**JPIAMR-ACTION Joint Transnational Call for Proposals 2024**

**“Interventions Moving forward to Promote ACTion to counteract the emergence and spread of bacterial and fungal resistance and to improve treatments (IMPACT)”**

**Full Proposal application form**

**Submission Deadline: July 9th, 2024 (14:00 CEST)**

**History of modifications**

Initial version

***All fields must be completed using "Arial font, size 11" characters. Paper format: A4 with all margins minimum 1.27 cm. Please remove instructions in the final application.***

***Please note that incomplete full proposals, full proposals using a different format or exceeding length limitations of any sections will be rejected without further review.***

*All the information requested in this document must be compiled into one single PDF-document and uploaded to the electronic submission system available at* <https://ptoutline.eu/app/jpiamr2024_impact>*. PDF documents not uploaded into the electronic submission system before the call closes will not be reviewed.*

*Please note that in the online system the pre-proposal document from step 1 will be replaced by this one. However,* ***the information given in the pre-proposal is binding.*** *Thus, any fundamental changes between the pre- and full proposals, e.g. composition of the consortia, objectives of the project, or the budget must be communicated to the Joint Call Secretariat and the respective funding organisation(s) with detailed justification. In the case of inconsistency between the information registered in the submission tool and the information included in the PDF of this application form, the information registered in the submission tool shall prevail. Proposals that do not meet the national eligibility criteria and requirements will be declined without further review.*

* ***General conditions:***

*Some Funding Partner Organisations (FPOs) require the submission of additional documents. Any additional documents required by specific FPOs (e.g. UK budget proforma) should be submitted to them directly. Such documents should* ***NOT*** *be included in this full proposal. Proposals including national documents will be rejected.*

*Signature: The coordinator must sign the full proposal (section B14). Insertion of an electronic or scanned signature is possible/sufficient.*

*Non-funded partners: Non-funded partners must also indicate their budget in the budget table (Total in-kind/in cash costs). The sum/amount requested should be set to 0. The budget of non-funded partners shall not exceed 30% of the total transnational project budget requested. Non-funded partners are aware of their ineligibility to receive funding and a signed statement declaring that they conduct the project with their own in kind/in cash resources must be included in their letter of intent.*

*Widening mechanism: Consortia invited to the second stage of the call and which consist of fewer than seven (7) members will be able to increase their initial size by adding one non-funded partner or one new partner eligible for funding by an under-subscribed organisation from the list below. If you wish to integrate a new funded partner, the funding organisation of the new partner must confirm the eligibility of the additional partner before submitting the full proposal* ***at least ten days before the submission closure (by June 28rth, 2024)****. In addition, please inform the Joint Call Secretariat of any change of your consortium (including the addition of a non-funded partner). More details regarding the procedure are included in the invitation letter.*

***List of under-subscribed organisations eligible for widening in the IMPACT Call:***

* *ANCD (Agentia Nationala Pentru Cercetare si Dezvoltare, Moldova)*
* *FRRB (Fondazione Regionale per la Ricerca Biomedica, Italy)*
* *It-MoH (Ministero della Salute, Italy)*
* *LMT (Lietuvos mokslo taryba/Research Council of Lithuania, Lithuania)*

*Please note that it will not be possible to include a new partner funded by a funding organization that is not in the list of the under-subscribed organizations.*

The maximum eligible size of the consortium is seven (7) members (including the coordinator).

**A. General Information**

|  |
| --- |
| *NOTE: the information provided in this section has to be copied to the electronic submission system. Please update and/or correct any mistakes from stage 1.* |

**A1. Project Title: (max. 150 characters including spaces)**

**A2. Project Acronym: (max. 20 characters)**

**A3. Keywords**

Identify between three (3) and seven (7) keywords that represent the scientific content.

**A4. One Health Settings considered in the proposal**

Choose one or more One-Health setting(s) relevant to your project:

Human Health

Animal Health (incl. wildlife, livestock, aquatic organisms, and companion animals)

Plants (incl. trees and crops)

Environment (incl. natural and built)

**A5. Scientific area**

Choose **ONE** scientific area relevant to your project:

**Topic 1:** Design novel or improved interventions to prevent, mitigate and /or treat fungal infections, which are resistant to treatments and/or are at risk of developing resistance.

**Topic 2:** Improve and/or compare and/or evaluate strategies, technologies, treatments, methods, protocols or data collection based on existing interventions, aiming to prevent or reduce the emergence or spread of antibacterial or antifungal resistance or to treat/cure infections caused by resistant bacteria/fungi and recommend new policies.

