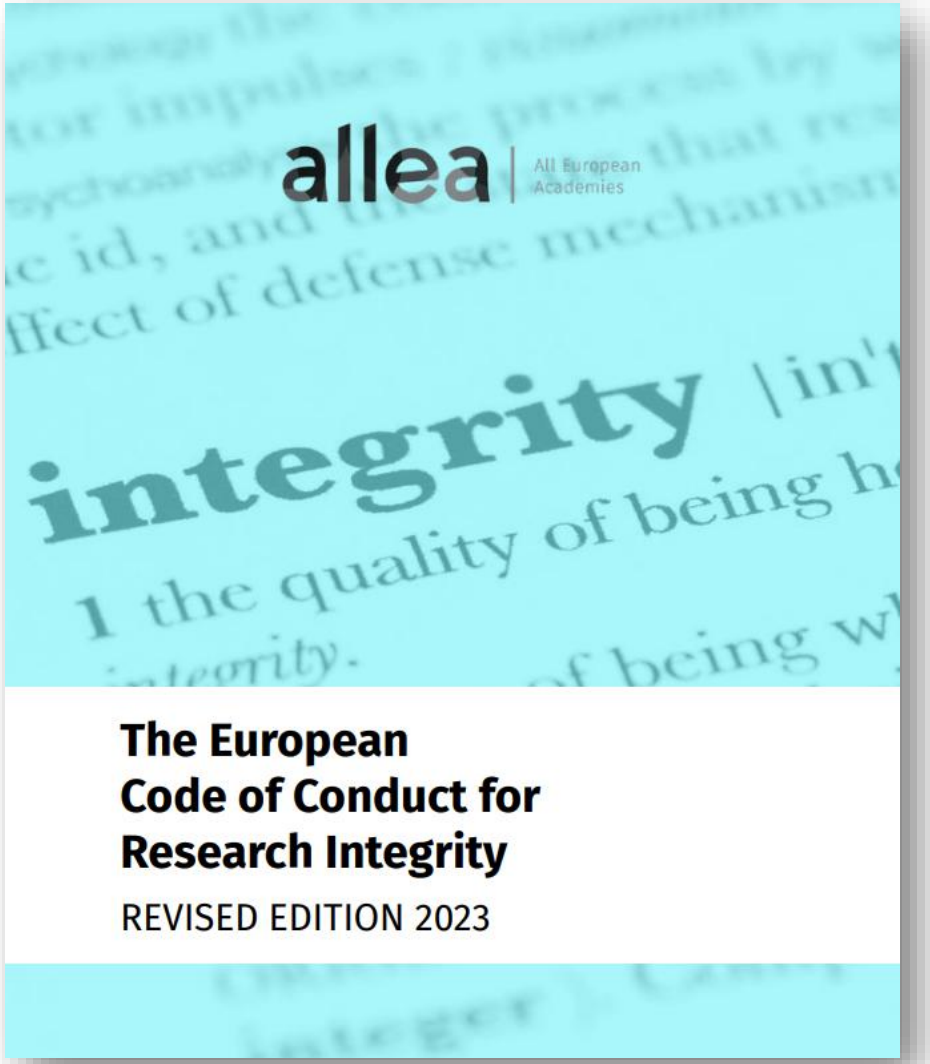
Horizon Europe: ethics self-assessment

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe: European Code of Conduct for Research Integrity



https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe: European Code of Conduct for Research Integrity

- **Respect and Protection of Participants**: Researchers are required to respect the dignity, rights, safety, and privacy of individuals participating in research. This includes obtaining informed consent from participants and providing them with full information about the purpose, methods, and potential consequences of the research.
- **Compliance with Ethical Standards**: Research involving human participants must adhere to international and national ethical standards and relevant legal regulations. This includes obtaining approval from the appropriate ethics committees before starting the research.
- **Confidentiality and Data Protection**: Researchers must ensure the confidentiality of participants' personal data and protect it from unauthorized access. Data processing and storage should comply with applicable data protection regulations, such as the General Data Protection Regulation (GDPR).
- **Risk Minimization**: Potential physical, psychological, and social risks to participants should be minimized. Researchers must carefully assess the risk-benefit ratio before commencing a research project.
- **Transparency and Accountability**: Researchers are responsible for clearly communicating the objectives, methods, and findings of their research. Any conflicts of interest should be disclosed, and research should be conducted honestly and responsibly.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe: National Ethics Committees and Institutional Review Boards

In Europe, both **National Ethics Committees** (NECs) and **Institutional Review Boards** (IRBs) play a key role in the ethical assessment of scientific research, particularly those involving human subjects. Their structure, role, and authority vary by country but are regulated by national and EU laws.

