



STANDARD OPERATING PROCEDURE (SOP) FOR THE SUBMISSION OF HARMONY RESEARCH PROJECT PROPOSALS

OBJECTIVES AND SCOPE

This Standard Operating Procedure (SOP) describes the procedures and steps for the submission and approval of research projects to the HARMONY Platform. It outlines the responsibilities of the HARMONY Bodies/Beneficiaries involved and details the interactions required to ensure the application of a standard procedure in a timely manner.

WHO MAY SUBMIT A RESEARCH PROJECT PROPOSAL?

Proposals to conduct a Research Project using the HARMONY Platform may be submitted by:

1. Any HARMONY Beneficiary(ies):

see overview: <https://www.harmony-alliance.eu/en/partners>

- a. HARMONY Third Parties under article 11 and 12 of the Grant Agreement,
- b. Linked Third Parties, and
- c. Affiliates Entities

must submit their research project proposals through the Beneficiary that controls (in the case of affiliated entities) or has a legal link with them;

2. Any Associated Member(s), with relevant data contribution judged on a case-by-case basis.

See overview: <https://www.harmony-alliance.eu/associated-members>

3. Any other organization or institution with interest in the project (Third Party), via the payment a fee in cash or making an in-kind contribution to support the objects of the Action.

The diagram in Annex IV outlines the processes by which the HARMONY Project reviews and evaluates any submitted Research Project Proposal. The HARMONY Coordination Office will coordinate the Admission and Evaluation processes: harmonyoffice@ibsal.es.



INDEX

A. HOW TO SUBMIT A RESEARCH PROJECT PROPOSAL

B. ASSESMENT AND EVALUATION PROCEDURE

B. TIMELINE FOR ASSESSMENT AND EVALUATION

C. EVALUATION CRITERIA

D. HOW TO SUBMIT A RESEARCH PROJECT PROPOSAL

ANNEX I – DEFINITIONS

ANNEX II – SUBMISSION AND EVALUATION OF A RESEARCH PROJECT PROPOSAL

ANNEX III – ADMISSION REVIEW FORM

LEGENDA

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Revision Chronology			
SOP ID Number:	Effective date:	Reason for Change:	Author:
HARMONY/SOP/01/01	04/02/2017	New SOP	Santiago Moralejo
HARMONY/SOP/01/02	05/02/2017	Coordinator Review	Jesús M. Hernández
HARMONY/SOP/01/03	06/02/2017	WP2 Review	Lars Bullinger
HARMONY/SOP/01/04	15/03/2017	EC Approval	
HARMONY/SOP/01/05	27/03/2017	SC Approval	



A. HOW TO SUBMIT A RESEARCH PROJECT PROPOSAL?

1. Complete the HARMONY Research Project Submission Form (Annex V). The following is the minimum information that is required for the research project proposal to be considered:
 - a. An **abstract** or summary of the research project, describing:
 - i. the significance/unmet need of the project;
 - ii. the hypothesis and/or anticipated major outcome of the research project;
 - b. An overview of the analysis including in particular:
 - i. The **key variables** which need to be available in the data to address the research project;
 - ii. an estimation of the minimum number of patient **datasets needed** to conduct the research project;
 - iii. A list of recommended **data sources** or data custodians and the estimated number of available datasets from the recommended data sources;
 - iv. and the suggested **statistical analysis plan** to address the research project
 - c. The potential impact of the research outcome.
 - d. A description of any anticipated ethical difficulties and the procedures adopted to prevent or address them.
2. Submit the Form electronically on the HARMONY website or by email to the HARMONY Coordination Office at Harmonyoffice@ibsal.es with the subject: RP – IS “title of the research project”.
3. The HARMONY Coordination Office (HCO) will acknowledge the receipt of the research project proposal.
4. **ADMISSION:** All submitted Research Project Proposals will undergo a review for admission. The proposal will be admitted and eligible for evaluation if it is complete and all the required documentation is enclosed. The Coordinator together with the WP2 Leadership will have a period of **15 days** to review it for admission (Annex VI).
5. The HCO must contact the submitter when a decision is made regarding the admission and eligibility for evaluation of the research project proposal, and if missing documentation, additional information, or clarification of the project research proposal arises during the review.



B. ASSESSMENT AND EVALUATION PROCEDURE

All admitted Research Project Proposals will be anonymised by the HCO before submission to peer expert members of the HARMONY Project to minimise evaluation biases. In addition, all the reviewers will reveal any potential conflict of interest.