**For Topic 2: please indicate the existing intervention (s) your proposal is considering to improve, compare or evaluate**

**A6. Project duration in months** (max. 36 months):

**A7. Total requested funding** (€)**:**

*Please make sure that the total funding requested is consistent with the funding requested in the on-line submission platform and with the funding request mentioned in sections B12 and B13 of this template.*

**A8. Composition of the consortium**

* *The total number of consortium members listed in sections A8 a (Coordinator) and A8 b (Project Partners) must not exceed the maximum allowed, which is 7 members.*
* *Each partner should be represented by a* ***single*** *Principal Investigator (co-PIs are* ***not*** *accepted)*
* ***Early Career Researcher*** *(ECR) for the purpose of the IMPACT call is a PhD holder, up to 8 years after the year of PhD award, holding a position at a recognized institution. The 8-year period may be extended to allow for career breaks including: parental leave, positions of trust in trade union organizations and student organizations, mandatory military or civil service, illness (own illness or care for close family members), medical internships or medical fellowship (applies to clinically active professionals). The last two categories may involve periods of up to 24 months each.*
* *Information about the* ***type of entity*** *is collected for statistical purposes only. Healthcare Institutions should be classified as Public Organisation (i.e. Public Hospital) or Private non-profit organisation/ company (i.e. Private Clinic) depending of the legal status of your institution. Please refer to your central administration for any doubts.*
* *Please make sure that your type of entity can be supported by your funding organisation. Companies and Industrial partners asking for funding are strongly advised to contact their funding organisation before applying.*
* *For each partner please specify the One Health setting(s) relevant to the task(s) specifically managed by the partner in this project. Please make sure that the indicated One Health setting(s) can be supported by your funding organisation.*

**A8 a. Project coordinator (Partner 1):**

|  |  |
| --- | --- |
| **Academic title, family name, first name** |  |
| **Gender** | Male/Female/Please Specify |
| **Career stage** | Early Career Researcher/Other |
| **Country** |  |
| **Funding Partner Organisation** |  |
| **Institution name** |  |
| **Institution Acronym** |  |
| **Department** |  |
| **Position** |  |
| **Address** | street, town/city, Zip/postal code |
| **Phone/Fax** |  |
| **E-mail** |  |
| **Type of entity**  *(select one)* | Public research organisation/  Public organisation/  Higher Education Institution/  Private Non-profit research organisation/  Private – Small and Medium Enterprise (SME)/  Private – large company |
| **One Health Setting**  *(select one or more as applicable to the tasks in this project)* | Human Health/  Animal Health/  Plants/  Environment |

**A8 b. Project Partners**

|  |
| --- |
| ***Please do not include the project coordinator in this section.*** |

| **Partner No.** | **Partner 2** | **Partner 3** | **Partner 4** | **Partner 5** | **Partner 6** | **Partner 7** |
| --- | --- | --- | --- | --- | --- | --- |
| **Principal Investigator**  (*first/family name*) |  |  |  |  |  |  |
| **PI’s Gender**  (Male/Female/Please specify) |  |  |  |  |  |  |
| **PI’s Career Stage**  (*ECR/Other*) |  |  |  |  |  |  |
| **Country** |  |  |  |  |  |  |
| **Funding Partner Organisation /not asking for funding** |  |  |  |  |  |  |
| **Affiliation: Institution, Department** (name) |  |  |  |  |  |  |
| **Institution Acronym** |  |  |  |  |  |  |
| **Address**  (*street, town/city, Zip/postal code*) |  |  |  |  |  |  |
| **Phone/fax** |  |  |  |  |  |  |
| **E-mail** |  |  |  |  |  |  |
| **Type of entity**  **(**Public research organisation/ Public organisation/  Higher Education Institution/  Private Non-profit research organisation/  Private – SME/  Private – large company**)** |  |  |  |  |  |  |
| **One Health Setting** (*select one or more as applicable to the tasks in this project*)  (Human Health/  Animal Health/  Plants/  Environment) |  |  |  |  |  |  |

**A9. Abstract** (max. 1600 characters including spaces)

**A10. Popular Science Summary** (max. 1600 characters including spaces)

**B. Project description**

**B1. Changes brought to the proposal submitted at the 1st stage** (max 2 pages)

|  |
| --- |
| * *Information for the reviewers or comments on the reviewers’ feedback from the pre-proposal evaluation.* * *Please summarise your modifications regarding the pre-proposal.* |

**B2. Project description** (max. 4 pages)

|  |
| --- |
| * *Background, context, current state of the art and preliminary results;* * *Description of the knowledge gap, unmet medical/societal need or One Health benefit and/or technical or implementation challenge that is addressed by the proposed work;* * *Highlight any prior work related to proposal.* |

**B3. Description of the aims** (max. 1 page).List the main objectives in order of priority

|  |  |  |
| --- | --- | --- |
| Aim No. | Description | Partner(s) responsible for the aim / workload |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| N |  |  |

