Expression of Interest

Guidance Notes for Submission and Preparation

Contents

Guidelines for Coordinators – How to Prepare the Expression of Interest submission

These guidelines do not replace the IMI Submission Rules and requirements which are published on the IMI web site: www.imi.europa.eu

For the Stage 1 of the Call for proposals, each Applicant Consortium will have to submit **an Expression of Interest (EoI)**:

The Expression of Interest must contain the necessary information for the Innovative Medicines Initiative Joint Undertaking (IMI JU) to perform its administrative and evaluation obligations.

The Actors for an Expression of Interest Submission:

The Coordinator of the Applicant Consortium:

The Coordinator's responsibilities include:

- the scientific content of the Expression of Interest
- the formal submission and finalisation of the Applicant Consortium's Expression of Interest to IMI via the IMI electronic submission tool (SOFIA: Submission OF Information Application)

The Participants: all organisations (research organisations, universities, SMEs, patients organisations etc) participating in the Applicant Consortium. The Coordinator is also a Participant.

The Expression of Interest Submission:

The submission will be via the IMI electronic submission tool (SOFIA: Submission OF Information Application). Access to SOFIA will be available for a minimum of 1 month before the closing deadline for submission. The opening and closing dates for Expressions of Interest submissions are published on the IMI website on the relevant Call pages.

It is necessary for the Coordinator to complete a Request for Access to the IMI JU on-line electronic submission tool. Applicant Consortium Coordinators wishing to submit an Expression of Interest will first be required to complete the request for access in order to receive an URL access link with a login and password to access the IMI electronic submission tool. This access link, password and login will be sent by automatic email on completion of the request for access form.

The Coordinator checklist:

The following checklist may help Coordinators to ensure that all steps are taken for submitting the Expression of Interest.

Action	When
Request for Access to SOFIA	From the submission start date (for submitting EoIs) mentioned on IMI website for the specific Call.
Coordinator to invite the Applicant consortium participants to enter their OWN institution-specific data into the system.	Upon receipt of email with credentials to access SOFIA
Coordinator should inform Participants that they will receive an invitation by email from the sender: noreply@imi.europa.eu.org. Participants should ensure that email spam filters do not block this mail.	
Inform all participants of the need for a PIC. The required procedure and forms and a more detailed explanation can be found at http://ec.europa.eu/research/participants/portal/page/myorganisations	From the submission start date (for submitting EoIs) mentioned on IMI website for the specific Call.
Ensure all partners are aware of the IMI funding model and IP policy	From the submission start date (for submitting EoIs) mentioned on IMI website for the specific Call.
Complete all sections of the EoI	
Collect partner descriptions from each partner	From the submission start date (for submitting EoIs) mentioned on IMI website for the specific Call.
Ensure all partners have completed the administrative data	Before submission deadline (preferably more than one week)
Finalise Scientific Section and upload final version in SOFIA	Before the submission deadline mentioned on IMI website for the specific Call
Formal submission and finalisation of the Applicant Consortium's Expression of Interest to IMI via SOFIA	Before the submission deadline mentioned on IMI website for the specific Call

The Expression of Interest:

The Expression of Interest will consist of two sections:

Administrative Section: This captures the information about the legal status of each Participant, as well as an overview of the eligible project costs, the IMI JU contribution requested by entities eligible to receive IMI JU funding.

Scientific Section: This captures the proposed project's scientific description and objectives, the proposed project work plan with an outline of the Work-Packages, deliverables, timelines and the partnership case.

Guidelines for Completing the Administrative Section

(See appended specimen online forms)

The administrative section has to be filled primarily by the 'Coordinator'. Some information shall be filled directly by the participants (see below) under guidance of the Coordinator. The different forms need to be completed on-line using the IMI submission tool (SOFIA).

By default, the **'Coordinator'** will always be identified as **'Participant 1'**.