Regulations at the European Union Level

The European Union defines general rules for the functioning of NECs and IRBs through the following legal acts:

- **Regulation 536/2014 on Clinical Trials** – establishes common rules for clinical trials in the EU, requiring clear ethical assessment by independent bodies.
- **Directive 2001/20/EC** (previous clinical trial regulation) – defined the requirements for clinical trial approvals and the role of ethics committees.
- **General Data Protection Regulation (GDPR)** – mandates strict protection of personal data in scientific research.
- **Oviedo Convention** (Convention on Human Rights and Biomedicine) – set by the Council of Europe, defining fundamental bioethical principles for scientific research.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Horizon Europe: National Ethics Committees and Institutional Review Boards

National Ethics Committees (NECs) – National Advisory Bodies
In most European countries, NECs function as **national advisory bodies** that assess ethical issues related to science, healthcare, and biotechnology policies.

Institutional Review Boards (IRBs) – Local Ethics Committees
IRBs (often called **Bioethics Committees** or **Local Ethics Committees**) operate at universities, research institutes, and hospitals. They are responsible for:

- Ethical evaluation of scientific research, especially those involving human subjects,
- Monitoring compliance with ethical principles,
- Ensuring adherence to national and EU regulations.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Grant Agreement

ARTICLE 14 — ETHICS AND VALUES

14.1 Ethics

The action must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles.

Specific ethics rules (if any) are set out in Annex 5.

14.2 Values

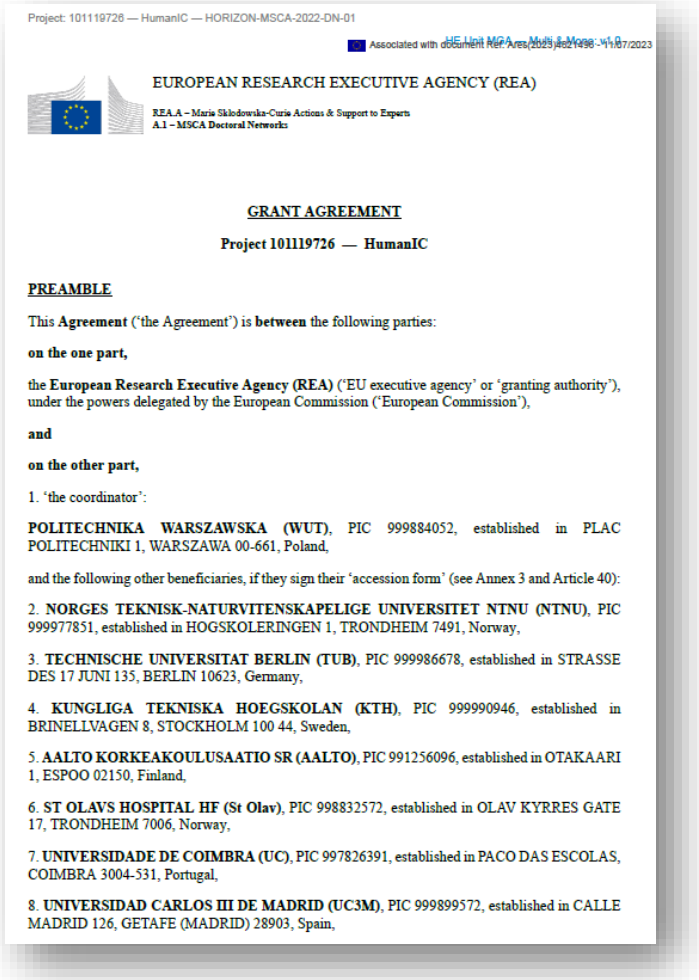
The beneficiaries must commit to and ensure the respect of basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

Specific rules on values (if any) are set out in Annex 5.