**B4. Work plan** (max. 10 pages)

|  |
| --- |
| * *Description of the work plan including the importance of the research, objectives, the activities to reach the objectives, rationale, novelty, originality, methodology, feasibility, expected deliverables, and economical sustainability;* * *Explain and justify the statistical power of your experiments using power calculations based on relevant evidence.* * *Clearly defined role and responsibilities and workloads [expressed in person months] of each participating research partner. Comment on how participation and integration of partners in the project is allowed and facilitated. Comment on how the management of the proposal will be achieved, using diagrams where helpful.* * *Please use the following table for detailing the distribution of work in person/months (PM) in different work packages (WP), including partners not asking for funding (adapt if necessary). This table should include the sums of all the persons working in the project in each partner team (PI, researchers, Technicians, PhD, post-docs.).* * *Person/months contribution should not be limited to the person/month for which funding is requested. For example, person/months provided in kind by your research institution should be indicated in this table as well.* * *Please note that this table is included in the 10-page limit.* |

| **No.** | **Research Partner** | | **WP1 (PM)** | **WP2 (PM)** | **WP3 (PM)** | **WP4 (PM)** | **WP5 (PM)** | **WP6 (PM)** | **WP… (PM)** | **SUM** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 |  | |  |  |  |  |  |  |  |  |
| 2 |  | |  |  |  |  |  |  |  |  |
| 3 |  | |  |  |  |  |  |  |  |  |
| 4 |  | |  |  |  |  |  |  |  |  |
| 5 |  | |  |  |  |  |  |  |  |  |
| 6 |  | |  |  |  |  |  |  |  |  |
| 7 |  | |  |  |  |  |  |  |  |  |
|  |  | SUM |  |  |  |  |  |  |  |  |

**B5. Work plan and timeline as diagram** (max. 1 page)

|  |
| --- |
| *The diagram must demonstrate the work plan, timeline, sequencing of work packages, the contribution of the partners to each work package and their interactions (i.e. Gantt chart, Pert or similar).* |

**B6a. Impact** (max. 2 pages)

|  |
| --- |
| * *Expected impact on preventing or mitigating fungal infections Or on preventing or reducing the emergence or spread of antibacterial or antifungal resistance and guiding new policies against antimicrobial resistance.* * *Potential of the expected results for clinical, public health, and animal health, agriculture, or environmental benefit (including economic viability where appropriate);* * *Expected added value of transnational collaboration and potential for fostering a longer-term international network of researchers;* * *Explanation of how the project results will be disseminated and communicated. (will the proposed innovative strategy be accessible in different geographical areas, to different populations?)* * *Description of end-user and stakeholder participation/engagement (who will benefit from the project results?)* |

**B6b. Impact pathway** (complete the table, max. 2 pages)

* *Present schematically in the diagram below how the research is thought to achieve impact, by integrating scientific and development objectives.*
* *For outputs and outcomes, please also include indicators.*

|  |  |  |
| --- | --- | --- |
| **Outputs**: direct results, products or solutions delivered by the research project.  For instance:   * New knowledge and insights gained, applied, and shared in policies, business practices, NGO programmes * Innovations made available to markets, governments and society   Indicators may include:   * Publications, data sets, models, patenting requests * Policy briefs, lobby and advocacy materials, other communication products and services * Pilots/proof of concept * workshops/trainings | **Outcomes:** external use, adoption or influence of the project’soutputs by various stakeholders and the effects produced by the outputs. (The uptake by early adopters may be part of the project. The uptake by next- and final users that results in adopter-level changes needed to achieve the intended impact fall outside the span of control of the research).  For instance:   * Uptake of new processes, tools or technologies * New institutional arrangements, rules and regulations | **Impact:** changes in financial, institutional, environmental, technical and social conditions that a project is working towards.  This should be in line with the aim of the JPIAMR IMPACT Call “to improve, compare and evaluate the effectiveness, cost effectiveness, and uptake of existing interventions against bacterial or fungal infections and/or to design new interventions against fungal infections". |

**Table: Research impact pathway and indicators**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Research outputs** | **Indicators** |  | **Research outcomes** | **Indicators** |  | **Impact** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |

**B6c. Narrative (Theory of Change)** (max 1 page)

* *Please describe in the narrative the Theory of Change, notably the relationship, logical flow and/or causalities and contingencies between planned activities, expected results (outputs), desired changes (outcomes) and main objective (contribution to impact) as presented in the impact pathway.*
* *The context and the assumptions underlying the impact pathway should be part of the description.*

**B7. Outputs, dissemination and data management** (max 3 pages)

* *Explain how you are going to exploit and disseminate your research results; please specify your research uptake strategy per target group and/or stakeholder;*
* *Explain how your data will be managed within and outside of the consortium (short data management plan, including: a description of the types, format and scale of the data, data collection and metadata, security, confidentiality, storage, sharing and access). Explain how your data management will follow the FAIR principles (Findable, Accessible, Interoperable, Reusable);*
* *Explain the potential exploitation (including strategy to identify and address potential barriers) and relevance of the outcomes of the findings beyond the current project (long term strategy);*
* *Include Open Science practices, intellectual property management, and Freedom to Operate where appropriate.*

**B8. Risk assessment and Contingency plan** (max 1 page)

**B9. If applicable, description of patents and present / future position regarding intellectual property rights, both within and outside the consortium (max. ½ page)**