1. The Research Project Proposal will be sent to the KOL (public and private) of the appropriate disease pillar(s) within **WP2** for evaluation. The HM disease pillar will issue a structured **approval / rejection assessment**, (Annex VII) evaluating the scientific, socioeconomic and other merits and viability of the proposal. In case of approval, the assessment might expand the scope and data sources of the initial proposal.
2. The assessment will be sent to the HCO, who will inform the Executive Committee.
3. The HCO must contact the submitter if the research project is rejected.
4. The HCO will then send the approval assessment to **WP4, WP5** and **WP6** Leaders for intra-work package analysis. Both WPs will issue an **evaluation report** (Annex VIII) that might expand the initial proposal with recommendations about (but not limited to) additional data sources; outcomes; applicable analytic tools; and end- points.
5. These reports will be sent to the HCO for compilation, and will be added to the approval assessment issued by WP2.
6. The HCO will send all previous documents to **WP8** Leaders for their **report on the compliance with legal and ethical requirements** (Annex IX). WP8 Leaders might request the advice of the External Ethics Advisory Board and their non-binding recommendations will be considered in the WP8 compliance report.
7. The HCO must be contacted immediately should a reviewer identify a major flaw that makes the project not approvable in any of the previous stages and the review can stop until this issue is resolved.
8. The HCO must contact the submitter if the proposal does not receive a favourable legal/ethical opinion by WP8 Leadership. The research project may be resubmitted as a new application upon revision to comply with the legal recommendations.
9. If the proposal receives a favourable opinion from WP8, the Coordinator must confirm the economic viability of the research project against the resources needed and inform the **Executive Committee** for final approval and estimation for execution, pending the recommendation for assigned budget of the **DQSC**.



C. TIMELINE FOR ASSESSMENT AND EVALUATION

The HARMONY Project estimates that a decision to conduct the Research Project will be made within 60 days once the Research Project Proposal Submission has been admitted. The overall number of proposals received and/or the need for additional information or clarifications during the evaluation process may affect this time period. The submitter will be notified if this timeline is longer than anticipated.

This period is composed of the following steps:

1. The HM disease pillar will have a period of **15 days** from the reception of the research project application to issue a structured **approval or rejection assessment** of the research project Proposal.
2. WP4, WP5 and WP6 will have a period of **15 days** to issue an **evaluation report** about the research proposal.
3. WP8 will have a period of **15 days** from the reception of the report to issue their reasoned clearance with regard to the **legal and ethical elements** of the research proposal.
4. The HARMONY **Executive Committee** will have a period of **15 days** to inform the submitter and start negotiations towards execution.

D. EVALUATION CRITERIA

The following elements will be considered during the evaluation:

1. The relevance of the HM-specific research project or unmet need submitted to study, its specific aims and objectives;
2. The hypothesis and/or anticipated major outcomes of the research project;
3. The suitability of the recommended data sources and data custodians;
4. The existing datasets available in the platform and the estimation of the additional number of patient datasets needed to conduct the research project;
5. The appropriateness of the proposed statistical analysis plan and sample size and;
6. The availability of the key variables required to address the research project on the existing and suggested data sources.
7. The potential impact of the research project.
8. The anticipated ethical difficulties and the procedures adopted to prevent them.

WP2 Special attention should be placed on points 1 to 4 and 7 of the evaluation criteria.

WP4 and WP5 should give special consideration to points 4, 5 and 6 of the evaluation criteria.

WP6 should give special consideration to on points 1, 2, 6 and 7 of the evaluation criteria.

WP8 should focus in the compliance of the Research Project proposal with the legal and ethical aspects of the HARMONY project.