The Coordinator is responsible for:

- the completion of forms **A1** and **A2**;

Each organisation, in the Applicant consortium (including the Coordinator), must complete the A2 forms with their respective own institution specific data: In order to help the Consortium to fill in all the forms explanatory notes are provided on the last pages of these guidance notes. Please read them carefully.

Invitation to Participants – Submitting Data

The IMI electronic submission tool has a function for the Coordinator to invite the Applicant consortium participants to enter their **OWN institution-specific** data into the system.

An invitation e-mail is sent to all participants requesting them to enter their respective **institution-specific** data directly into the IMI electronic submission tool.

The Coordinator should inform Participants that they will receive an invitation by email from the sender: noreply@imi-europe.org. **Participants should ensure that email spam filters do not block this mail.**

Important information:

Information provided within the **A2** form will allow the IMI JU to perform a legal assessment to verify the existence and status of the legal Entity.

Coordinators are advised to start collecting the following administrative information as soon as possible:

For completion of form

- Full legal names for all of the Participants in the consortium
- Full details of all key contacts for all Participants' e-mail addresses
- **Participant Identity Code (PIC) for each participant,** if already available

If the PIC is not yet available at the time of the submission of the EoI, it will have to be at the time of the submission of the full project proposal for the purpose of this legal assessment. This PIC will serve as a customer number and will be needed for the preparation of the Grant Agreement to be signed between the IMI Consortium and the IMI JU. Participants that are already participating in FP7-supported projects will already have a PIC assigned. If a participant does not have a PIC, they must request one. The required procedure and forms and a more detailed explanation can be found at http://ec.europa.eu/research/participants/portal/page/myorganisations#

Explanatory notes for Administrative Forms

Expression of Interest Number

The number will be assigned by the IMI JU as the unique identifier for your EoI.

EoI acronym

The Applicant Consortium should propose an acronym for the proposal.

IMI Call (part) identifier

The IMI Call (part) identifier is the reference number given in the Call or part of the Call you were addressing, as indicated in the publication of the Call.

Expression of Interest Title

It should be no longer than 200 characters. The title should be understandable to non-specialists.

Topic code:

The topic code is the reference code given in the Call or part of the Call you were addressing, as indicated in the publication of the Call.

Abstract

The executive summary should be entered in Form A1 and it should not use more than 8,000 characters. It should, at a glance, provide the reader with a clear understanding of the objectives of the project and how the objectives will be achieved, and their relevance in the context of the objectives of the Call and the specific topic. It must be short and precise.

Please use plain typed text, avoiding formulae and other special characters.

Estimated cost and estimated requested IMI contribution:

Please refer to the IMI Rules for Participation available on the IMI website.

Participant short name

The short name chosen by each participant. This should normally be no more than 20 characters and the same short name should be used for the participant in all documents relating to the proposal.

Participant identity code (PIC)

If the participant has a PIC code already, the corresponding information can be retrieved by entering the PIC code. Information which has been automatically completed should still be double-checked for accuracy. If a participant does not have a PIC, they must request one. The required procedure and forms and a more detailed explanation can be found at http://ec.europa.eu/research/participants/portal/page/myorganisations#

Participant legal name

The official name of the participant's organisation. If applicable, this should be the name under which the participant is registered in the official trade registers. This name should be identical to the one given by the PIC.

Address data

The complete legal address should be provided. This data should be identical to those associated with the corresponding PIC if available. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

Country

The name of the country as commonly used. For the legal address of the participant, this data should be identical to those associated with the corresponding PIC if available. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

Phone and fax numbers

Please insert the full numbers including country and city/area code.

Example +32-2-2991111.

Title

Please choose one of the following: Prof., Dr., Mr., Ms.

Gender

This information is required for statistical purposes. Please indicate with an F for female or an M for male as appropriate.

Position

Please indicate the position in your organisation e.g. Rector, President, Chief Executive Officer, Director etc.

Department/faculty/institute/laboratory name/…

Please indicate the postal address for contact purposes.