14.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

Associated with document Ref. Ares(2023)4621496 - 11/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Sklodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

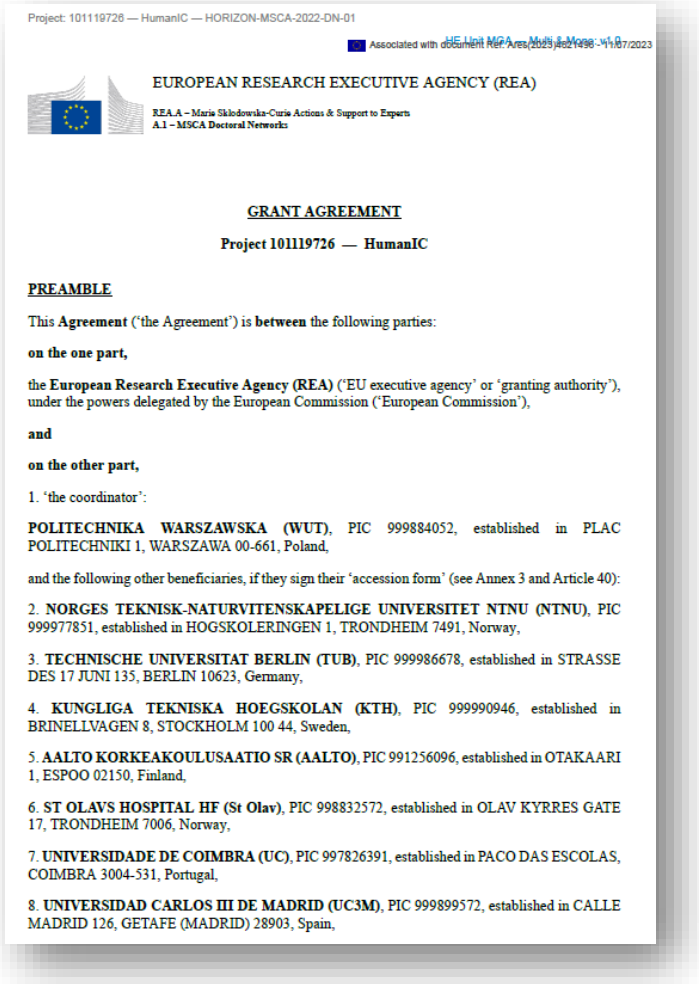
Funded by the European Union

Grant Agreement - DoA

4 Ethics Issues

Consortium members confirm that compliance with ethical principles and applicable international, EU and national law in the implementation of research activities not originally envisaged (or not described in detail) in the DoA will be ensured.

Consortium members confirm that any ethical concerns raised by those activities will be handled following rigorously the recommendations provided in the European Commission Ethics Self-Assessment Guidelines.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

Associated with document Ref. Ares(2023)4621496 - 11/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Sklodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Grant Agreement - DoA

