|  |
| --- |
| **IMIBIC-P2Med Project Proposal Template****Delete these guidance notes before submitting your project proposal.****Document Structure:**The structure of this template must be followed when preparing your project proposal.The project proposal should be composed as follows (detailed description below):- Cover page *(1 page)*- Section 1: Excellence - Section 2: Impact Max 10 pages- Section 3: Implementation- Section 4: Ethics *(no page limit)***Document length and page limits:**The maximum length of sections 1, 2 and 3 is 10 pages. All tables, figures, references and any other element pertaining to these sections must be included as an integral part of these sections and are thus counted against this page limit.Of the maximum 10 pages applied to sections 1, 2 and 3, applicants are free to decide on the allocation of pages between the sections. However, the overall page limit will be strictly applied: after the call deadline, excess pages will be made invisible, and will not be taken into consideration by the evaluators.Section 4 has no page limit.**Formatting conditions:*** The reference font for the body text is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions).
* The minimum font size for body text allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used.
* The minimum fort size for text elements other than the body text, such as headers, foot/end notes, captions, formula's, is 8 points.
* The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm.
* All pages should be numbered.
* It is the responsibility of the applicant to verify that the submitted PDF documents are readable and are within the page limit. PDF documents can contain colours.
 |

**COVER PAGE** *(1 Page)*

*NOTE: Guidance notes are indicated in grey background. Delete all guidance notes before submitting your project proposal.*

|  |  |
| --- | --- |
| Project Acronym: |  |
| Project title: |  |
| Project duration in months: |  |
| Project keywords (up to 5): |  |

***START PAGE COUNT – MAX 10 PAGES\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**1 EXCELLENCE**

**1.1 Abstract** (max 2000 characters including spaces)

Provide a short introduction to your research and career development project.

**1.2 State of the art**

Discuss the state-of-the-art. Include bibliographical references as footnotes.

**1.3 Objectives**

Describe, in concise way (preferably in bullet points), your main research objective, and sub-objectives if relevant. The objectives should be clear, measurable, realistic and achievable within the duration of the project and within the selected IMIBIC research group and its facilities and resources.

**1.4 Methodology**

Discuss the research methodology and approach, highlighting the type of research activities proposed.

Discuss the gender dimension in the research content. In research activities where human beings are involved as subjects or end-users, gender differences may exist. In these cases the gender dimension in the research content has to be addressed to ensure the highest level of scientific quality. If gender is **not** relevant in your research project, please indicate and justify.

**1.5 Originality and innovative aspects**

Explain the originality and innovative aspects of the planned research as well as the contribution that the project is expected to make to advancements within the research field. Describe any novel concepts, approaches or methods that will be implemented.

**2 IMPACT**

**2.1 Scientific impact**

Describe the expected impact of your proposed research for science and specifically for personalised and precision medicine.

**2.2 Impact of the fellowship on your career**

Explain the expected impact of the planned research and training on your future career prospects. Focus on how the new competences and skills can make you more successful in your career.

**3 IMPLEMENTATION**

**3.1 Research plan**

Describe the research tasks, their duration and timing. Refer to the set objectives (section 1.3) and chosen methodology (section 1.4).

Describe the relevant resources, infrastructure, equipment and any other services that are available at IMIBIC and your host group, and are **necessary for your research**.

Briefly describe the initial **Data Management Plan** of your project, including answers for the following (if applicable):

* What is the purpose of the data collection/generation and its relation to the objectives of the project?
* What types and formats of data will the project generate/collect?
* Will you re-use any existing data and how?
* What is the origin of the data?
* What is the expected size of the data?
* To whom the data might be useful ('data utility')?

Note: IMIBIC-P2Med participates in the Open Research Data Pilot of the H2020. All Fellows are requested to prepare a Data Management Plan (deliverable) based on the template provided by H2020 (<http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf#page=10>) within the first 4 months of their Fellowship.

For more information about Data Management Plan, see: <http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm#A1-template>

Note: Concrete planning for research activities must be included in the Gantt chart (section 3.6)

**3.2 Training Plan**

Describe the training activities or training topics that you consider necessary in order to reach your project and career development objectives.