Legal status

Please refer to the IMI Council Regulation and the IMI JU Rules for Participation for further information on the types of legal entities available on the IMI website.

Any other legal entities, who do not meet the conditions defined in the Rules, will be classified as “none of the above”.

Dependencies between participants

Two participants (legal entities) are dependent on each other where there is a controlling relationship between them:

A legal Entity is under the same direct or indirect control as another legal Entity, or

A legal Entity directly or indirectly controls another legal Entity, or

A legal Entity is directly or indirectly controlled by another legal Entity.

Control:

Legal Entity A controls legal Entity B if:

A, directly or indirectly, holds more than 50% of the share capital or a majority of voting rights of the shareholders or associates of B, or

A, directly or indirectly, holds in fact or in law the decision-making power in B

Direct or indirect holding of more than 50% of the nominal value of the issued share capital in a legal Entity or a majority of voting rights of the shareholders or associates of the said Entity by public investment corporations, institutional investors or venture-capital companies and funds shall not in itself constitute a controlling relationship.

Ownership or supervision of legal entities by the same public body shall not in itself give rise to a controlling relationship between them.

Character of dependence

Insert the appropriate abbreviation according to the list below to characterise the relationship between your organisation and the other participant(s):

SG: Same group: if your organisation and the other participant are controlled by the same third party;

CLS: Controls: if your organisation controls the other participant;

CLB: Controlled by: if your organisation is controlled by the other participant.

Guidelines for Completing the Scientific Section

(See appended specimen template form)

The Scientific Section is a downloadable Word document to be prepared 'off-line' and then uploaded as a pdf file via the IMI electronic submission tool (pdf <10MB, graphics 300dpi, avoid colour, Times New Roman, 12 point).

All the following fields have to be included:

Front Page

Please complete with the Expression of Interest acronym and title. The information has to be the same as in the Administrative Part.

1. List of Abbreviations

This Section should include a full list of all abbreviations used in the EoI.

2. Scientific case

It consists of 3 sub-sections. This section should be **no longer than 12 pages (excluding the reference list)**:

2.1 Concept and Objectives

Please use the section to explain the concept of your project and the rationale for proposing this project plan. Please also describe the overall innovative approaches, research strategy, methodology and analyses intended to be used in order to achieve the key objectives of the Call topic and to meet what is expected from the Applicant Consortium for complementing the EFPIA Consortium.
Please refer also to the Stage 1 Evaluation Form (available on-line on the IMI website) that will be used by the independent experts to evaluate your proposal, and ensure that your proposal addresses the Evaluation criteria 1, 2, 3 & 4.

You should also describe in this part the level of novelty and the advances that the proposed project would bring beyond the state of the art. Briefly describe the potential scientific and technological impact of the results of your project.

2.2 Potential impact and risks

Describe the proposed approaches to ensure balance between the potential impact and residual risks based on the consideration i.e., of potential complications, alternatives strategies and benchmark for success

2.3 References List

This refers to all the scientific and reference material cited in the EoI.

3. Project Plan

This section should be **no longer than 3 pages**.

An outline of project plan should be broken down into individual Work-Packages (WPs) that will implement the objectives of the project. The proposed Work-Packages should cover all project activities including management, training and communication.

It consists of the following sub-sections:

3.1 Outline of Structure and Timelines of the Project

The general work plan should be outlined, including for instance a high-level description of the Work Packages and how they interconnect. Please provide an overall description of the structure and timelines of the project, including a schematic representation (e.g. Gantt chart).

3.2 Work Package list

The table should provide a list of the required details about each Work Package.

3.3 Main Deliverables list for all Work-Packages for the whole project

The table should include a summary of the main deliverables for all the Work Packages during the duration of the project with indicative timelines.

3.4 Indicative budget plan

An indicative budget plan should be presented.