Ethics Self-Assessment

Ethical dimension of the objectives, methodology and likely impact

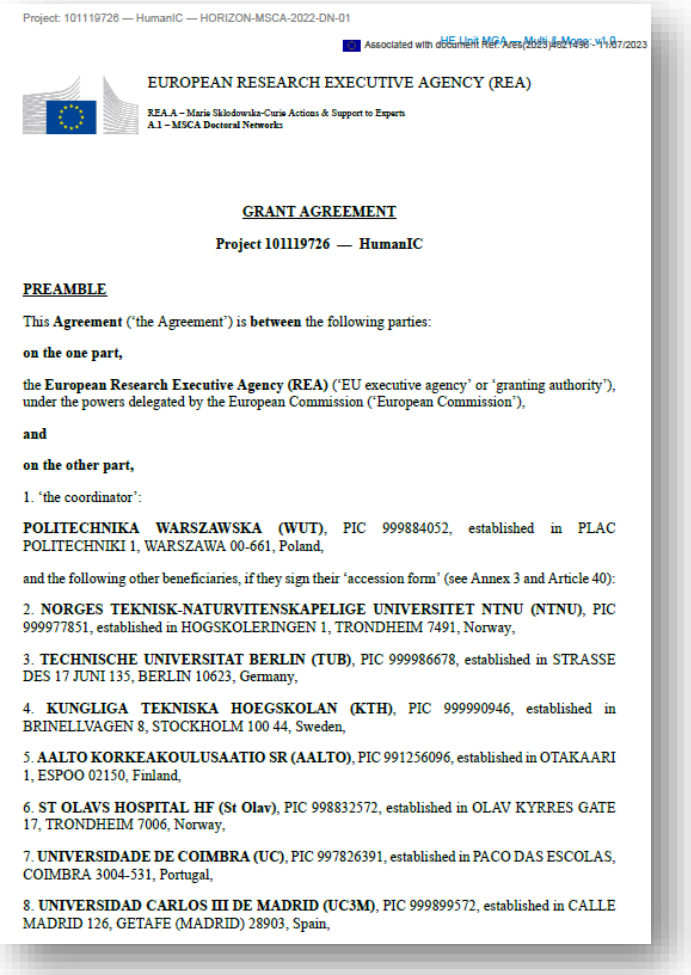
Research objectives (e.g. study of vulnerable populations, dual use, etc.): No vulnerable populations will be involved in HumanIC. Projects DC1, DC3, DC10 and DC12 all require data on activities of anonymous healthy people in hospital environments, which will be collected through observation of hospital personnel and/or healthy volunteers in real or mock-up hospital environments, and measurement of the indoor air parameters at the same time. This information is essential to enable numerical models and laboratory studies of contaminant dispersion to be developed that accurately represent real hospital environments.

• Projects DC4 and DC 9 require data on surgical procedures and thermal comfort surveys of hospital staff who are present in operating rooms during surgery. This knowledge is essential to correlate indoor air conditions and activity.

• Project DC 7 requires the measurement of human heat transfer and thermal comfort in a chamber environment, using healthy volunteers. This data is necessary to build accurate numerical models.

• Project DC 14 requires data on airborne microbial concentrations in a hospital environment together with observation of the activity that is happening at the time of the sampling.

Research methodology: No personal data about the person carrying out the activity is to be recorded and hence all data will be collected and stored anonymously. Project DC 7 will be carried out in a chamber environment and so will require ethical approval from Aalto University Ethics committee. The other seven projects highlighted above are expected to collect data from hospital environments and so will require approval from the hospital research ethics committee where the research is conducted. In all cases the relevant permissions will be sought and the ethical approval will be ratified by the EAG before the research activity will commence. DCs will be expected to take responsibility for developing the research protocol and securing ethical approval as this forms an important part of the training during their project; they will be supported in doing this by their supervisors and clinical partners.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

Associated with document Ref. Ares(2023)4621496 - 11/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Skłodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