ANNEX I - DEFINITIONS

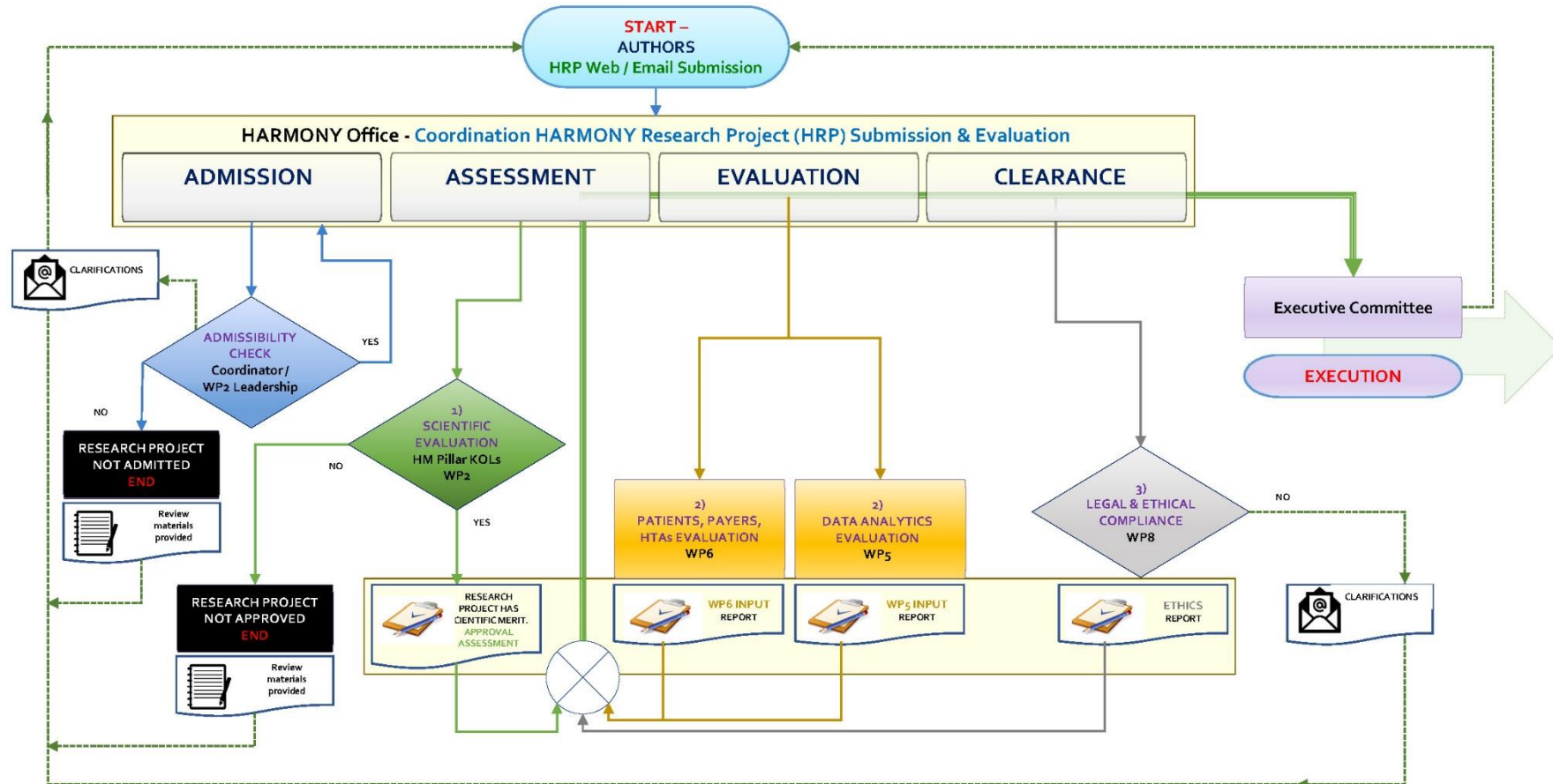
1. **“Beneficiary”** or **“Participant”** means a legal entity who has signed the Grant Agreement number 116026 with the IMI2 JU or the Form of Accession. There can be two types of Beneficiaries in an IMI2 Action, i.e.:
 - a) Beneficiaries receiving IMI2 JU funding; and
 - b) Beneficiaries not receiving IMI2 JU funding, such as in particular those EFPIA Beneficiaries not eligible to IMI2 JU funding or not requesting it.For the list of Beneficiaries, please refer to Annex II.
2. **“Affiliated Entity”** means any legal entity that is under the direct or indirect control of a Beneficiary, or under the same direct or indirect control as the Beneficiary, or that is directly or indirectly controlling a Beneficiary. Control may, in particular, take either of the following forms:
 - a) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
 - b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
3. **“Associated Member”** means a legal entity not signing the Grant Agreement 116026 with the IMI2 JU or the Form of Accession (it is not a “Beneficiary”) with not assigned budget. As such they participate in the provision of patient datasets and can receive supportive funding (variable budget).

Associated Members will join the project by signature of an “Associated Member Engagement Framework” and an “Associated Member Agreement”.