**B10. Research grants related to the current proposal**

***Current grants*** (Please indicate "No funding" when applicable)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Researcher name | Project Title | ID number | Funding Source | Amount (Euros) | Period | Role of the researcher | Relation to current proposal |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**On-going and submitted grant applications** (Please indicate "No funding" when applicable)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Researcher name | Project Title | ID number | Funding Source | Amount (Euros) | Period | Role of the researcher | Relation to current proposal |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**B11. References** (max. 1 page)

**B12.** **Scientific justification of requested budget** (max. ½ page per research partner).

|  |
| --- |
| * *Justify the requested budget.* * *Comment on the rational distribution of resources in relation to planned project tasks and activities, partners’ responsibilities and time frame;* * *Please also specify co-funding from other sources necessary for the project (if applicable)* |

**B13.** **Financial plan: sum of years 1-3. The budget of the non-funded partners listed in section A8b must be included as well.**

|  |
| --- |
| ***NOTE:***  ***The total amounts indicated for each partner in the last two lines of the budget (Total requested budget €; Total cost of the project) must be copied into the electronic submission platform.*** *Please make sure that the total funding in the on-line submission platform is consistent with financial data in sections B12 and B13 of this template.* |

| **Acronym:** | |  | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Partner No. | | Partner 1 (Project coordinator) | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 | Partner 7 |
| Principal Investigator | |  |  |  |  |  |  |  |
| Country | |  |  |  |  |  |  |  |
| Funding Partner Organisation | |  |  |  |  |  |  |  |
| Person Months, € (1)**\*** | |  |  |  |  |  |  |  |
| Person Months, € (2)**\*** | |  |  |  |  |  |  |  |
| Person Months, € (3)**\*** | |  |  |  |  |  |  |  |
| Person Months, € (4)**\*** | |  |  |  |  |  |  |  |
| Personnel € | Sum requested |  |  |  |  |  |  |  |
| Total =  Requested + In kind |  |  |  |  |  |  |  |
| Consumables € | Requested |  |  |  |  |  |  |  |
| Total =  Requested + In kind |  |  |  |  |  |  |  |
| Equipment € | Requested |  |  |  |  |  |  |  |
| Total =  Requested + In kind |  |  |  |  |  |  |  |
| Subcontracting \*\* | Requested |  |  |  |  |  |  |  |
| Total =  Requested + In kind |  |  |  |  |  |  |  |
| Other direct costs €\*\*  (including travels\*\*\*) | Requested |  |  |  |  |  |  |  |
| Total =  Requested + In kind |  |  |  |  |  |  |  |
| Overheads €\*\*\*\* |  |  |  |  |  |  |  |  |
| **Total requested budget €** |  |  |  |  |  |  |  |  |
| **Total cost of the project** | Total =  Requested + In kind |  |  |  |  |  |  |  |
| Partner No. | | Partner 1 (Project coordinator) | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 | Partner 7 |
| \* Please detail in each cell the number of person months (PM), qualification (**Si**: scientist, e.g. postdoc; **PhD**: PhD-student; **N**: non-scientist, e.g. technician; **Ot**: other) and € requested (or mention “in-kind” if funding is not requested for this person). Please use one cell per person to provide this information. Please note that students are funded according to national regulations. | | | | | | | | |
| \*\* e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according legal framework and funding body regulations). Check at the respective national funding organisations. | | | | | | | | |
| \*\*\* Travel expenses should include the participation of the coordinators and/or national partner leaders at an intermediate and/or a final status symposium to present the results of their projects (organised by the JPIAMR Secretariat) | | | | | | | | |
| \*\*\*\*Overhead costs: funding according to national legal framework and funding body regulations. Check at the respective national funding organisations. | | | | | | | | |

**PLEASE CHECK THAT THE FINANCIAL DATA ENTERED IN THE PLATFORM**

**AND IN THE PROPOSAL ARE CONSISTENT**

**B14. Date and signature of the coordinator** (electronic or scanned signature possible)

**C. Annex**

**C1. Brief CV of each Principal Investigator** (including non-funded partners)

(max. 1 page per Principal Investigator)

|  |
| --- |
| * *Each partner should be represented by a single Principal Investigator (co-PI are not accepted)* * *The CV for each Principal Investigator should include a description of PI’s main domain of research and a list of the five (5) publications most relevant to the project published within the last five (5) years, and if applicable, a list of 5 patents and/or freely available computer programs that the PI has developed and that are relevant for the project.* * *Proposals with extra-CVs will be rejected.* |

**C2. Ethics self-assessment**

**C2a. Ethic Contact point for the consortium:**

* *To complete this section, please ensure you provide all information requested.*
* *Please remove all the guiding text in red.*

|  |  |
| --- | --- |
| Contact information for ethics contact point for the consortium | *Please indicate here the person in charge of monitoring the ethical issues raised in your project. This person will also be responsible for maintaining the project ethics file. The contact point can be the coordinator of the consortium, or one of the project partners. Please note that an ethics report will have to be drafted by the ethics contact point. This report needs to be submitted along with the periodic mid-term scientific report, unless stated otherwise by the JPIAMR Ethics Review Board.* |
| Name and surname |  |
| Email address |  |
| Phone |  |