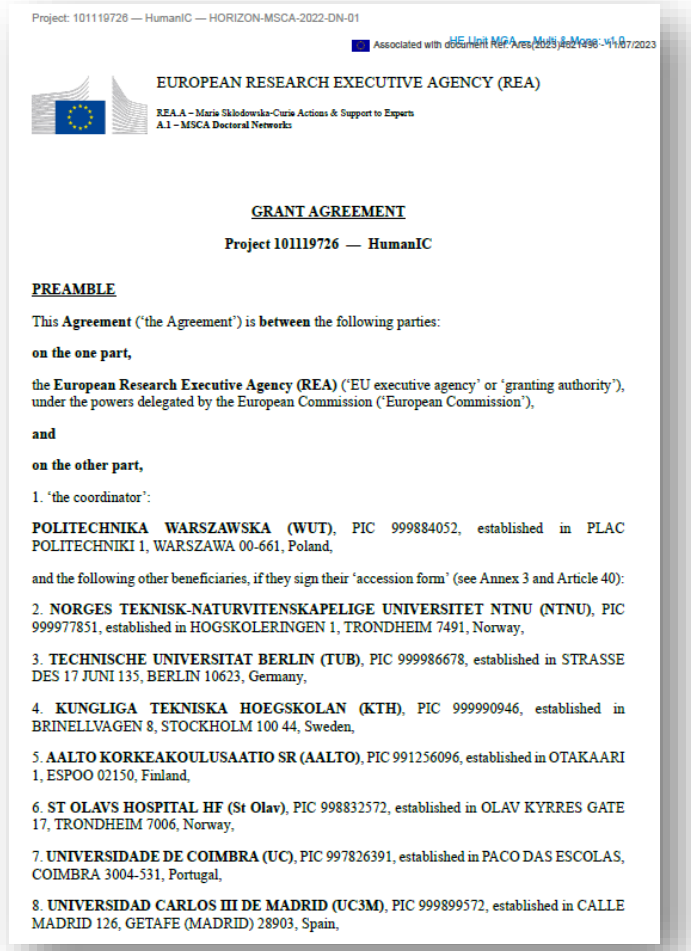
Funded by
the European Union

Grant Agreement - DoA

Studies involving observation of activities (DC 1,3,4,9,10,12,14) will record the activity taking place, the duration of the activity, the location and the indoor air parameters such as temperature, humidity, carbon dioxide, velocity during the activity. In the case of DC 14 bioaerosol samples will be taken at the same time. In observations of individuals, the person being observed will give written consent. In observations of hospital wards or surgery, consent for anonymous observation will be given by the ward manager or surgical manager as appropriate. In some cases with healthy volunteers in mock-up environments video footage will be taken to characterise movements for numerical simulations. In these cases, volunteers will give explicit consent to be recorded and for how their video can be used within the research.

Studies involving questionnaires (DC 4,9,7) will record anonymous personal data such as gender, age group along with perceived thermal sensation vote and satisfaction with the environment. Environmental measurements including temperature, velocity, and humidity will be made alongside this. In addition, in some cases (DC 7) the subjects' physiological data will be collected including skin temperature, heart rate, blood pressure. All participant survey responses will be coded to anonymise their response, and all participants will give written consent for their data to be used in the project.

Governance of research data will be an important consideration in all of these projects. Data and documentation will be stored in appropriate university and hospital site files, in accordance with the local ethics regulations. Any data transferred between locations will be done securely using appropriate encryption. All DCs will receive training in data management. All human participant data will be reported anonymously between DC projects and in any external publications; no raw data will be shared between projects without the explicit consent in the appropriate ethical approval. All studies will be appropriately risk assessed. The use of research data will be monitored by the HumanIC EAG. Copies of all research protocols, consent forms, information sheets and ethical approvals will be held by the HumanIC project coordinator.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

Associated with document Ref. Ares(2023)4221496 - 11/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Skłodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