For the list of Associated Members, please refer to Annex III.
4. **“Third Party”** shall mean a legal entity which is not a party to the Grant Agreement number 116026, neither falls in the “Associated Member” category.
5. **“Linked Third Parties”** shall mean any legal entity which has a legal link to a Beneficiary implying collaboration that is not limited to the Action.
6. **“Data Quality Supervision Committee”** means the governance body responsible for the management of quality patient data sets as further defined in Clause 11.7 of the Consortium Agreement.
7. **“Coordinator”** means the Beneficiary in charge of the grant administration. In this case, Prof Dr Jesús María Hernández Rivas.
8. **“Executive Committee”** means the governance body responsible for the provision of overall leadership of the Action and coordination of the different consortium bodies.
9. **“Work Package”** or **“WP”** means a sub-division of the Action as described in Annex 1 of the Grant Agreement number 116026. **“Work Package Leader(s)”** means the leader(s) of a Work Package.
10. **“Research Project”** means the HM-specific research question, study, outcome to be analysed.



ANNEX II – SUBMISSION AND EVALUATION OF A RESEARCH PROJECT PROPOSAL





ANNEX III – ADMISSION REVIEW FORM

ADMISSION Review - Research Project Proposal			
Title:			
Author(s):		E-mail:	
Organisation:		Date:	

ADMISSIBILITY CRITERIA	
1	RESEARCH PROJECT PROPOSAL: The HM-specific research project is clearly stated, describing the significance and/or unmet need and the major outcome with well-defined aims. <input type="checkbox"/> Yes <input type="checkbox"/> No
	Comments / Clarification request: _____
2	ANALYSIS PROPOSAL:
	<ul style="list-style-type: none"> Suitable data sources are identified <input type="checkbox"/> Yes <input type="checkbox"/> No
	<ul style="list-style-type: none"> Number of available datasets is stated <input type="checkbox"/> Yes <input type="checkbox"/> No
	<ul style="list-style-type: none"> Statistic Approach is present <input type="checkbox"/> Yes <input type="checkbox"/> No
	<ul style="list-style-type: none"> Suggested sample size is stated <input type="checkbox"/> Yes <input type="checkbox"/> No
	<ul style="list-style-type: none"> Key variables are identified <input type="checkbox"/> Yes <input type="checkbox"/> No
Comments / Clarification request: _____	
3	IMPACT: The anticipated major outcome and potential impact of work is well described. <input type="checkbox"/> Yes <input type="checkbox"/> No
	Comments / Clarification request: _____
ADMISSIBILITY RECOMMENDATION: <i>Check one (type letter X in the appropriate box).</i>	
Admitted	<input type="checkbox"/>
Admitted with minor revisions/ additions (state in "Comments / Clarifications")	<input type="checkbox"/>
Invite re-submission for a new review after major revisions/additions	<input type="checkbox"/>
Reject	<input type="checkbox"/>
HM-PILLAR: <i>Please indicate the HM pillar(s) that should evaluate the proposal</i>	



Research Project Proposal Assessment	
Project title:	
Reviewer:	Email:
Organization	WP #: 2
Role/Function in HARMONY	
ASSESSMENT	
1	<p>RESEARCH PROJECT PROPOSAL: <i>The HM-specific research project is clearly stated, describing the significance and/or unmet need and the major outcome with well-defined aims. Please consider whether implementing the research project would enhance the scientific and/or medical knowledge, result in improved outcomes for the patients, and/or empower policy makers and clinicians to optimize care for patients.</i></p> <p>General Comment:</p> <p>Additional Comments: (i.e. recommendations)</p>
	<p>ANALYSIS PROPOSAL: <i>Please review the feasibility, reliability, and appropriateness of the following topics of the research project</i></p> <ul style="list-style-type: none"> • Suitable data sources are identified • Number of available datasets is stated • Statistic Approach is present • Suggested sample size is stated • Key variables are identified <p>General Comment:</p> <p>Additional Comments: (i.e. recommendations)</p>
3	<p>IMPACT: <i>Please provide your comments and recommendations to whether the anticipated major outcome and potential impact of work is well described and the HARMONY stakeholders would care or benefit from the hypothesis and/or outcome of the research project</i></p> <p>General Comment:</p> <p>Additional Comments: (i.e. recommendations)</p>
	<p>ASSESSMENT: <i>Check one (type letter X in the appropriate box).</i></p> <p>Accept <input type="checkbox"/></p> <p>Reject <input type="checkbox"/></p>