4. Partnership case

The section includes the following subsections:

4.1. Individual Participants: Short profile of the key staff members undertaking the work

For each participant please provide a short profile of the key staff members who will be allocated to the project including a record of accomplishments that have advanced the field. Explain how the tasks allocated match their experience.

Complete one table for each participant.

In the specific case where planned clinical trials are to be conducted, **each** participant clinical centre should also provide evidence of their ability to fulfil all the clinical sites requirements as outlined in the Call topic text (max 2 pages **per** participant clinical site). Each criteria outlined in the Call topic text should be carefully considered – if any criteria cannot be fulfilled, these should be clearly stated.

4.2 Consortium as a whole

This section should be **no longer than one and a half** pages.

Please provide details of the complementarity of consortium partners. Mention any unique features of the consortium. Please explain strengths, complementarities, appropriateness of the allocation of role/ contribution of each participant, including manageability and balance of your consortium.

Please refer also on the Stage 1 Evaluation Form (available on the IMI website) that will be used by the independent experts to evaluate your proposal, and ensure that your proposal addresses in particular criterion 2, bullet point 1 & 3.

5. Ethical issues

This section should be **no longer than 1/2** pages.

Potential ethical issues should be declared (not scored during evaluation). The types of issues to be considered include:

Informed consent: Illustrate an appropriate level of ethical sensitivity, considering issues of insurance, incidental findings and consequences of leaving the study.

Data protection issues: Avoid unnecessary collection/use of personal data, how it is used and protected and consider issues of informed consent. Identify the source of data as being from previous studies, or generated as part of the on-going research.

Use of animals: Where animals are used, consider and address convincingly the 3Rs (Replace, Reduce, Refine), specifying numbers of animals used.

Human embryonic stem cells: Research proposals that will involve human embryonic stem cells (hESC) should address the following:

- How the project serves important research aims to advance scientific knowledge and to increase medical knowledge for development of diagnostic, preventative or therapeutic methods to be applied to humans.
- Why it is necessary to use hESC to achieve the scientific objectives in the proposal and why appropriate validated alternatives (in particular stem cells from other sources or origins) are not suitable and/or available to achieve expected goals. This latter provision does not apply to research comparing hESC with other human stem cells.
- Take into account the relevant legislation, regulations, ethical rules and/or codes of conduct in place in the countries where research using hESC is to take place, including the procedures for obtaining informed consent.
- Assurance that for all hESC lines to be used, they were derived from embryos:
- Donor express, written and informed consent is provided freely in accordance with national legislation prior to the procurement of the cells
- Result from medically-assisted *in vitro* fertilization designed to induce pregnancy and were no longer to be used for that purpose
- Measures are in place to ensure protection of personal data (including genetic) and privacy of donors during the procurement of hESC and for any use thereafter. All data should be presented in a form to ensure donor anonymity.
- The conditions for donation are adequate and no pressure or financial inducement was used to procure the hESC lines and that infertility and research activities were kept appropriately separate.
- Identify which ethical committees and regulatory organizations in the countries of research need to be approached during the life of the project.

5.1 Ethical Issues Table

Please complete the Ethical issues table 5.1 in order for the Ethical Experts to decide in an ethical review is required. If there are no ethical issues for your proposal, please indicate this in the final square of the table by ticking “YES”.

Declaration

The declaration is submitted by the Applicant Consortium coordinator on behalf of the Applicant Consortium.

No change to the declaration text shall be made.

By participating in this Expression of Interest and submitting it to the IMI Joint Undertaking, each participant declares that (i) he/she has read and understood the IMI IP policy incorporated in the Grant Agreement, and (ii) to the best of his/her knowledge, as of the submission date, there is no agreement, or contract to which he/she is a party or to which he/she is bound, which might encumber his/her ability to comply with the IMI IP policy and the corresponding Grant Agreement provisions.