**C2b. Short description of ethics and legal aspects in your proposal:**

* *To complete the ethics self-assessment, please go through the table below and for each section for which your answer is yes, please add a description of information in the relevant sections at the end of the table. Please also provide an overview on related tasks, responsible partners and documents to be provided for each question.*
* *For more information please see:*

[*https://ec.europa.eu/research/participants/data/ref/h2020/grants\_manual/hi/ethics/h2020\_hi\_ethics-self-assess\_en.pdf*](https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf)

* *Please attach any supporting documents that are already available and, for the documents that are not yet available, state when they will be provided. All relevant documents listed in the table and that are not yet available have to be ready to be submitted upon request.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: HUMAN EMBRYOS/FOETUSES** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve Human Embryonic Stem Cells (hESCs)?** | |  |  |
| **If** **YES**: | Will they be directly derived from embryos within this project? |  |  |
| Are they previously established cells lines? |  |  |
| **Does this research involve the use of human embryos?** | |  |  |
| **If** **YES**: | Will the research lead to their destruction? |  |  |
| **Does this research involve the use of human foetal tissues / cells?** | |  |  |
| **Section 2:  HUMANS** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve human participants?** | |  |  |
| **If YES**: | Are they volunteers for social or human sciences research? |  |  |
| Are they persons unable to give informed consent? |  |  |
| Are they vulnerable individuals or groups? |  |  |
| Are they children/minors? |  |  |
| Are they patients? |  |  |
| Are they healthy volunteers for medical studies? |  |  |
| **Does this research involve physical interventions on the study participants?** | |  |  |
| **If YES**: | Does it involve invasive techniques? |  |  |
| Does it involve collection of biological samples? |  |  |
| **Section 3:  HUMAN CELLS / TISSUES** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve human cells or tissues?** (o*ther than from Human Embryos/Foetuses, see section 1)* | |  |  |
| **If YES:** | Are they available commercially? |  |  |
| Are they obtained within this project? |  |  |
| Are they obtained from another project, laboratory or institution? |  |  |
| Are they obtained from a biobank? |  |  |
| **Section 4:  PERSONAL DATA** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve personal data collection and/or processing?** | |  |  |
| **If YES:** | Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*? |  |  |
| Does it involve processing of genetic information? |  |  |
| Does it involve tracking or observation of participants? |  |  |
| **Does this research involve further processing of previously collected personal data (secondary use)?** | |  |  |
| **Section 5: ANIMALS** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve animals?** | |  |  |
| **If YES:** | Are they vertebrates? |  |  |
| Are they non-human primates (NHPs)? |  |  |
| Are they genetically modified? |  |  |
| Are they cloned farm animals? |  |  |
| Are they endangered species? |  |  |
| *Please indicate the species involved***:** | |  |  |
| **Section 6:  THIRD COUNTRIES** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?**  *Specify the countries involved:* | |  |  |
| 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.)? | |  |  |
| Is it planned to import any material – including personal data – from non-EU countries into the EU? | |  |  |
| **If Yes:** | *Specify material and countries involved*: |  |  |
| Is it planned to export any material – including personal data –from the EU to non-EU countries? | |  |  |
| In case this research involves [low and/or lower-middle income countries,](http://data.worldbank.org/about/country-classifications/country-and-lending-groups) are any benefit-sharing actions planned? | |  |  |
| Could the situation in the country put the individuals taking part in the research at risk? | |  |  |
| **Section 7: ENVIRONMENT, HEALTH AND SAFETY**  (Including genetically modified material) | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does your research involve the use of organisms and microorganisms, tissues or cells genetically modified (GMO, GMM)?** | |  |  |
| **Does this research involve the use of elements that may cause harm to the environment, to animals or plants?** | |  |  |
| **Does this research deal with endangered fauna and/or flora/protected areas?** | |  |  |
| **Does this research involve the use of elements that may cause harm to humans, including research staff?** | |  |  |
| **Section 8:  DUAL USE** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?** | |  |  |
| **Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Could this research raise concerns regarding the exclusive focus on civil applications?** | |  |  |
| **Section 10:  MISUSE** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Does this research have the potential for misuse of research results?** | |  |  |
| **Section 11: OTHER ETHICS ISSUES** | | YES/NO | If yes,  Add description in the appropriate section at the end of the table |
| **Are there any other ethics issues that should be taken into consideration?** | |  |  |
| **Section 12: ETHICS COMPLIANCE** (check the box) | | | |
| **The consortium confirms the full compliance with national and EU law on the protection of individuals with regard to the processing of personal data and that the ethical standards and guidelines of Horizon 2020 will be applied.** | | | |

For each section which you answered yes please add the descriptions under each section below **when applicable:**

**Section 1: HUMAN EMBRYOS/FOETUSES**

**Please note that the project is ineligible if it includes the collection of material from embryos derived within the project itself.**

Please describe:

*For previously established cell lines:*

1. Origin and line of cells.
2. Details of the licensing and control measures by the competent authorities of the Member States involved.