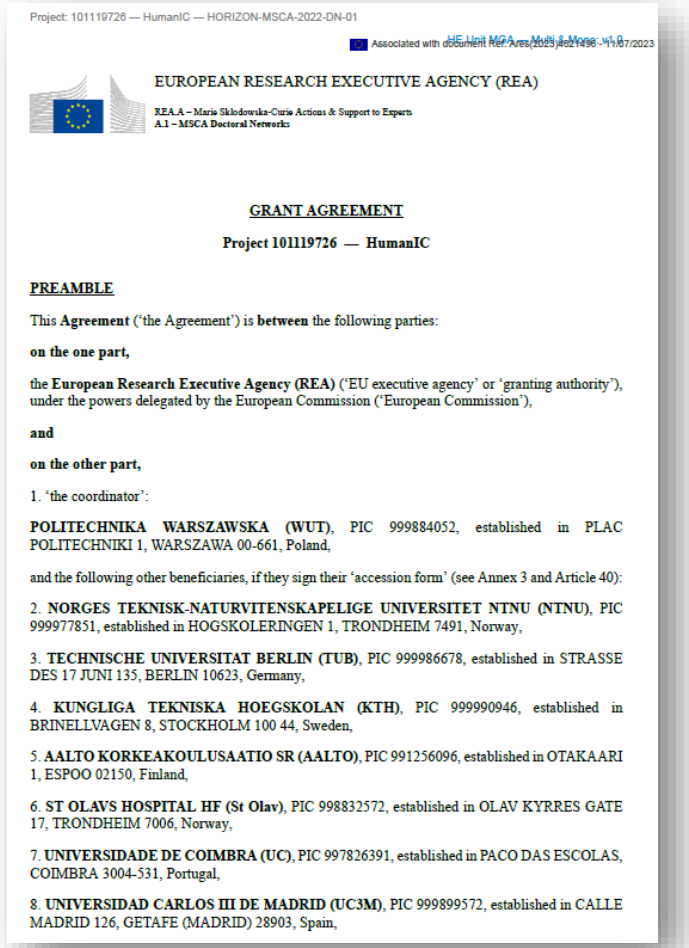
Funded by
the European Union

Grant Agreement - DoA

Environmental Impact: Environmental impacts of the research are expected to be positive. Understanding of fundamental knowledge of protected indoor environment of health care and pharmaceutical environment will help decrease supply airflow rate which will contribute to energy reduction as well. The replacement of existing ventilation solution may contribute significantly to the effort of greenhouse gas emission reduction. The results and methods from this project can be used by many consultants dealing with operating room design.

Compliance with ethical principles and relevant legislations

The HumanIC network lead Prof. Anna Bogdan will be ultimately responsible for ensuring all research meets ethical requirements. HumanIC will set up an Ethics Advisory Group (EAG) chaired by Prof. Hans Martin Mathisen at NTNU. The membership of the Ethics Advisory Group will include ethics committee members from KTH, WUT, TUB, Leeds and Aalto together with members from the hospital partners St. Olavs and FIBHGM. In the HumanIC project, several members of the supervisor group of DCs are experienced in research ethical issues. Prof. Hans Martin Mathisen, Prof. Guangyu Cao, Prof. Risto Kosonen, Prof. Martin Kriegel, Prof. Catherine Noakes and Prof. Anna Bogdan have previous experience in human subject survey and climate chamber research, while Prof. Guangyu Cao, Prof. Anna Bogdan and Prof. Catherine Noakes have experience in conducting studies in hospital environments.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

HE Unit MGA – Multi & Mono – v1.0

Associated with document Ref. Ares(2023)4021496 - 01/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Skłodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

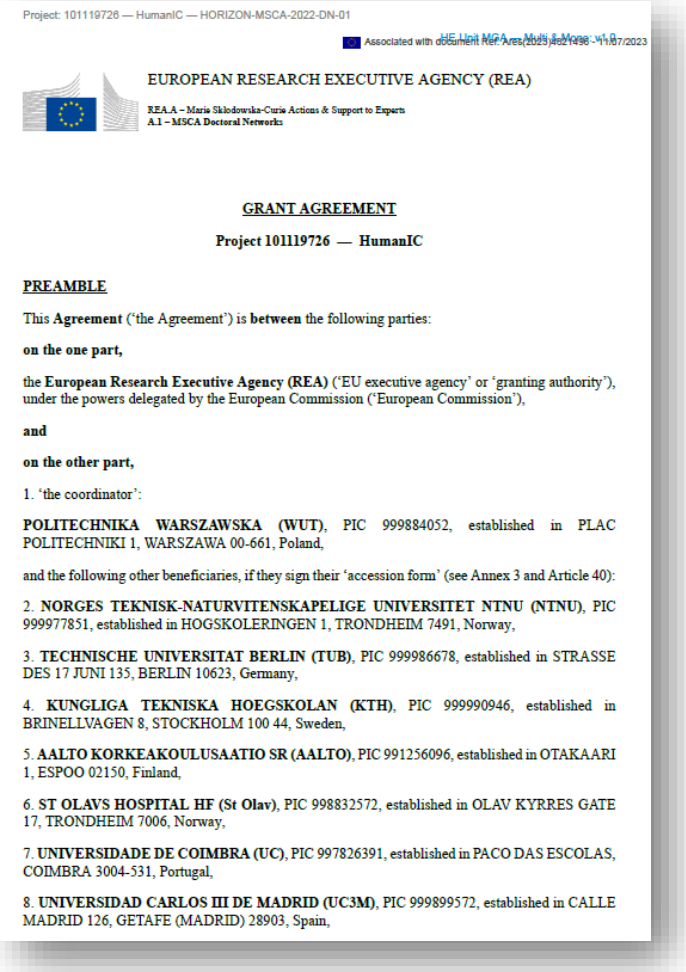
7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

Funded by
the European Union

Grant Agreement - DoA

All research activities respect fundamental ethics principles, including those reflected in the Charter of Fundamental Rights of the European Union. All partner universities provide detailed guidance and training on the ethical issues. The HumanIC project will strictly follow this guidance and will secure approval prior to any human studies from the relevant University or hospital ethics committee as appropriate to the study. Data collected will be strictly stored and kept within the research project period and anonymity will be protected. In particular, informed consent and confidentiality will be sought from all participants, they will be free to withdraw their participation at any time, and they will be fully debriefed on the purpose of the experiments. The role of the EAG will be in monitoring all relevant research activities of DCs and to provide guidance and network approval for any elements of the research that involve human participants.