Appendix 1 EoI Submission : Administrative Section- Specimen Online Forms

Expression of Interest number 115485-1
EoI Acronym NS

General Information

Call Identifier IMI_Call_2012_NS
Expression of Interest Title
Topic Code IMI_Call_2012_NS_01

Abstract (max. 2000 char)

Part B - Scientific Case

Current EoI Document
EoI Document (PDF, Max. 10MB) Browse...

Legal representative of the Applicant Consortium Coordinator

Family Nam
First Name(
Legal name of organisation
Title
Sex (M/F) M F
Position in the Organisation

Address (if different from the legal address in form A2)

Street name
Number
Town
Postal Code / Cedex
Country Select country
Phone 1
Phone 2
E-Mail
Fax

Costs and funding

Organisation	Estimated costs (k€)	Estimated requested IMI contribution (k€)	Add Participant
	0.00	0.00	Leading Finalize Edit
	0.00	0.00	Finalize Edit Delete
	0.00	0.00	Finalize Edit Delete
Total	0.00	0.00	

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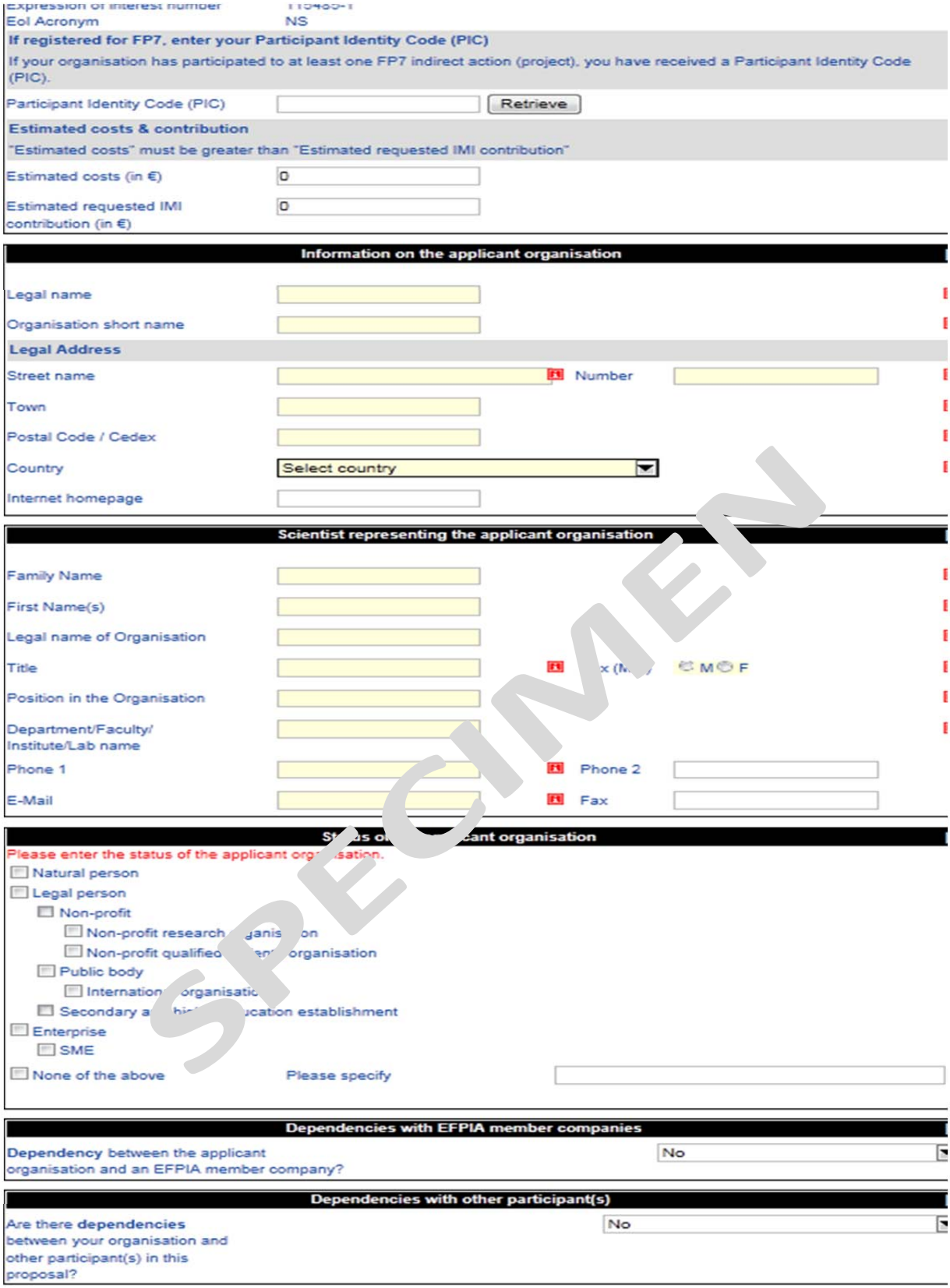