*For research involving human embryos:*

1. Origin of embryos.
2. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.
3. Confirm that informed consent has been obtained.

*For research involving human foetuses and cells:*

1. Origin of human foetal tissues/cells.
2. Details of the informed consent procedures.
3. Confirm that informed consent has been obtained.

*Supporting documents to be provided, if applicable:*

1. Copies of Ethics Approval(s)
2. Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines
3. Declaration confirming that the specific conditions for research activities involving human embryonic stem cells are met.
4. Informed Consent Forms + Information Sheets.

**Section 2:  HUMANS**

Please describe:

*For volunteers for social or human sciences research:*

1. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.

*For persons unable to give informed consent (including children/minors):*

1. Details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors.
2. An outline of steps to be taken to ensure that participants are not subject to any form of coercion.

*For vulnerable individuals or groups:*

1. Details of the type of vulnerability.
2. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.

*For children and minors:*

1. Details of the age range.
2. Description of the assent procedures and parental consent for children and other minors.
3. Description of the steps to be taken to ensure the welfare of the child or other minors.
4. A justification for the involvement of minors in the study.

*For patients:*

1. An overview of their disease/condition /disability.
2. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures
3. Description of the policy on incidental findings

*For physical interventions on subjects:*

1. Risk assessment for each technique
2. Description of samples to be collected
3. Description of procedures for collecting biological samples

*Supporting documents to be provided, if applicable:*

1. Informed Consent Forms + Information Sheets:
2. Copies of ethics approvals:

**Section 3:  HUMAN CELLS / TISSUES**

*Please describe:*

1. Details of the cells or tissue types.
2. Details of the provider (company or other), or how the source material for the cells, informed consent and a description of how the cells will be collected, stored and maintained after project completion.
3. Description of the source/biobank.

*Supporting documents to be provided, if applicable:*

1. Copies of relevant ethics approvals.
2. Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required).
3. Copies of import licences (if relevant).
4. Statement of laboratory/institution that informed consent has been obtained.
5. Informed Consent Forms + Information Sheets.

**Section 4:  PERSONAL DATA**

*Specify the type of personal data and countries involved.*

*Please describe:*

1. Details of the technical and organisational measures to safeguard the rights of the research participants.
2. Details of the data protection policy for the project (i.e. project-specific, not general).
3. Details of the informed consent procedures.
4. Details of the security measures to prevent unauthorised access to personal data.
5. How is all of the processed data relevant and limited to the purposes of the project (‘data minimisation’ principle)? Explain.
6. Details of the anonymization /pseudo-anonymization techniques.
7. Justification of why research data will not be anonymised/ pseudo-anonymized (if relevant).
8. Details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).

*Supporting documents to be provided, if applicable:*

1. Informed Consent Forms + Information Sheets used (if relevant).
2. Declaration confirming lawful basis for the data processing.
3. Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).
4. Declaration confirming compliance with the laws of the country in which the data was collected.
5. Declaration of confirming compliance with Chapter V of the GDPR.
6. Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).

**Section 5: ANIMALS**

*Please describe:*

1. Details of the species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used.
2. Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used.

*For Non-Human Primates (NHP):*

1. A description of why NHPs are the only research subjects suitable for achieving your scientific objectives.
2. Details of the purpose of the animal testing.
3. Details on the origin of the animals.

*For genetically modified vertebrates:*

1. Details of the phenotype and any inherent suffering expected.
2. Scientific justification for producing the animals.
3. Overview of measures to be taken to minimise suffering in breeding, maintaining the colony and using the GM animals.

*For cloned farm animals:*

1. Details of the phenotype and any inherent suffering expected.
2. Scientific justification for producing the animals.
3. Overview of measures to be taken to minimise suffering in breeding, maintaining the colony and using of the GM animals

*For endangered species:*

1. Description of why is there no alternative to using this species.
2. Description of the purpose of the research.

*Supporting documents to be provided, if applicable:*

1. Personal history file of NHPs.
2. Copies of GMO authorisations.
3. Copies of authorisations for cloning (if required).
4. Copies of authorisations for supply of endangered animal species (including CITES).

**Section 6:  THIRD COUNTRIES**

*Please describe:*

1. Risk-benefit analysis.
2. Description of activities that will be carried out in non-EU countries.
3. Description of the type of local resources that will be used and how they will be used.
4. Description of the type of materials that will be imported/exported.
5. Details of the safety measures you intend to take, including training for staff and insurance cover.

*For studies involving LMICs:*

1. Details of the benefit sharing measures.
2. Details of the responsiveness to local research needs.
3. Details of the procedures to facilitate effective capacity building.

