MODULO H

**BANDO PUBBLICO PER LA SELEZIONE DI PROPOSTE PROGETTUALI, FINALIZZATE ALLA CONCESSIONE DI FINANZIAMENTI PER ATTIVITA’ COERENTI CON IL PROGRAMMA A VALERE SULLE RISORSE DEL PIANO NAZIONALE RIPRESA E RESILIENZA (PNRR) MISSIONE 4, “ISTRUZIONE E RICERCA” - COMPONENTE 2, “DALLA RICERCA ALL’IMPRESA” - LINEA DI INVESTIMENTO 1.4, FINANZIATO DALL’UNIONE EUROPEA – NEXTGENERATIONEU”, PROGETTO “ICSC” CN00000013 SPOKE 3, CUP C53C22000350006**

**RISPETTO DEI PRINCIPI ETICI**

|  |  |  |  |
| --- | --- | --- | --- |
| Il sottoscritto |  | | |
| Nato a |  | Il |  |
| Codice fiscale |  | | |
| Cittadinanza[[1]](#footnote-1) |  | | |
| *Nella sua qualità di Legale Rappresentante* | | | |
| Del richiedente |  | | |
| Denominazione o ragione sociale |  | | |
| Forma giuridica |  | | |
| Con sede legale in |  | | |
| Via/Piazza/… |  | | |
| N° civico | CAP | | |
| Codice fiscale |  | | |
| Partita IVA |  | | |
| PEC |  | | |
| E-mail |  | | |
| Telefono |  | | |

Consapevole delle sanzioni penali previste in caso di dichiarazioni non veritiere e di falsità negli atti di cui all’art. 76 del D.P.R. 28 dicembre 2000, n. 445 e della conseguente decadenza dei benefici di cui all’art. 75 del citato decreto, nella qualità di Legale rappresentante con potere di firma del richiedente sopraindicato,

**DICHIARA**

PER IL PROGETTO \_\_\_(acronimo)\_\_\_\_\_\_\_\_\_\_ la seguente valutazione rispetto agli aspetti etici.

Compilare la tabella seguente, scegliendo “YES” o “NO” ad ogni domanda.

Nel caso la risposta sia “YES”, indicare in quale pagina del MODULO B si possano trovare ulteriori informazioni; inoltre, aggiungere nella seconda parte del presente documento “Ethics self-assessment” dettagli specifici.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS | | |  |  | Page |
|  | | |  |  |  |
| Does this activity involve Human Embryonic Stem Cells (hESCs)? | | | Yes | No |  |
| If **YES**: | Will they be directly derived from embryos within this project? | | Yes | No |  |
| Are they previously established cells lines? | | Yes | No |  |
| Are the cell lines registered in the European registry for human embryonic stem cell lines? | | Yes | No |  |
| Does this activity involve the use of human embryos? | | | Yes | No |  |
| If **YES**: | Will the activity lead to their destruction? | | Yes | No |  |
| 2. HUMANS | | |  |  | Page |
| Does this activity involve human participants? | | | Yes | No |  |
| If **YES**: | Are they volunteers for non medical studies (e.g. social or human sciences research)? | | Yes | No |  |
| Are they healthy volunteers for medical studies? | | Yes | No |  |
| Are they patients for medical studies? | | Yes | No |  |
| Are they potentially vulnerable individuals or groups? | | Yes | No |  |
| Are they children/minors? | | Yes | No |  |
| Are there other persons unable to give informed consent? | | Yes | No |  |
| Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants? | | | Yes | No |  |
| If **YES**: | | Does it involve invasive techniques? | Yes | No |  |
| Does it involve collection of biological samples? | Yes | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products) | | | | Yes  No |  |
| If **YES**: | | Is it a clinical trial? | | Yes  No |  |
| Is it a low-intervention clinical trial? | | Yes  No |  |
| 3. HUMAN CELLS / TISSUES (not covered by section 1) | | | |  | Page |
| Does this activity involve the use of human cells or tissues? | | | | Yes  No |  |
| If **YES**: | Are they human embryonic or foetal cells or tissues? | | | Yes  No |  |
| Are they available commercially? | | | Yes  No |  |
| Are they obtained within this project? | | | Yes  No |  |
| Are they obtained from another project, laboratory or institution? | | | Yes  No |  |
| Are they obtained from biobank? | | | Yes  No |  |
| 4. PERSONAL DATA | | | |  | Page |
| Does this activity involve processing of personal data? | | | | Yes  No |  |
| If **YES**: | | Does it involve the processing of special categories of personal data (e.g.: sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)? | | Yes  No |  |
| If **YES**: | Does it involve processing of genetic, biometric or health data? | Yes  No |  |
| Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)? | | Yes  No |  |
| Does this activity involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)? | | | | Yes  No |  |
| Is it planned to export personal data from the EU to non-EU countries? | | | | Yes  No |  |
| If **YES**: | | Specify the type of personal data and countries involved: | |  |  |
| Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? | | | | Yes  No |  |
| If **YES**: | | Specify the type of personal data and countries involved | |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does this activity involve the processing of personal data related to criminal convictions or offences? | | Yes | No |  |
| 5. ANIMALS | | |  | Page |
| Does this activity involve animals? | | Yes | No |  |
| If **YES**: | Are they vertebrates? | Yes | No |  |
| Are they non-human primates (NHP)? | Yes | No |  |
| Are they genetically modified? | Yes | No |  |
| Are they cloned farm animals? | Yes | No |  |
| Are they endangered species? | Yes | No |  |
| 6. NON-EU COUNTRIES | | |  | Page |
| Will some of the activities be carried out in non-EU countries? | | Yes | No |  |
| If **YES**: | Specify the countries: |  |  |  |
| In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? | | Yes | No |  |
| If **YES**: | Specify the countries: |  |  |  |
| Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? | | Yes | No |  |
| Is it planned to import any material from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4. | | Yes | No |  |
| If **YES**: | Specify material and countries involved: |  |  |  |
| Is it planned to export any material from the EU to non-EU countries? | | Yes | No |  |
| If **YES**: | Specify material and countries involved: |  |  |  |
| Does this activity involve [low and/or lower-middle income countries?](https://datahelpdesk.worldbank.org/knowledgebase/articles/906519) (if yes, detail the benefit-sharing actions planned in the self-assessment) | | Yes | No |  |
| Could the situation in the country put the individuals taking part in the activity at risk? | | Yes | No |  |
| 7. ENVIRONMENT, HEALTH and SAFETY | |  |  | Page |
| Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)? | | Yes | No |  |
| Does this activity deal with endangered fauna and/or flora / protected areas? | | Yes | No |  |
| Does this activity involve the use of substances or processes that may cause harm to humans, including those performing them (during the implementation of the activity or further to the use of the results, as a possible impact)? | | Yes | No |  |
| 8. ARTIFICIAL INTELLIGENCE | |  |  | Page |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed). | | Yes | No |  |
| 9. OTHER ETHICS ISSUES | |  |  | Page |
| Are there any other ethics issues that should be taken into consideration? | | Yes | No |  |
| *Please specify: (Maximum number of characters allowed: 1000)* | | |  |  |