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Appendix 2 Expression of Interest Submission: Scientific Section – Specimen Form

Innovative Medicines Initiative	**EXPRESSION OF INTEREST** **Scientific Section** **Proposal Acronym:** **Proposal Full Name:**

SPECIMEN

1. List of Abbreviations

2. Scientific case

2.1 Concept and Objectives

2.2 Potential impact and risks

2.3 References List

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3. Project Plan

3.1 Outline of the structure and timelines of the project

3.2 Work-packages List

Work-package No.	Work-package title	Type of activity
WP1		
WP2		
…		

3.3 Main Deliverable list for all work-packages for the entire project

Del. No.	Deliverable name	WP No.	Nature	Indicative Delivery date

3.4 Indicative budget plan

4. Partnership case

4.1 Individual Participants: Short profile of the key staff members undertaking the work

Name	Sex	Job title and role in the project	Mini-CV including 3 most relevant publications/patents

When relevant:

Individual participant clinical site: Evidence of the ability to fulfill **all** the clinical site requirements as outlined in the Call topic text.

Institution/clinical centre name: <name>

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4.2 Consortium as a whole

5. Ethics

5.1 Ethical Issues Table

Ethical Issues Table:	YES	PAGE
Research on Humans:		
Does the proposed research involve children?		
Does the proposed research involve patients?		
Does the proposed research involve patients or persons not able to give consent?		
Does the proposed research involve adult healthy volunteers?		
Does the proposed research involve Human Genetic Material?		
Does the proposed research involve Human biological samples?		
Does the proposed research involve Human data collection?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research on Human embryo/foetus:		
Does the proposed research involve Human embryos?		
Does the proposed research involve Human Foetal Tissue/Cells		
Does the proposed research involve Embryonic Stem Cells (hESCs)		
Does the proposed research on hECSs involve cells in culture?		
Does the proposed research involve the derivation of cells from Embryos?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Privacy:		
Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
Does the proposed research involve tracking the location or observation of people?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research on Animals		
Does the proposed research involve research on animals?		
Are those animals transgenic small laboratory animals?		
Are those animals transgenic non-rodents?		
Are those animals transgenic farm animals?		
Are those animals cloned farm animals?		
Are those animals non-human primates?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research Involving Developing Countries:		
Does the proposed research involve the use of local resources (genetic, animal, plant etc.)		
Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc.)?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Dual Use:		
Research having direct military application		
Research having the potential for terrorist abuse		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

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Declaration *(submitted by the Applicant Consortium coordinator on behalf of the Applicant Consortium)*

By participating in this Expression of Interest and submitting it to the IMI Joint Undertaking, each participant declares that (i) he/she has read and understood the IMI IP policy incorporated in the Grant Agreement, and (ii) to the best of his/her knowledge, as of the submission date, there is no agreement, or contract to which he/she is a party or to which he/she is bound, which might encumber his/her ability to comply with the IMI IP policy and the corresponding Grant Agreement provisions.

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