Note: Concrete planning for training activities must be included in the Gantt chart (section 3.6)

**3.3 Dissemination and Communication Plan**

Describe how you plan to disseminate and communicate your project and its results to the scientific and non-scientific audiences.

Note: In the context of Horizon 2020 providing open access to scientific publications is an obligation (Article 29.2 of the Grant Agreement). For more information about open access, see: <https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/open-access_en.htm>

Note: that you are obliged to incorporate in your plan at least the following activities:

* At least 1 IMIBIC group seminar and IMIBIC research seminar per year
* Abstract submission for poster/oral presentation at the IMIBIC Young investigators Meeting every year (event organised in May)
* At least 1 participation in one of the public engagement activities in which IMIBIC participates (European Researchers' Night; Science Week; Walk for Science; Pint of Science; Guided visits at IMIBIC) every year
* At least 1 communication activity involving a patient organisation, if relevant
* At least 1 communication activity involving industry organisation, if relevant

Note: Concrete planning for dissemination and communication activities must be included in the Gantt chart (section 3.6)

Note: Dissemination means sharing research results with potential users - peers in the research field, industry, other commercial players and policymakers. By sharing your research results with the rest of the scientific community, you are contributing to the progress of science in general. For more information about Dissemination, please see: <http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/dissemination-of-results_en.htm>

Note: Communication means promoting your project and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange. For more information about Communication, please see: <http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/communication_en.htm>

**3.4 Research Stay Plan (if any)**

Describe the plan for a research stay, if any, and how it will benefit both your proposed research and your research career.

Briefly describe the **relevant** competences (including the supervisor), infrastructures, equipment and any other services available at the **research stay host organisation**.

Note: Concrete planning for research stay must be included in the Gantt chart (section 3.6)

If you do not plan a research stay, write “none”.

Note: A Research Stay may have a duration of up to 3 months for fellowships that last 18 months or less, and up to 6 months for fellowships that last more than 18 months. Research Stays are an integral part of the research plan. They imply the Fellow’s mobility to a Partner Organisation with specific supervision arrangements.

**3.5 Risks and alternate approaches**

Describe any risks and propose alternate approaches. Evaluate the probability of the risk to happen, and its impact to your research project.

Add as many risks as you consider relevant.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of risk** | **Probability** (low, medium, high)  | **Impact** (low, medium, high) | **Alternate approach** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**3.6 Gantt chart**

Include a Gantt chart including:

* Work Packages (WP), including: Research activities, as described in section *3.1 Research Plan*; Training activities, as described in section *3.2 Training Plan*; Dissemination and communication activities, as described in section *3.3 Dissemination and Communication Plan*, and Research stays, as described in section *3.4 Research Stay Plan* (if any)
* Important milestones (“M”) (if any)
* Deliverables (“D”) (Note: **Data Management Plan** is obligatory latest on Month 4 of the project. An update is due halfway the project and at the end of the project.)
* Any other relevant activity (optional)

This is an example Gantt chart only.

* The titles of the WPs indicated here do not have to be strictly followed or included in the Gantt chart for your specific proposal. Adapt as needed.
* The number of WPs provided here is an example only. Add or remove WPs as needed.
* Remove any columns for a duration longer than that of your proposal, and add as much detail as needed for your proposal.



Note: Milestones are control points in the action that help to chart progress. Milestones may correspond to the completion of a key task, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the researcher must decide which of several technologies to adopt for further development.

Note: A deliverable is a distinct output of the action, meaningful in terms of the action’s overall objectives and may be a report, a document, a technical diagram, software, etc. Deliverable numbers should be ordered according to delivery dates. Use the numbering convention: <WP number>.<Number of deliverables within that WP> For example, deliverable 4.2 would be the second deliverable from work package 4.

***STOP PAGE COUNT – MAX 10 PAGES\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**4 ETHICS** *(No page limit)*

**4.1 Ethics checklist**

Compliance with the relevant ethics provisions is essential from the beginning to the end of the project and is an integral part of research funded by the European Union within Horizon 2020.