*Supporting documents to be provided, if applicable:*

1. Copies of import/export licences.

**Section 7: ENVIRONMENT & HEALTH AND SAFETY**

*Please describe:*

1. Details of the health and safety procedures (for health and safety).
2. Risk-benefit analysis (for environment).
3. Show how you apply the precautionary principle (if relevant) (for environment).
4. Describe safety measures to be taken.

*Supporting documents to be provided, if applicable:*

1. Safety classification of laboratory (for health and safety):
2. Copy of GMO and other authorisations (if required) (for environment)

**Section 8:  DUAL USE**

*Please describe:*

1. What goods and information used and produced in your research will need export licences?
2. How exactly will you ensure compliance?
3. How exactly will you avoid negative implications?

*Supporting documents to be provided, if applicable:*

1. Copies of export licences:

**Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS**

*Please describe:*

1. Explain the exclusive civilian focus of your research.
2. Justify inclusion of military partners or military technologies (i.e. explain how they relate to civilian applications, e.g. in the context of law enforcement activities).

**Section 10:  MISUSE**

*Please describe:*

1. Risk-assessment:
2. Details of the applicable legal requirements:
3. Details of the measures to prevent misuse:

*Supporting documents to be provided, if applicable:*

1. Copies of authorisations.
2. Copies of security clearances.
3. Copies of ethics approvals.

**Section 11: OTHER ETHICS ISSUES**

*Please describe:*

1. Any relevant information:

*Supporting documents to be provided, if applicable:*

1. Any relevant information:

**Section 12: ETHICS COMPLIANCE**

*Please provide any additional information.*

**C3. Letter of Intent of each participating partner** (including non-funded partners).

|  |
| --- |
| * *Declaration on their willingness to cooperate within the research consortium.* * *Please use the appropriate template below – there is a separate template for funded partners and a different one for non-funded partners. Both scanned and electronic signatures are accepted.* * *Please note that the signature of the legal representative of each partner is obligatory at the full proposal stage.* * *Letters of support from external institutions, researchers, stakeholders, etc. will not be accepted.* * *Proposals with extra letters will be rejected.* |

**Letter of intent**

Date: 2024-MM-DD

**LETTER OF INTENT TO ENTER A JPIAMR PROJECT CONSORTIUM**

**(Partner asking for funding)**

|  |  |
| --- | --- |
| **JPIAMR Call:** | JPIAMR-ACTION Call 2024 IMPACT |
| **Project Proposal Title:** | INSERT TITLE |
| **Project Acronym:** | INSERT ACRONYM |
| **Partner Principal Investigator**: | First Name Last name |
| **Partner Institution:** | Name of Institution |
| **Requested Partner Budget:**  **Total Partner Budget:** | XXXXX Euro  XXXXX Euro |

By signing below the Principal Investigator and the legal representative of the Partner Institution agree to participate in a JPIAMR Consortium for the purpose of jointly carrying out a research project according to the project description of the above-mentioned JPIAMR proposal.

The Principal Investigator and the legal representative of the Partner Institution agree also certify that they will:

* enter into a consortium agreement consistent with the proposal;
* provide personal consent to publish data on a web-based publicly available database affiliated to JPIAMR;[[1]](#footnote-2)
* not initiate any work without necessary ethical approvals according to national/regional laws and regulations, and EU directives;
* provide the necessary staff and resources for their commitment to the project work plan;
* conduct all project activities, share data, and report project outcomes in accordance with the Call text (<https://www.jpiamr.eu/app/uploads/2024/01/Call-text_AMR-Interventions-2024_v.2024-01-24.pdf>)

I understand that by submitting the full proposal to the JPIAMR-ACTION Call 2024 I agree to share my personal data with Funding Partner Organizations based outside the European Economic Area and with third parties such as evaluators (some of which may be based outside the European Economic Area) for the purposes described in the Call text (<https://www.jpiamr.eu/app/uploads/2024/01/Call-text_AMR-Interventions-2024_v.2024-01-24.pdf>)

|  |  |
| --- | --- |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Principal Investigator** Signature | Date |
| **Principal Investigator**  Print Full Name: First Name Last name |  |
|  |  |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Legal representative of the Department/Faculty/Institution** Signature | Date |

**Letter of intent**

Date: 2024-MM-DD

**LETTER OF INTENT TO ENTER A JPIAMR PROJECT CONSORTIUM**

**(non-funded Partner)**

|  |  |
| --- | --- |
| **JPIAMR Call:** | JPIAMR-ACTION Call 2024 IMPACT |
| **Project Proposal Title:** | INSERT TITLE |
| **Project Acronym:** | INSERT ACRONYM |
| **Partner Principal Investigator**: | First Name Last name |
| **Partner Institution:** | Name of Institution |
| **Total Partner Budget:** | XXXXX Euro |

By signing below the Principal Investigator agrees to participate in a JPIAMR Consortium for the purpose of jointly carrying out a research project according to the project description of the above-mentioned JPIAMR proposal.