Project: 101119726 — HumanIC — HORIZON-MSCA-2022-DN-01

Associated with document Ref. Ares(2023)4621496 - 11/07/2023

EUROPEAN RESEARCH EXECUTIVE AGENCY (REA)

REA.A – Marie Skłodowska-Curie Actions & Support to Experts
A.1 – MSCA Doctoral Networks

GRANT AGREEMENT

Project 101119726 — HumanIC

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Executive Agency (REA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

POLITECHNIKA WARSZAWSKA (WUT), PIC 999884052, established in PLAC POLITECHNIKI 1, WARSZAWA 00-661, Poland,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET NTNU (NTNU)**, PIC 999977851, established in HOGSKOLERINGEN 1, TRONDHEIM 7491, Norway,

3. **TECHNISCHE UNIVERSITAT BERLIN (TUB)**, PIC 999986678, established in STRASSE DES 17 JUNI 135, BERLIN 10623, Germany,

4. **KUNGLIGA TEKNISKA HOEGSKOLAN (KTH)**, PIC 999990946, established in BRINELLVAGEN 8, STOCKHOLM 100 44, Sweden,

5. **AALTO KORKEAKOULUSAATIO SR (AALTO)**, PIC 991256096, established in OTAKAARI 1, ESPOO 02150, Finland,

6. **ST OLAVS HOSPITAL HF (St Olav)**, PIC 998832572, established in OLAV KYRRES GATE 17, TRONDHEIM 7006, Norway,

7. **UNIVERSIDADE DE COIMBRA (UC)**, PIC 997826391, established in PACO DAS ESCOLAS, COIMBRA 3004-531, Portugal,

8. **UNIVERSIDAD CARLOS III DE MADRID (UC3M)**, PIC 999899572, established in CALLE MADRID 126, GETAFE (MADRID) 28903, Spain,

Funded by
the European Union

General rules

- Participants must voluntarily consent to research and be well-informed.
- Research should maximize benefits while minimizing risks for participants.
- Research should avoid harm to participants, including psychological, legal, and social harm.
- Fair treatment of participants and equal distribution of research benefits and burdens.
- Researchers must be honest, disclose conflicts of interest, and ensure reproducibility of results.
- Sensitive information must be safeguarded in accordance with GDPR regulations.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Tips for Formulating Ethical Research Plans

- Clearly define research objectives and ethical considerations.
- Consult ethical guidelines and legal requirements.
- Design research to minimize risks and maximize benefits.
- Establish transparent communication with participants.
- Use clear, understandable language.
- Allows participants to withdraw consent at any time.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Practical Considerations for Ethical Research Plans

- Obtain informed consent from participants.
- Ensure data protection and confidentiality.
- Conduct risk-benefit analysis to ensure minimal harm.
- Implement mechanisms for participant withdrawal at any stage.

- Obtain ethical approval from relevant authorities.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

How to Obtain Ethical Approval

- Submit proposals to ethics committees
- Justify methods and participant protection measures
- Follow institutional and legal guidelines

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Common Ethical Issues in Research with Human Participants

- Coercion or lack of informed consent.
- Privacy violations and improper data handling.
- Risk of psychological or physical harm.
- Misrepresentation or manipulation of research findings.
- Unethical participant selection leading to bias.

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Selecting Vulnerable Populations

- Avoid conflicts of interest
- Avoid bias in research
- Use diverse participant groups
- Ensure statistical validity

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Protecting Vulnerable Populations

- Protect volunteers through medical supervision.
- Additional safeguards for children, elderly or disabled participants
- Insure the examination (if the institution does not have group insurance covering this type of examination).