Applicants submitting proposals for funding for the IMIBIC-P2Med programme should demonstrate proactively that they are aware of, and will comply with, ethical principles and applicable International, European and national law. Key sources of EU and international law are the [Charter of Fundamental Rights of the European Union](http://www.europarl.europa.eu/charter/pdf/text_en.pdf) and the [European Convention on Human Rights and its Supplementary Protocols](https://www.echr.coe.int/Documents/Convention_ENG.pdf). Another important source is the [UN Convention on the Rights of Persons with Disabilities (UN CRPD)](https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html).

Main ethical principles:

* Respecting human dignity and integrity
* Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
* Protecting vulnerable persons
* Ensuring privacy and confidentiality
* Promoting justice and inclusiveness
* Minimising harm and maximising benefit
* Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
* Maximising animal welfare, in particular by ensuring replacement, reduction and refinement (‘3Rs’) in animal research
* Respecting and protecting the environment and future generations

Please be aware that it is the applicants' responsibility to identify any potential ethical issue, to handle the ethical aspects of the proposal and to detail how these aspects will be addressed.

All eligible proposals will be subject to an evaluation including the evaluation of Ethics, carried out by independent experts. When submitting a proposal to IMIBIC-P2Med, all applicants are required to complete an Ethics Checklist (section 4.1) Applicants who flag ethical issues in section 4.1 have to complete also a more in depth Ethics Self-Assessment in section 4.2.

Answer YES/NO to **each question** in the table below, and indicate the corresponding page(s) of your Project Proposal that include information about the research activities that raise Ethical Issues. **Do not delete any lines of the table.**

|  |  |
| --- | --- |
| **1. HUMAN EMBRYOS/FOETUSES** | PAGE |
| Does your research involve Human Embryonic Stem Cells (hESCs)? | YES / NO |  |
| Does your research involve the use of human embryos? | YES / NO |  |
| Does your research involve the use of human foetal tissues / cells? | YES / NO |  |
| **2. HUMANS** |  |
| Does your research involve physical interventions on the study participants?  | YES / NO |  |
| Does your research involve human participants?  | YES / NO |  |
| **3. HUMAN CELLS / TISSUES** |  |
| Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, i.e. section 1)? | YES / NO |  |
| **4. PERSONAL DATA** |  |
| Does your research involve personal data collection and/or processing? | YES / NO |  |
| Does your research involve further processing of previously collected personal data (secondary use)? | YES / NO |  |
| **5. ANIMALS** |  |
| Does your research involve animals? | YES / NO |  |
| **6. THIRD COUNTRIES** |  |
| In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?  | YES / NO |  |
| Do you plan 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 |  |
| Do you plan to import any material - including personal data - from non-EU countries into the EU?  | YES / NO |  |
| Do you plan to export any material - including personal data - from the EU to non-EU countries?  | YES / NO |  |
| In case your research involves low and/or lower middle income countries, are any benefits-sharing actions planned?  | YES / NO |  |
| Could the situation in the country put the individuals taking part in the research at risk? | YES / NO |  |
| **7. ENVIRONMENT & HEALTH and SAFETY**  |  |
| Does your research involve the use of elements that may cause harm to the environment, to animals or plants?  | YES / NO |  |
| Does your research deal with endangered fauna and/or flora and/or protected areas?  | YES / NO |  |
| Does your research involve the use of elements that may cause harm to humans, including research staff?  | YES / NO |  |
| **8. DUAL USE**  |  |
| Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?  | YES / NO |  |
| **9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS**  |  |
| Could your research raise concerns regarding the exclusive focus on civil applications?  | YES / NO |  |
| **10. MISUSE**  |  |
| Does your research have the potential for misuse of research results?  | YES / NO |  |
| **11. OTHER ETHICS ISSUES**  |  |
| Are there any other ethics issues that should be taken into consideration? Please specify:  | YES / NO |  |
| *[specify here]* |  |  |

**4.2 Ethics Self-Assessment**

Provide information about the ethics issues concerning your proposed project (as indicated in section 4.1).