The Principal Investigator also certifies that they will:

* enter into a consortium agreement consistent with the proposal;
* provide personal consent to publish data on a web-based publicly available database affiliated to JPIAMR;[[2]](#footnote-3)
* not initiate any work without necessary ethical approvals according to national/regional laws and regulations, and EU directives;
* provide the necessary staff and resources for their commitment to the project work plan;
* conduct all project activities, share data, and report project outcomes in accordance with the Call text (<https://www.jpiamr.eu/app/uploads/2024/01/Call-text_AMR-Interventions-2024_v.2024-01-24.pdf>)

I am aware that I am ineligible to receive funding and I declare that I will carry out the project based on my institution’s own contribution in kind and/or in cash to the amount indicated above.

I understand that by submitting the full proposal to the JPIAMR-ACTION Call 2024 I agree to share my personal data with Funding Partner Organizations based outside the European Economic Area and with third parties such as evaluators (some of which may be based outside the European Economic Area) for the purposes described in the Call text (<https://www.jpiamr.eu/app/uploads/2024/01/Call-text_AMR-Interventions-2024_v.2024-01-24.pdf>)

|  |  |
| --- | --- |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Principal Investigator** Signature | Date |
| Print Full Name: First Name Last name |  |
|  |  |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Legal representative of the Department/Faculty/Institution** Signature | Date |

**C4. Clinical trial Interventional Study Form – to be completed for studies that will test or evaluate a Clinical trial intervention**

|  |  |  |
| --- | --- | --- |
| **Study type** | Indicate the type of study (feasibility, pilot study, regulated, non-regulated) |  |
|  | Indicate the study design (e.g. randomised or non-randomised, cluster, factorial |  |
| **Recruitment & monitoring** | Detail target recruitment (include controls) |  |
|  | Detail number of centres involved |  |
|  | Indicate duration of intervention period |  |
|  | Indicate duration of follow up |  |
|  | List Primary and secondary outcome measures |  |
|  | Detail measurement method for outcome measures |  |
|  | Are you using Core Outcome Sets |  |
| **Data Collection & Management** | Is interim analysis planned? If so when and how frequent |  |
| **Research Governance** | What appropriate governance arrangements are planned, given the complexity and level of risk of the study? |  |
|  | List Study Sponsor, where relevant |  |
|  | Indicate if insurance or indemnity is required |  |
|  | Provide details on independent governance committee for study |  |

C5. Checklist for Intervention studies

Regardless of whether your project involves an evaluation of a simple or complex intervention, the review Panels will take into account the following key questions when assessing the application. It is recommended that you consider the following issues and provide descriptions in the application **if and where relevant**. It is also recommended that you seek advice from individuals or centres that are experts in study design and statistics before submitting your application.

The need for the study

* What is the problem to be addressed?
* What is/are the principal research question(s) to be addressed?
* Is there a robust evidence-based rationale/coherent hypothesis for the study
* What outcome are you aiming for and how might this bring about change?
* Describe any risks to the safety of participants involved in the intervention (if relevant)

The Proposed Study

* Describe the planned intervention and where relevant compare with standard of care. Fully describe the intervention in PICO terms (Population/Patient group, Intervention, Comparison group/Control, Outcomes)
* Has any pilot or feasibility work been conducted to be confident that the intervention can be implemented as intended?
* What are the proposed practical arrangements for allocating participants to study groups? E.g. Randomization method.
* What are the proposed methods for protecting against sources of bias? e.g. Blinding or masking.
* What are the planned inclusion/exclusion criteria?
* What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include for both control and intervention groups, a brief description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate.
* What is the planned recruitment rate (overall and per site if relevant)? What evidence is there that the planned recruitment rate is achievable over a given timeframe
* What are the planned Stopping criteria?
* Will health service research issues be addressed? Justify inclusion/exclusion of health economics and quality of life measures.
* Have you considered compliance issues, acceptability testing, user involvement, any local or other contextual issues?

Data Collection and Management

* Describe arrangements for day-to-day management and monitoring of the trial e.g. randomisation, data handling, and coordination.
* Is there an Independent Data Management Committee planned. If not, justify why not. If so, describe the membership. Where members have been confirmed, include names.
* Will the design chosen really enable you to draw conclusions about effectiveness?

1. Detailed information regarding the projects eventually awarded/supported through JPIAMR would be stored with the Swedish Research Council. The Swedish Research Council complies with the Personal Data Act (1998:204) and the Public Access to Information and Secrecy Act (2009:400) that follows the directive of data protection rules in EU and will handle the data accordingly. [↑](#footnote-ref-2)
2. Detailed information regarding the projects eventually awarded/supported through JPIAMR would be stored with the Swedish Research Council. The Swedish Research Council complies with the Personal Data Act (1998:204) and the Public Access to Information and Secrecy Act (2009:400) that follows the directive of data protection rules in EU and will handle the data accordingly. [↑](#footnote-ref-3)