XVIVO Investigator Initiated Research proposal

This form can be used to submit a research proposal to XVIVO, whether or not you are requesting financial support. Please submit your Investigator Initiated Research (IIR) proposal via email to XVIVO (iir@xvivogroup.com). If you have not previously engaged in research collaborations with XVIVO, please attach your CV to the proposal.

If you have not discussed your proposal with XVIVO: Please complete ONLY SECTION I, and submit this for initial review. If you already have a detailed research plan/proposal you may attach this to the submission but it is not mandatory at this stage.

XVIVO will review the initial Section I proposal, and determine if the proposal is potentially eligible for XVIVO support. In that case you will be asked to complete Section II of the form.

If you have discussed your proposal with XVIVO and a full proposal has been requested: Please complete BOTH SECTIONS I and II, and submit this for full review.

XVIVO will then start a more comprehensive review and communicate the result back to the applicant. The outcome can be rejected, approved with modifications, or approved. We will always provide some comments to explain the basis for our decision.

The review of a Section I or Section II proposal will take several aspects into consideration, for example the following:

1. Are the objectives of the research clear and well described?
   - Assess if the goals of the research are understandable and detailed enough to be evaluated effectively.

2. Could the proposed research contribute by adding novel insights, developing new or refining existing methods, ultimately adding to the field of organ transplantation?

3. Could the proposed research improve outcomes for organ recipients?
   - Evaluate if the research could lead to better clinical outcomes, such as increased transplant success rates, improved patient survival, or reduced complications for organ recipients.

4. Are the personnel and resources being supplied/requested by the researcher reasonable to achieve the objectives?
   - Evaluate whether the researcher has the necessary team and resources (equipment, expertise, funding) to meet the objectives.

5. Does the proposed research program fit well in the context of XVIVO strategy, roadmaps, and product development?

6. Is there (or might there be) significant overlap and redundancy with what XVIVO or our research partners are already doing? If so, are there components of the proposed research that should either be eliminated or added?

7. Is the requested funding reasonable in relation to the expected deliverables, and can it be accommodated within XVIVO's available budget for the current or next period?

8. Will scientific publications (papers in peer-reviewed journals, abstracts, or presentations at professional meetings) be generated as a result of this program?

These questions aim to assess the feasibility, relevance, and strategic fit of the proposed research, ensuring that it can provide scientific benefits within the company's framework.

XVIVO Investigator Initiated Research proposal form

SECTION I: Abstract of research proposal

THIS SECTION SHOULD PROVIDE A SUMMARY OF THE KEY ELEMENTS OF YOUR RESEARCH PROPOSAL.

SECTION I.A: Project title

Enter the title of the proposed research project.

SECTION I.B: Contact details of the principal investigator

Principal investigator name:	Position title of principal investigator:
Mail correspondence address:	**Telephone number and email address:**

SECTION I.C: Other key personnel engaged in this project

Name	Email	Organization	Role in project

CONTINUATION OF SECTION I: ABSTRACT OF RESEARCH PROPOSAL

SECTION I.D: Abstract of research plan

This abstract is intended to serve as a succinct and accurate description of the proposed work when separated from the full proposal.

PLEASE LIMIT SECTION TO ~300 WORDS.

General objectives:

Specific aims:

Summary of research design and methodology:

Key outcomes and deliverables (in general and to XVIVO):

Expected benefits to patients (clinical) and/or clinics (administrative):

CONTINUATION OF SECTION I: ABSTRACT OF RESEARCH PROPOSAL

SECTION I.E: Budget and resources

In-kind support requested from XVIVO: (describe any non-monetary support and/or services from XVIVO, e.g. XVIVO devices, disposables or machines, that the project requires to be completed).

Product name (e.g. STEEN solution)	**Quantity**	**Comments**

Estimated total cash funding requested from XVIVO: describe any monetary support requested from XVIVO that the project requires to be completed.

Direct costs	**EUR**
Indirect costs (including institutional overhead)	**EUR**

END OF SECTION I

SECTION II: Full research proposal

THIS SECTION EXPANDS THE INFORMATION IN SECTION I

II.A: Aims of the project

How will the broad, long-term objectives of the research be achieved? What are the specific goals that the proposed research project is intended to accomplish within a realistic time frame? What will be the potential of this research for technological innovation, commercial application and clinical utilization?

II.B: Significance of the research

Describe the background of this project. Discuss its significance in terms of advancing knowledge and promoting innovation. Please include a brief evaluation of existing technology and current knowledge.

II.C: Clinical and/or administrative benefit

Describe and quantify the projected clinical and/or administrative benefit that would be expected either as a direct or indirect result of this work. Please specify objectively and (if available) provide a summary of the evidence basis of your projection.

II.D: Research design and methods

Discuss the research design, procedures and protocols to be used, and the means by which resulting data will be analyzed and interpreted. Describe any new research methodology and its advantage over existing methodologies. If applicable, discuss the criteria that will be used to determine that the feasibility of the method has been demonstrated.

CONTINUATION OF SECTION II: FULL RESEARCH PROPOSAL

II.E: Data sets and data sharing

Describe any data sets generated from the research, how will they be obtained and managed (including patient consent), and if/how they will be shared with XVIVO and other research partners.

II.F: IRB and clinicaltrials. gov registration

Where applicable, will research be cleared via Institutional Review Boards (IRB) or Human Subjects Committees? Will the research be registered on clinicaltrials.gov?

II.G: Schedule of activities

Please provide a schedule of research tasks in the chart below, including milestones and deliverables to be submitted. Information in the EQUIPMENT/SOFTWARE/MATERIAL COSTS in the budget below will need to be associated with the details entered in this table.

Start date:

Time period	Research tasks	Milestone and deliverable

CONTINUATION OF SECTION II: FULL RESEARCH PROPOSAL

II.H: Literature cited

II.I: In-kind support

Describe any non-monetary support and/or services from XVIVO, e.g. XVIVO devices, disposables or machines, that the project requires to be completed.

Product name (e.g. Steen Solution)	**Quantity**	**Time period(s)** required (referenced to Section II.G above)	**Comments**

External funding opportunities

Describe whether this proposal will support an application to an external grant opportunity. Include where possible the details of this opportunity and the application due dates.

CONTINUATION OF SECTION II: FULL RESEARCH PROPOSAL			
Budget – direct costs	**From date**	**To date**	
Personnel			
Name	**Time period(s)** required (referenced to section II.G above)	**% Effort**	**Cost**
EQUIPMENT / SOFTWARE / MATERIAL COSTS			
TOTAL DIRECT COSTS		**EUR**	
TOTAL INDIRECT COSTS (including institutional overhead)		**EUR**	
TOTAL COSTS		**EUR**	
Cash funding requested from XVIVO		**EUR**	
END OF SECTION II			

Please submit your proposal via email to XVIVO

iir@xvivogroup.com