Specifically: Explain in detail how you intend to address the ethical issues flagged:

***Delete those sections (1-11) that do not apply.***

**1. HUMAN EMBRYOS/FOETUSES**

1.1 Does your research involve Human Embryonic Stem Cells (hESCs)? **If Yes,**

1.1.1 Are they previously established cells lines? **If Yes:**

* What is the origin and line of cells?
* Give details of the licensing and control measures by the competent authorities of the Member States involved

1.1.2 Does your research involve the use of human embryos? **If Yes,**

* What is the origin of embryos?
* Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.
* Confirm that informed consent has been obtained.

1.1.3 Does your research involve the use of human foetal tissues / cells? **If Yes,**

* What is the origin of human foetal tissues/cells?
* Give details of the informed consent procedures.
* Confirm that informed consent has been obtained.

**2. HUMANS**

2.1 Does your research involve physical interventions on the study participants? **If Yes,**

2.1.1 Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)? **If Yes,**

* Detail risk assessment for each technique and overall.

2.1.2 Does it involve collection of biological samples? **If Yes,**

* What type of samples will be collected?
* What are your procedures for collecting biological samples?

2.2 Does your research involve human participants? **If Yes**

2.2.1 Are they volunteers for social or human sciences research? **If Yes,**

* Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.

2.2.2 Are they persons unable to give informed consent (including children/minors)? **If Yes,**

* Give details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors.
* What steps will you take to ensure that participants are not subjected to any form of coercion?

2.2.3 Are they vulnerable individuals or groups? **If Yes,**

* Give details of the type of vulnerability.
* Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

2.2.4 Are they children/minors? **If Yes,**

* Give details of the age range.
* What are your assent procedures and parental consent for children and other minors?
* What steps will you take to ensure the welfare of the child or other minor?
* What justification is there for involving minors?

2.2.5 Are they patients? **If Yes,**

* What disease/condition/disability do they have?
* Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.
* What is your policy on incidental findings?

**3. HUMAN CELLS / TISSUES**

3.1 Does your research involve human cells or tissues (other than from Human Embryos/Foetuses)? **If Yes,**

3.1.1 Are they available commercially? **If Yes,**

* Give details of the provider (company or other).

3.1.2 Are they obtained within this project? **If Yes,**

* Give details of the source of the material, the amount to be collected and the procedure for collection.
* Give details of the duration of storage and what you will do with the material at the end of the research.
* Confirm that informed consent has been obtained.

3.1.3 Are they obtained from another project, laboratory or institution? **If Yes,**

* What is country where the material is stored?
* Give details of the legislation under which material is stored.
* How long will the material be stored and what will you do with it at the end of the research project?
* Give name of the laboratory/institution.
* In which country the laboratory/institution is located?
* Confirm that material is fully anonymised or that consent for secondary use has been obtained.

3.1.4 Are they obtained from a biobank? **If Yes,**

* What is the name of the biobank?
* In which country the biobank is located?
* Give details of the legislation under which material is stored.
* Confirm that material is fully anonymised or that consent for secondary use has been obtained.

**4. PERSONAL DATA**

4.1 Does your research involve personal data collection and/or processing? **If Yes,**

* Give details of the technical and organisational measures to safeguard the rights of the research participants. For instance: For organisations that must appoint a DPO under the GDPR: Involvement of the data protection officer (DPO) and disclosure of the contact details to the research participants. For all other organisations: Details of the data protection policy for the project (i.e. project-specific, not general).
* Give details of the informed consent procedures.
* Give details of the security measures to prevent unauthorised access to personal data.
* How is all of the processed data relevant and limited to the purposes of the project (‘data minimisation’ principle)?
* Give details of the anonymisation /pseudonymisation techniques.
* Give justification of why research data will not be anonymised/ pseudonymised (if relevant).
* Give details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).

4.1.1 Does it involve the processing of special categories of personal data (e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)? **If Yes,**

* Give justification for the processing of special categories of personal data.
* Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?

4.1.2 Does it involve processing of genetic, biometric or health data? **If Yes,**

* Confirm that you will obtain a declaration confirming compliance with the laws of the country where the data was collected.

