**JPI HDHL**

 **Call for Joint Transnational Research Proposals**

**New food resources and technologies to improve public health and food security**

**(FOODRETEC)**

# Guideline proposal template

**Submission deadline for proposals:**

**21st of April 2023 at 15h CEST**

**Link to:** “[call text](https://www.healthydietforhealthylife.eu/index.php/call-activities/calls/98-calls-site-restyling/703-foodretec-2023)”

**Link to:** [“Electronic submission system”](https://ptoutline.eu/app/foodretec)

The submission system will be opened by 24th of February

For further information, please visit us on the web

<http://www.healthydietforhealthylife.eu/>

Or contact the Joint Call Secretariat (JCS):

French National Research Agency

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86 rue Regnault, 75013 Paris

Email: JPI-HDHLCalls@agencerecherche.fr

1. **Background**

The Joint Programming Initiative “[A Healthy Diet for a Healthy Life](http://www.healthydietforhealthylife.eu/index.php/joint-actions/nutricog)” launched a call on the **new food resources and technologies to improve public health and food security** (FOODRETEC). The main aim of this call is to build knowledge to prepare for and succeed with a dietary shift towards a healthier and more sustainable diet. It will focus on new food ingredients, new food or technologies and their contribution to healthy, sustainable diets. Important aspects to be addressed in this regard are safety, nutritional quality, digestibility, bioeconomic aspects, and consumer acceptance of new ingredients, food and framework conditions.

1. **Proposal submission**

There is a **single submission procedure** (full proposals) including a rebuttal phase. Proposals and rebuttal must be written in English and must be submitted to the JCS by the coordinator through [the electronic submitting system](https://ptoutline.eu/app/foodretec) before the **21st of April 2023 at 15h CEST**.

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) 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](https://www.healthydietforhealthylife.eu/images/documents/HDHL-INTIMIC-Cofund-Call.pdf)).

In particular:

**[ ]** If my consortium includes an Austrian partner funded by FFG/BMBWF, I made sure that the Austrian partner ONLY requests funding for oriented basic research.

**[ ]** If my consortium includes a Polish partner funded by the NCN, I made sure that the Polish partner ONLY requests for basic research.

**Please note:**

* Proposals that **do not meet the national and transnational 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) must 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:**

1. **Duration of the project** **(months)**:
2. **Total funding applied for (€):** (this budget must be identical to the one present in the electronic submission tool)
3. **Keywords** (Please identify ten keywords that represent the scientific content of the full proposal)
4. **Project Summary** (max.350 words)
5. **Research focus:** (Indicate with a cross the research focus of your proposal, multiple choice is allowed)
* Ensuring consumer acceptance of new products and more sustainable technologies, i.e., addressing knowledge barriers, enhancing sensory properties of food from new sustainable (protein) sources or functional ingredients (e.g. foods containing bio-actives).
* Investigating new components (e.g. plant-based, marine ingredients, insects, side stream valorisation, biomass, cell cultures etc.) as a source of nutrients and functional food ingredients (e.g. protein, fibre, bio-active compounds etc.)
* Ensuring food safety in the entire food chain focussing on residues, degradation products and (process) contaminants including aspects of sustainable food processing and side-stream valorisation.
* Improving nutritional quality aspects of using new ingredients or new food processing technologies as well as their impact on health.
* Other, (please specify in the textbox below; its relevance will be evaluated by the expert panel)

|  |
| --- |
|  |

1. **Approaches and methodologies** (Indicate with a cross the research focus of your proposal, multiple choice is allowed)
* Exploratory research where consumer insight is included (social labs, living labs, etc.)
* Systemic reviews to map and organise current research on the area.
* Building more research and knowledge on the food science aspects.
1. **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 the name of the national/ regional funding organization the funding is requested from  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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**national/ regional funding organisation the funding is requested from  |
| 1 |   |   |   |  |  |
| 2 |   |   |   |  |  |
| 3 |   |   |   |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |

1. **Project Partners applying for funding** (*max. 6 in total, incl. coordinator*)

x Please list here only the project partners, the coordinator’s details are given in the upper table (under 8.)

1. **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 inserted at the end of this template.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 |  |  |  |  |

1. **Date and signature of the consortium**

---------------------------------------------------------------------

Full name of partner 1, place, date, signature

[ ]  I declare my willingness to cooperate with the research consortium

[ ]  I declare not receive other public funds to perform the described tasks in this application

---------------------------------------------------------------------

Full name of partner 2, place, date, signature

[ ]  I declare my willingness to cooperate with the research consortium

[ ]  I declare not receive other public funds to perform the described tasks in this application

---------------------------------------------------------------------

Full name of partner 3, place, date, signature

[ ]  I declare my willingness to cooperate with the research consortium

[ ]  I declare not receive other public funds to perform the described tasks in this application

---------------------------------------------------------------------

Full name of partner 4, place, date, signature

[ ]  I declare my willingness to cooperate with the research consortium

[ ]  I declare not receive other public funds to perform the described tasks in this application

Full name of collaborator 1, place, date, signature

[ ]  I declare my willingness to cooperate with the research consortium

***Please adapt according to the composition of your consortium. Each PI (eligible partner and collaborator) has to sign. Electronic or scanned signature possible***.

**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.

1. **Relevance of the aims of the call** *(max. 1 page)***:**

Describe how the research question(s) of your proposal address the aim of the call

1. **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; if applicable, provide details on 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 in order to better align both the research and its outcomes with the values, needs and expectations of society.
* 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.

* **In addition, clinical trial/ animal study template in section D.Annexes should be filled:** mandatory for interventional studies and/or animal studies (see respective separate templates)

**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)
1. **Added value of collaboration on scientific and transnational level** – sharing of resources, data, know-how etc. (max. 1 page)
2. **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
1. **Data management and data sharing** (max. 1 page), taking into account the [FAIR data management principles.](https://www.healthydietforhealthylife.eu/images/documents/FAIR-PRINCIPLES-guidelines-JPI-HDHL-Epigenetics-call.pdf) 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.
2. **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)

1. **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

1. **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*](http://www.businessdictionary.com/definition/schedule.html)[*event*](http://www.businessdictionary.com/definition/event.html)*s that indicate the* [*completion*](http://www.businessdictionary.com/definition/completion.html) *of major* [*deliverable*](http://www.businessdictionary.com/definition/deliverable.html)*s. Milestones are measurable / observable events and serve as* [*progress*](http://www.businessdictionary.com/definition/progress.html) *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