Research Project Proposal Evaluation	
Title: <input type="text"/>	
Reviewer: <input type="text"/>	WP #: <input type="text"/>
EVALUATION (WPs 4, 5 & 6)	
1	RESEARCH PROJECT PROPOSAL: <i>The HM-specific research project is clearly stated, describing the significance and/or unmet need and the major outcome with well-defined aims. Please consider whether implementing the research project would enhance the scientific and/or medical knowledge, result in improved outcomes for the patients, and/or empower policy makers and clinicians to optimize care for patients.</i>
	General Comment: <input type="text"/> Additional Comments: <i>(i.e. recommendations)</i> <input type="text"/>
2	ANALYSIS PROPOSAL: <i>Please review the feasibility, reliability, and appropriateness of the following topics of the research project</i>
	<ul style="list-style-type: none">• Suitable data sources are identified• Number of available datasets is stated• Statistic Approach is present• Suggested sample size is stated• Key variables are identified General Comment: <input type="text"/> Additional Comments: <i>(i.e. recommendations)</i> <input type="text"/>
3	IMPACT: <i>Please provide your comments and recommendations to whether the anticipated major outcome and potential impact of work is well described and the HARMONY stakeholders would care or benefit from the hypothesis and/or outcome of the research project</i>
	General Comment: <input type="text"/> Additional Comments: <i>(i.e. recommendations)</i> <input type="text"/>



Research Project Proposal Ethics Clearance	
Title:	
Reviewer:	WP #: 8
ETHICAL REVIEW (WP8 ONLY):	
General Considerations:	
Ethics clearance <i>(The proposal is "ethics ready")</i>	<input type="checkbox"/>
Conditional Ethics Clearance <i>(The proposal raises ethical issues that must be addressed before the research project is executed)</i>	<input type="checkbox"/>
1 Reasons: <i>Please provide your comments and recommendations on the ethics requirement(s) that need to be considered for ethical clearance. Please specify any additional documents or information that needs to be submitted</i>	
No Ethics clearance <i>(If this option is selected the proposal will not be estimated for execution)</i>	<input type="checkbox"/>
Reasons: <i>Please provide a clear explanation of the ethical issues that preclude the research project from execution</i>	

Completing all parts of this form is mandatory, even if there is no financial relationships to disclose.

Kindly complete this section to identify any situation in which you might have an actual, perceived, or potential conflict of interest you may have as HARMONY Reviewer for this Research Project Proposal.

Even when financial relationship does not result in bias, the integrity of HARMONY may be considered at risk because of the potential perception that bias may occur. Transparency regarding the financial interest of the HARMONY Reviewers is critical.

You are responsible for the accuracy and completeness of the submitted information.

Your disclosure is part of the Research Project Assessment and will be published with it.

Financial Support for the Research Project Proposal:

(Financial Support consists of anything of monetary value received by you (direct financial support) or the institution of which you are an employee (indirect financial support) during the two preceding calendar year, including but not limited to, salary, royalty, intellectual property rights, consulting fees, honoraria, ownership interest, research support or any other financial benefit from any commercial entity which has (potentially or perceived) interests that may conflict with those of HARMONY.)

- Did you or your institution at any time receive financial support or services from a third party (Government entity, commercial entity, private foundation, academic institution, or other) for any aspect of the submitted Research Project Proposal? Yes No



Please declare any financial relationship(s) to disclose, namely:

(Use the table below to disclose your financial relationships with entities in the biomedical arena that could be perceived to influence your decision about the submitted Research Project Proposal. Report all sources of revenue paid to you or your institution on your behalf during the two preceding calendar years. If there is a question, it is better to disclose a relationship than not to do so.)

Name of the company or institution	Direct	Indirect
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
(Add rows as needed)		

2. Would anyone associated with you benefit from or be detrimentally affected by your proposed decision about the submitted Research Project Proposal?

No

Yes Explain:

Intellectual Property:

3. Do you have patents, whether planned, pending or issued, broadly relevant to the submitted Research Project Proposal?

No

Yes Explain:

Relationships not covered above:

4. Are there other relationships or activities or do you hold any personal or professional views or biases that may lead others to reasonably conclude that you are not an appropriate person to deal with the submitted Research Project Proposal?

No

Yes Explain:

By signing below, you attest that the information provided is correct, that you have disclosed any financial relationship, and that none of the information provided disqualify or limit your professional skills to participate as an expert in the evaluation of the submitted Research Project Proposal under review, even if some of the answers above are affirmative.

Signature:

Date:

Print name:

Or

Decline your participation as HARMONY Reviewer for this Research Project Proposal.