ERA-HDHL
Call for Joint Transnational Research Proposals

Addressing adverse and beneficial effects of food ingredients and food processing on hypersensitivities to food (FOOD_HYPERSENS)

Guideline proposal template

Submission deadline for proposals:

8th of April 2021 at 17h CEST

Link to: Call Text
Link to: "Electronic submission system"

For further information, please visit us on the web

http://www.healthydietforhealthylife.eu/

Or contact the Joint Call Secretariat (JCS):

French National Research Agency
Dr. Sophie Gay & Dr. Martine Batoux
+33 1 78 09 80 39/+33 1 73 54 81 40
50 avenue Daumesnil, 75012 Paris
Email: JPI-HDHLCalls@agencerecherche.fr

1. Background

Under the umbrella of the ERA-Net ERA-HDHL, the Joint Programming Initiative “A Healthy Diet for a Healthy Life” launched a call on the **adverse and beneficial effects of food ingredients and food processing on hypersensitivities to food** (FOOD_HYPERSENS)

The aim of this call is to support transnational, collaborative research projects that address important research questions regarding the prevention of undernutrition in European older citizens through the consumption of appropriate nutritious food.

2. Proposal submission

There is a **single submission procedure** (full proposals) including a rebuttal phase. Proposals and rebuttal should be written in English and must be submitted to the JCS by the coordinator through the electronic submitting system before the **8th of April 2021 at 17h CEST**. Before submission of the proposal, coordinators and all principal investigators of the consortium should complete their profile on the Meta Data Base present on the JPI HDHL website.

The Call deadline is final and will be strictly enforced. The electronic system will not allow submissions after the deadline. Please take into account that the online data entry may be overloaded by the day of the deadline. It is therefore recommended to upload all the required material well beforehand.

IMPORTANT: Each project partner will be subject to the rules and regulations of its respective national/regional funding agency. Details of the national/regional eligibility criteria and guidelines from individual funding agencies are provided in the Annex of the call text.

Checklist for the Coordinator:

In order to make sure that your proposal will be eligible for this call, please collect the information required to tick all the sections below before starting to complete this application form. Please consult the call text for further details.

- **General condition:**

☐ The project proposal addresses the **AIM/S** of the call

- **The composition of the consortium:**

☐ The project proposal involves at least 3 eligible project partners from at least 3 different countries participating in the call. *Please note:* Each project partner (i.e research group participating in the consortium) must be represented by a single principle investigator.

☐ The project proposal does not exceed the maximum of 6 eligible project partners requesting funding

☐ The total number of partners in the consortium, including additional collaborators who are not applying for funding, must not exceed eight.

Please note: Collaborators are researcher(s) or international organizations that are not applying for funding from the participating funding organizations or that are from countries not participating in this call. Collaborators may participate in projects if they clearly demonstrate an added value to the consortium and are able to secure their own funding.

☐ The coordinator and the majority of partners in the consortium are eligible for funding.

☐ The project proposal does not include more than two partners eligible for funding from the same country.

- **Eligibility of project partners:**

☐ I have made sure that each project partner involved in the proposal has checked their eligibility to receive funding by its funding agency (see Annex of the call text).

Please note:

- Proposals that **do not meet the national eligibility criteria and requirements will be declined without further review**.
- All fields must be completed using **Arial 11, single-spaced, margins of 1.27 cm**. Incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review.
- Once completed the full-proposal must be converted in a **single PDF document** before being uploaded to the submission website.

In case of inconsistency between the information registered in the electronic submission system and the information included in the PDF of this application form, the **information registered in the electronic submission tool shall prevail.**

Full proposal application form

All fields must be completed using "Arial font, size 11" characters, margins of 1.27 cm.

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

One joint full proposal document (in English) shall be prepared by the partners of a joint transnational project. All the information requested in this document must be compiled into one single pdf-document and uploaded into the electronic submission system.

Full proposal structure

A. General Information

1 a Project Title: (max 20 words)

1 b Project acronym:

2. Duration of the project (months):

3. Total funding applied for (€): (this budget should be identical to the one present in the electronic submission tool)

4. Keywords (Please identify ten keywords that represent the scientific content of the full proposal)

5. Project Summary (max.350 words)

6. Topic: (Indicate with a cross the topic of your proposal)

- ☐ food hypersensitivities mechanisms
- ☐ modulation of food hypersensitivity by food processing and food ingredients
- ☐ new food processing approaches/ingredients to decrease food hypersensitivity
- ☐ diagnostics/methods to distinguish between actual and perceived hypersensitivity
- ☐ detection methods for food components generated through food processing