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment form as described in the  guidelines.

Se in qualche casella la risposta e’ stata “YES”, compilare il seguente modulo (vedere le linee guida in ["How to Complete your 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) per istruzioni dettagliate).

|  |
| --- |
| **Ethical dimension of the objectives, methodology and likely impact** |
| Explain in detail the identified issues in relation to:   * objectives of the activities (e.g. study of vulnerable populations, etc.) * methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) * the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.) |
| **Compliance with ethical principles and relevant legislations** |

Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

*Security issues table*



Compilare il seguente modulo in tutte le sue parti; se vi sono risopte “YES”, dichiarare la pagina del MODULO B dove trovare ulteriori informazioni.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. EU classified information (EUCI)[[2]](#footnote-2) | | |  |  | | Page |
| Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)? | | | Yes | No | |  |
| If **YES**: | Is the activity going to use classified information as background3 information? | | Yes | No | |  |
| Is the activity going to generate EU classified foreground[[3]](#footnote-3) information as results? | | Yes | No | |  |
| Does this activity involve non-EU countries? | | | Yes | No | |  |
| If **YES**: | Do participants from non-EU countries need to have access to EUCI? | | Yes | No | |  |
| Do the non-EU countries concerned have a security of information agreement with the EU? | | Yes | No | |  |
| 2. MISUSE | | |  |  | | Page |
| Does this activity have the potential for misuse of results? | | | Yes | No | |  |
| If **YES**: | | Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism? | Yes | No | |  |
| Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery? | Yes | No | |  |
| 3. OTHER SECURITY ISSUES | | |  |  | | Page |
| Does this activity involve information and/or materials subject to national security restrictions? | | | Yes | | No |  |
| If yes, please specify: *(Maximum number of characters allowed: 1000)* | | |  | |  |  |
| Are there any other security issues that should be taken into consideration? | | | Yes | | No |  |
| *If yes, please specify: (Maximum number of characters allowed: 1000)* | | | | |  |  |

Firma digitale[[4]](#footnote-4) del legale rappresentante/procuratore[[5]](#footnote-5)

1. Indicare se diversa da quella italiana [↑](#footnote-ref-1)
2. According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, “European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States”. 3 Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated. [↑](#footnote-ref-2)
3. EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission. [↑](#footnote-ref-3)
4. Per i soggetti italiani o stranieri residenti in Italia, la dichiarazione deve essere sottoscritta da un legale rappresentante ovvero da un procuratore del legale rappresentante, apponendo la firma digitale. Per gli operatori economici stranieri non residenti in Italia, la dichiarazione può essere sottoscritta dai medesimi soggetti apponendo la firma autografa ed allegando copia di un documento di identità del firmatario in corso di validità. [↑](#footnote-ref-4)
5. Nel caso in cui la dichiarazione sia firmata da un procuratore del legale rappresentante deve essere allegata copia conforme all’originale della procura oppure nel solo caso in cui dalla visura camerale dell’operatore economico risulti l’indicazione espressa dei poteri rappresentativi conferiti con la procura, la dichiarazione sostitutiva resa dal procuratore/legale rappresentante sottoscrittore attestante la sussistenza dei poteri rappresentativi risultanti dalla visura. [↑](#footnote-ref-5)