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Additional knowledge sources

- https://erc.europa.eu/manage-your-project/ethics-guidance
- https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html
- https://www.who.int/activities/ensuring-ethical-standards-and-procedures-for-research-with-human-beings

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

- Don’t be afraid.
- Contact your institution’s Ethics Committee for further guidance.
- Good luck!

HumanIC project has received funding from the European Union’s Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Workshop: Research Ethics and Ethical Research Plans

Anna Bogdan, Warsaw University of Technology

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Case study 1: Privacy & Data Confidentiality in Sensitive Research

Researchers are studying impact of mental health on IEQ sensation in young adults. The study includes personal interviews where participants discuss their experiences with mental health issues and the challenges of seeking professional help.

Ethical Challenges:

- Confidentiality Risks
- Data Protection
- Emotional Well-Being
- ....

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Case study 2: Ethical Considerations in Air Quality Monitoring in Patient Rooms

A team of engineers and medical researchers is conducting a study on indoor air quality (IAQ) in hospital patient rooms. The study involves installing air quality sensors to measure CO_2 levels, volatile organic compounds (VOCs), and particulate matter (PM2.5). The goal is to identify environmental factors that may impact patient recovery and hospital-acquired infections (HAIs).

Ethical Challenges:

- Patient Privacy & Consent
- Sensor Placement & Hospital Workflow
- Data Integrity & Bias
- ....

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Case study 3: Ventilation Efficiency & Ethical Data Collection in Operating Rooms

An engineering team is studying the effectiveness of hospital ventilation systems in operating rooms to reduce airborne contaminants and the spread of infections. They install real-time air flow monitors and conduct tracer gas experiments to evaluate ventilation effectiveness.

Ethical Challenges:

- Patient & Staff Safety
- Data Confidentiality
- Technological Limitations
- .....

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Case study 4: Smart HVAC Systems & AI-Driven Adaptive Air Quality Control

A research team is developing a smart heating, ventilation, and air conditioning (HVAC) system that dynamically adjusts airflow based on real-time occupancy and contamination levels in hospital wards. The system uses CO_2 sensors, temperature and humidity monitors, and machine-learning algorithms to optimize ventilation.

Ethical Challenges:

- System Reliability & Safety
- Impact on Vulnerable Patients
- Energy Consumption vs. Air Quality
- ....

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Case study 5: The Ethical Use of Wearable Air Quality Sensors for Hospital Staff Exposure Studies

A hospital research project involves equipping healthcare workers with wearable air quality sensors to measure their exposure to airborne pollutants and bioaerosols during shifts. The goal is to assess occupational risks and propose mitigation strategies.

Ethical Challenges:

- Informed Consent & Workplace Surveillance
- Data Accuracy & Contextual Factors
- Privacy Concerns
- ....

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

1. What additional risks might arise from real-time environmental monitoring in medical settings?

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

1. What additional risks might arise from real-time environmental monitoring in medical settings?
2. How can researchers balance the need for accurate data with the ethical considerations of patient and staff privacy?

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

1. What additional risks might arise from real-time environmental monitoring in medical settings?
2. How can researchers balance the need for accurate data with the ethical considerations of patient and staff privacy?
3. How can we ensure truly informed consent when conducting environmental monitoring in hospitals where patients and staff may not fully understand the study's implications?

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

1. What additional risks might arise from real-time environmental monitoring in medical settings?
2. How can researchers balance the need for accurate data with the ethical considerations of patient and staff privacy?
3. How can we ensure truly informed consent when conducting environmental monitoring in hospitals where patients and staff may not fully understand the study's implications?
4. Could increased monitoring lead to unintended ethical or psychological effects on staff and patients, such as stress or behavioral changes?

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union

Summary

1. What additional risks might arise from real-time environmental monitoring in medical settings?
2. How can researchers balance the need for accurate data with the ethical considerations of patient and staff privacy?
3. How can we ensure truly informed consent when conducting environmental monitoring in hospitals where patients and staff may not fully understand the study's implications?
4. Could increased monitoring lead to unintended ethical or psychological effects on staff and patients, such as stress or behavioral changes?
5. Who should have access to environmental data collected in hospitals (e.g., researchers, hospital administrators, government agencies), and how can it be used ethically?

HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

Funded by the European Union