7. Consortium Coordinator:

First Name	
Last Name	
Name of Institution	
Department	
Position	
Postal Address	
Email Address	

Country	
Type of Entity	University, Hospital, Research Institute, SME, Large Industry, associations, other
Funding organisation	Precise name of the funding organization to whom money is requested

8. Project Partners asking for funding (*max. 6 in total, incl. coordinator*)

No.	City, Country	Name and Surname of the Principal Investigator	Institution, Department, full affiliations and email	Type of entity: e.g. University, Hospital, Research Institute, SME, Large Industry, associations, other	Funding organisation to whom money is requested
1					
2					
3					
4					
5					

[x] Please list here only the project partners, the coordinator's details are given in the upper table (under 3.)

9. Project Collaborators -not applying for funding. (*Consortium size must not exceed 8 in total, including Collaborators).*

*Please remember that each collaborator has to precisely describe the resources that he will dedicate to the project (personnel, material, in kind/in cash , …) and the origin of these resources **in a letter of intent**. The letter of intent has to be signed by the director of the institution (NOT by the researcher himself). The letter should be uploaded on the on-line system.*

No.	City, Country	Name and Surname of the Principal Investigator	Institution, Department, full affiliations and email	Type of entity: e.g. University, Hospital, Research Institute, SME, Large Industry, associations, other
1				
2				

10. Date and signature of the coordination

B. Detailed Project Description

1. **Background, current state-of-the-art in the research field and preliminary results obtained by the consortium members** *(max. 2 pages)*

2. **Description of the objectives** *(max. 1 page in total)*

Objective No.	Description	Partner(s) responsible for the objective
1		
2		
3		
4		
5		
6		

Please adapt as necessary.

3. **Relevance of the aims of the call** *(max. 1 page)***:**
   Describe how the research question(s) of your proposal address one or more of the following topic (s)

   - the mechanisms, responsible for inducing or preventing food intolerances and food allergies, both in children and adults (e.g. immunity; inflammation; nutrient metabolism; genetics; microbiota; physiology);
   - how food processing and food ingredients can modulate the occurrence of food allergies/intolerances;
   - the development of new approaches to food processing (e.g. novel food ingredients, novel processing methods) to decrease food intolerance/food allergy;
   - the development and/or validation of diagnostics/methods to distinguish between actual and perceived food intolerances and allergies (IgE and non-IgE-mediated);
   - the development and/or validation of detection methods for adverse or beneficial food components generated through food processing.

4. **Workplan** *(max. 10 pages)*, containing:

- Description of the work program including the objectives, the rationale and the methodology (including statistical design and power; ensuring reproducibility of outcomes etc.), highlighting the novelty, originality and feasibility of the project; please describe, if applicable, provide details of how age, gender and/or ethnic differences or other relevant aspects will be taken into account;
- Please ensure that there is a clear rationale for each work package and how this contributes towards delivering the overall aims of the proposal
- If relevant: Description of the existing biobanks/cohorts used in the study
- If relevant: Description of the public involvement in the proposed research projects
- Clearly defined responsibilities and workloads [expressed in person months] of each participating research partner; time plan with milestones; including project coordination and management.

Please use the following table for detailing the distribution of work in person-months (PM) in the work packages (WP):

No.	**Research Partner** (principal investigator)	**WP1 (PM)**	**WP2 (PM)**	**WP3 (PM)**	**WP4 (PM)**	**WP5 (PM)**	**WP6 (PM)**	**WPxx (PM)**	**SUM**
1									
2									
3									
…									

	SUM								

Please adapt as necessary. Please include the contribution of your collaborators in this table.

Optional: two additional pages can be added to the work plan providing:

- a list of references (max. 1 page, for references; a font size of 6pt is acceptable.)
- a page of diagrams, figures, etc. to support the work plan description, timeline and interconnections of work packages (gantt chart, PERT - program evaluation and review technique- or similar) (max. 1 page)

5. **Added value of collaboration on scientific and transnational level** – sharing of resources, data, know-how etc. (max. 1 page)

6. **Exploitation and dissemination of expected results** (max. 2 pages)
   - Impact of expected results for public health, other socio-economic health applications and/or for industry
   - Measures of the consortium to exploit, disseminate and communicate the expected project results
   - Arrangements between participating partners regarding IPR

7. **Data management and data sharing** (max. 1 page), taking into account the FAIR data management principles. Include a description of how the data gathered through the project will be available to the wider research community and the sustainability of the research results within the wider research community.

8. **Ethical Issues** (max. 1 page)
   Ethical aspects of research on humans and/or human biomaterials, including informed consent, ethical approval, data protection (in accordance with national/regional regulations)

   If interventional studies are performed, please complete the relative document (Part D)
   If animal models are used, please complete the relative document (Part D)

9. **Samples/Cohorts and data used in the projects**
   - The consortium has the authorisation to use the samples/cohorts mentioned in the description of the full-proposal

     Yes ☐ No ☐ Not applicable ☐
     If no, please explain

   - The consortium has the authorisation to use the data mentioned in the description of the full-proposal

     Yes ☐ No ☐ Not applicable ☐
     If no, please explain

10. **CV for each principal investigator** (once converted into PDF document: max. 1 page DIN-A4, Arial 11, single-spaced, margins of 1.27 cm per principal investigator). Please follow this format:

Personal	*First name, last name, academic title* *Institution and department (complete name)*
Expertise	*Max: 200 words*
Role within the consortium	*Please indicate the WP you will be working in.*
Publications	*Please list your five most relevant publications of the last ten years*
Additional information	*Honors, awards, memberships or references; up to 5 relevant third-party funded projects conducted in the area in the past 5 years*

C. Budget (no size restriction)

Each partner that requests funding has to fill in a budgetary table. Please justify each of the budget items with a short description in the right column. You can use the examples and instructions that are given in purple.
In addition, **specification of co-funding from other sources necessary for the project** as well as secured funding of additional collaborators of the consortium should be explained here, if applicable.
All categories of the costs may not be eligible for all countries (it will be handled according national regulations(see call text Annex p15-31). Please ensure you refer to any specific national guidance.

	Coordinator		
Position	**Requested Amount (€)**	**Own contribution – in cash / in kind (€) (if applicable)**	**Mandatory: Details and justification**
Personnel			*Person-Months, position of employment, and role/tasks*
Consumables			*e.g., questionnaires, materials*
Equipment			*e.g., laboratory devices, IT infrastructure*
Travel			*Please provide information on expected travel expenses*
Other direct costs			*e.g., subcontracting, licensing fees*
Total direct costs			
Indirect costs (Overhead)[2]			*Brief information on the calculation of overheads*
Total requested budget (€)[3]			
Total costs (€)[4]			

[2]: *Overhead costs: funding according to national regulations*
[3] *This is the funding you will be requesting from your specific national funding organisation*
[4] *This is the funding requested, plus the in cash/in kind funding*

	Partner: 1		
Position	**Requested Amount (€)**	**Own contribution – in cash / in kind (€) (if applicable)**	**Mandatory: Details and justification**
Personnel			*Person-Months, position of employment and role/tasks*
Consumables			*e.g., questionnaires, materials*
Equipment			*e.g., laboratory devices, IT infrastructure*
Travel			*Please provide information on expected travel expenses*
Other direct costs			*e.g., subcontracting, licensing fees*
Total direct costs			
Indirect costs (Overhead)[2]			*Brief information on the calculation of overheads*
Total requested budget (€)[3]			
Total costs (€)[4]			

[2]: *Overhead costs: funding according to national regulations*
[3] *This is the funding you will be requesting from your specific national funding organisation*
[4] *This is the funding requested, plus the in cash/in kind funding*

Please add a table for each of the project partners (both partners asking for funding as well as collaborators not asking for funding).
Do not forget to include the *in kind/ in cash* contribution (including the salaries of the permanent staff scientists involved in the project but not directly paid on the project funds). For *in cash/ in kind* funding, please briefly mention how the funds will be secured.

We strongly recommend checking the national regulations in the call text and consulting with the national contact officers for any issue.

D- Annexes

Description of Interventional Studies

(to fill in case interventional studies are included in the proposal)

Please prepare your description in English not exceeding 7 pages for the headings 1. to 8. (Arial font, size 11" characters, margins of 1.27 cm)

1. Study Synopsis

Title of Study	
Objective(s)	
Intervention(s)	Experimental intervention: Control intervention: Duration of intervention per participant: Follow-up per participant:
Key Inclusion and Exclusion Criteria	Key inclusion criteria: Key exclusion criteria:
Outcomes	Primary endpoint: Key secondary endpoint(s):
Study type	*e.g. randomized / non-randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over*
Statistical Analysis	Description of the primary analysis Analysis of secondary endpoints:
Sample Size	To be assessed for eligibility (n = …) To be allocated to study (n = …) To be analysed (n = …)
Study Duration	Time for preparation of the study (months): Recruitment period (months): First participant in to last participant out (months): Time for data clearance and analysis (months): Duration of the entire study (months):

2 Intervention Scheme

Describe the intervention scheme in depth and give a schematic diagram (flow chart) of design, procedures and stages.

3 Strategies for data handling

3.1 Frequency and Scope of Data Collection

What is the proposed frequency and scope of data collection and, if applicable, the duration of post-trial follow-up?

3.2 Strategies for Data Management

Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate

4 Justification of Design Aspects

Please provide justifications. It is not sufficient to list respective parameters only.

4.1 Control(s)/Comparator(s)

Justify the choice of control(s) / comparison group(s).

4.2 Type, Mode and Scheme of Intervention
Describe the intervention scheme in depth and give a schematic diagram (flow chart) of design, procedures and stages Justify the type, the mode and the scheme of the intervention. How does the intervention compare to other interventions for the same condition?

4.3 Additional Treatments
Please describe additional treatment(s) permitted and not permitted before and / or during the trial, if applicable.

4.4 Inclusion/Exclusion Criteria
Justify the population to be studied, include reflections on generalisability and representativeness, specifically with regard to gender and age.

4.5 Outcome Measures
Justify the endpoints chosen. Discuss the relevance of the outcome measures for the target population/patient. Have the measures been validated? Justify appropriateness and limitations of composite endpoints, if applicable.

4.5.1 Determination of primary and secondary measures
How will primary and secondary endpoints be derived from actual measurements, e.g. how is the figure used in the statistical test calculated from the variables initially measured in the subjects?

4.6 Methods against Bias/ Assessment of Confounding Factors
Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to trial groups? Will trial site effects be considered in randomisation? Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome). What are possible confounding factors and how will they be considered?

4.7 Proposed Sample Size / Power Calculation
What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of difference that the trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial is powered to exclude. Give evidence / references for the estimated effect size. Sample size calculations need to take into account anticipated rates of non-compliance and losses to follow up.

4.7.1 Compliance / Rate of Loss to Follow Up
Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?
What is the assumed rate of loss to follow up? On what evidence is the loss to follow up rate based? How will losses to follow up or non-compliance be handled in the statistical analysis?

4.8 Feasibility of Recruitment
What is the evidence that the intended recruitment rate is achievable?
a) Pilot study
Has any pilot study been carried out using this design?
b) Achievability of recruitment rate

Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot studies and preceding trials in a similar population / same institutions).

4.9 Stopping Rules
Please specify the "stopping rules" or "discontinuation criteria"
a) for the individual participant,
b) for the whole study

5. Statistical Analyses
What is the proposed strategy of statistical analysis? If multiple hypotheses are foreseen for confirmatory testing what is the procedure to ensure Type I error control and what will be the primary data analysis set (e.g. ITT-population in case of superiority RCT). What is the strategy for analysing the primary outcome? If applicable, how will multiple primary end points be analysed statistically? If interim analyses are planned, please specify. Are there any subgroup analyses? How will missing data and subjects withdrawn from the trial be handled statistically?

6. Ethical Considerations
Give a description of ethical considerations relating to the study (assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, informed consent process).

7. Quality Assurance and Safety

7.1 Quality Assurance/Monitoring
What are the proposed measures for quality assurance? Which institution will perform the monitoring? Which SOPs will be utilized? Describe and justify the monitoring strategy (percentage of source data verification, number of monitor visits per study site).

7.2 Safety

Describe and justify briefly the proposed strategy for the assessment of participants' safety in the study (Monitoring of adverse events, documentation, reporting procedures, etc.).

7.3 Management Structure and Procedures

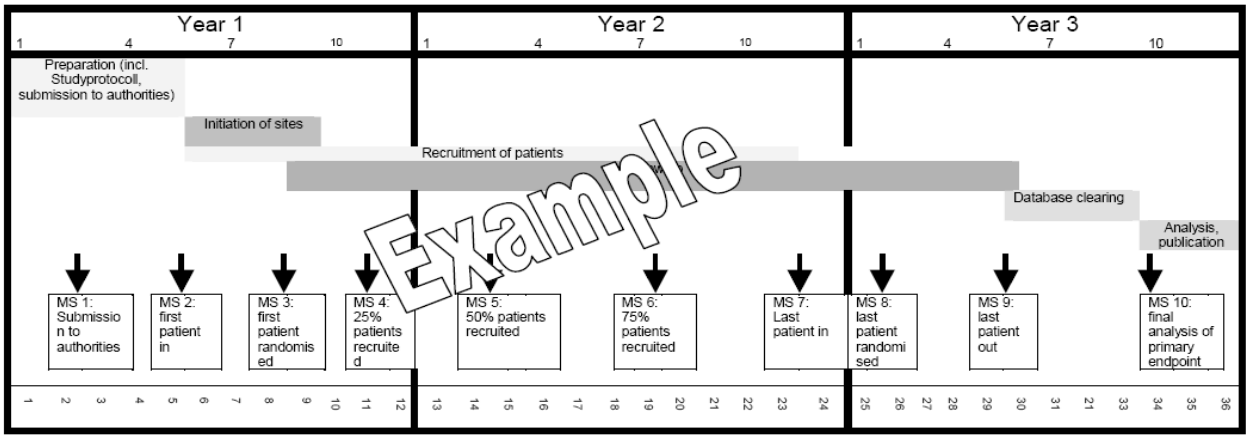
Arrangements for the management of the trials will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is entirely independent of the principal / coordinating investigator and the medical institutions involved. This can take the form of an external scientific supervisor with human clinical trial expertise.

8. References

For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

9. Trial Timeline Flow

Please provide a diagram reflecting preparation, recruitment, follow-up and data cleaning/analysis. An example of such a diagram is given below.



10. List of Investigators involved in the Study

Sponsor / Institution				
Management				
#	Name	Affiliation	Responsibility / Role	Signature
Statistician				
#	Name	Affiliation		Signature
1				
Supporting Facilities *(reference laboratories, food supplier etc.)*				
#	Name	Affiliation	Responsibility / Role	

A final version of the trial protocol has to be submitted to the funding agency together with the statement by the ethics committee after the review process. While funding for a preparatory phase might be provided upon the general funding decision, funding of the actual trial can only be provided if all necessary formal and legal requirements are met.

Description of Animal Research Projects

Please prepare your description in English not exceeding 5 pages. (Arial font, size 11" characters, margins of 1.27 cm) As a reminder, animal work should form only a small component of the overall proposal.

Project Synopsis

Principal Investigator	
Title of Project	
Topic	
Aim(s)	
Keywords	

Research Design & Workplan

Rigorous Experimental Design

Explain the experimental approach how the animal model being used can address the scientific objectives. Explain the study's relevance to human biology.
Please use the subsections below to further describe the experimental approaches, study designs and techniques of your research project. Indicate and justify if any of the subsections does not apply.

Experimental Procedures

Describe the experiments, study design and techniques that will be used. Please justify, e.g. drug formulation and dose, anaesthetic and surgical procedures, equipment (how, when, where, why?). Justify the number of experimental and control groups. Which steps will be taken to minimize the effects of subjective bias? How is an experimental unit defined?

Experimental animals

Please comment on the experimental animals: species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc

Housing and husbandry

Please comment on housing and husbandry: type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions, type of food, access to food and water, environmental enrichment etc.

Sample Size

Specify and justify the total number of animals used in the experiment (or each experiment), and the number of animals in each experimental group. Explain how the number of animals was arrived at. Provide details of any sample size calculation used (expected effect size, the software used for sample size calculation etc.). Give evidence/references for the estimated effect size. Indicate the number of independent replications of each experiment, if relevant.

Allocating Procedures & Methods against Bias

Describe how animals are allocated to the experimental groups. Is randomization and / or matching feasible? Describe steps to minimize the effects of subjective bias.

Experimental Outcomes

Define and justify the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioral changes).

Gender Aspects

Indicate how gender specific aspects are addressed regarding the research questions, the analyses, and the relevance of the results. If you find that gender aspects do not apply to your research questions, please give a comprehensive justification.

Statistical Analysis

What is the proposed strategy of statistical analysis? Provide details of the statistical methods used for each analysis. Justify any methods used to assess whether the data meet the assumptions of the statistical approach. Specify the unit of analysis for each dataset (e.g. single animal, group of animals)? How will missing data and subjects withdrawn from the trial be handled statistically? Please include a biostatistician for data analysis in your financial planning.

Work Packages

Explain your work plan in detail. Define and describe work packages. Which tasks will be done? How will the aims be reached?

Milestone Plan

Indicate work packages (WP) into which the project is divided and schedule events that indicate the completion of major deliverables. Milestones are measurable / observable events and serve as progress markers. Numbering of work packages should be identical in sections 4.2 and 4.3.

No. of WP	Milestone (▼)	year 1				year 2				year 3				year 4			

Team and Expertise

Major Participants

#	Name	Affiliation	Role
			Principal investigator
			Methodological expertise
			Biostatistician (required for animal studies)

Strategies for Data Handling

Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate

References