4.1.3 Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geolocation tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the research participants? **If Yes,**

* Give details of the methods used for tracking, surveillance or observation of participants.
* Give details of the methods used for profiling.
* Describe risk assessment for the data processing activities.
* How will harm be prevented and the rights of the research participants safeguarded? Explain.
* Give details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.

4.2 Does your research involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)? **If Yes**,

* Give details of the database used or of the source of the data.
* Give details of the data processing operations.
* How will the rights of the research participants be safeguarded? Explain.
* How is all of the processed data relevant and limited to the purposes of the project (‘data minimisation’ principle)?
* Give justification of why the research data will not be anonymised/ pseudonymised (if relevant).

4.3 Does your research involve publicly available data? **If Yes,**

* Confirm that the data used in the project is publicly available and can be freely used for the project.

4.4 Is it planned to export personal data from the EU to non-EU countries? **If Yes,**

* Details of the types of personal data to be exported.
* How will the rights of the research participants be safeguarded?

4.5 Is it planned to import personal data from non-EU countries into the EU? **If Yes,**

* Details of the types of personal data to be imported.

**5. ANIMALS**

5.1 Does your research involve animals? **If Yes,**

* Give 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.
* Give justification of animal use (including the kind of animals to be used) and why alternatives cannot be used.

5.2 Are they vertebrates? **If Yes,**

5.2.1 Are they nonhuman primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)? **If Yes,**

* Why are NHPs the only research subjects suitable for achieving your scientific objectives?
* What is the purpose of the animal testing?
* Where do the animals come from?

5.2.2 Are they genetically modified? **If Yes,**

* Give details of the phenotype and any inherent suffering expected.
* What scientific justification is there for producing such animals? Give details.
* What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals?

5.2.3 Are they cloned farm animals? **If Yes,**

* Give details of the phenotype and any inherent suffering expected.
* What scientific justification is there for producing such animals?
* What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals?

5.2.4 Are they an endangered species? **If Yes,**

* Why is there no alternative to using this species?
* What is the purpose of the research?

**6. THIRD COUNTRIES**

6.1 In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? **If Yes,**

* Describe risk-benefit analysis.
* What activities are carried out in non-EU countries?

6.2 Do you plan 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.)? **If Yes,**

* What type of local resources will be used and how exactly?

6.3 Do you plan to import any material from non-EU countries into the EU? **If Yes,**

* What type of materials will you import?
* Specify the materials and countries involved.

6.4 Do you plan to export any material from the EU to non-EU countries? **If Yes,**

* Give details of the type of materials to be exported.
* Specify the materials and countries involved.

6.5 Does your research involve low and/or lower middle income countries? **If Yes,**

6.5.1 Are any benefits-sharing actions planned? **If Yes,**

* Give details of the benefit sharing measures.
* Give details of the responsiveness to local research needs.
* Give details of the procedures to facilitate effective capacity building.

6.6 Could the situation in the country put the individuals taking part in the research at risk? **If Yes,**

* Give details of the safety measures you intend to take, including training for staff and insurance cover.

**7. ENVIRONMENT & HEALTH and SAFETY**

7.1 Does your research involve the use of elements that may cause harm to the environment, to animals or plants? **If Yes**,

* Describe risk-benefit analysis.
* Show how you apply the precautionary principle (if relevant).
* What safety measures will you take?

7.2 Does your research deal with endangered fauna and/or flora and/or protected areas? **If Yes,**

* Declare you will obtain specific authorisations (if required).

7.3 Does your research involve the use of elements that may cause harm to humans, including research staff? **If Yes,**

* Give details of the health and safety procedures.

**8. DUAL USE**

8.1 Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required? **If Yes,**

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

**9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS**

9.1 Could your research raise concerns regarding the exclusive focus on civil applications? **If Yes,**

* Explain the exclusive civilian focus of your research.
* 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).

**10. MISUSE**

10.1 Does your research have the potential for misuse of research results? **If Yes,**

* Describe risk-assessment.
* Give details of the applicable legal requirements.
* Details of the measures to prevent misuse.

**11. OTHER ETHICS ISSUES**

11.1 Are there any other ethics issues that should be taken into consideration? **If Yes,**

* Please specify.

For more information about Ethics Self-Assessment, please see: <http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf>