# Guideline and Full Proposal Application Form

1. **Background**

Under the umbrella of NEURON, the ‚Network of European Funding for Neuroscience Research‘ established under the ERA-NET scheme of the European Commission ([www.neuron-eranet.eu](http://www.neuron-eranet.eu)), a joint transnational call (JTC-2021) is now launched. The aim of the call is to facilitate multinational, collaborative research projects that will address translational approaches to neurodevelopmental disorders (see [Call Text](https://www.neuron-eranet.eu/_media/NEURON_JTC_2021.pdf) for further specifications).

1. **Proposal submission**

Full proposals must be written in English and must be submitted to the Joint Call Secretariat (JCS) by the coordinator through the electronic submitting system exclusively (https://ptoutline.eu/app/neuron\_ndd).

**Full proposals** must be submitted by the project coordinator before **the 30th of June 2021 at 14:00 CET**. Please note that full proposals will only be accepted from applicants explicitly invited by the JCS to submit them.

**Please use the template below, and delete the guiding instructions in *italic* font.**

Call deadlines are final and will be strictly enforced. The electronic system will not allow submissions after call deadlines. 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.

For further information, please contact the NEURON Joint Call Secretariat:

Dr Christina Müller

Project Management Agency (DLR-PT) – Department Health

Chr.mueller@dlr.de
+49 228 3821 2182**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.***

* **General conditions:**

**[ ]** The project proposal addresses and is in conformity with national/international regulations regarding human or animal experimentation.

**[ ]** The content of the proposal has not been submitted elsewhere (double funding is not allowed!).

**[ ]  I declare that I addressed all the detailed information asked for in the full proposal form (*i.e*. items 1, 2A to 2F, and 3 to 7)**

* **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

**[ ]** The project proposal involves a maximum of 5 eligible research partners (asking for funding as well as participating with own contribution), up to 6 if one of the underrepresented countries listed in Call Text is included.

**[ ]** The project proposal does not include more than two partners from the same country participating in the call.

**[ ]** There are not more than two partners who secure their own funding (additionally to the eligible partners).

**[ ]** The coordinator and the majority of partners in the consortium requesting budget are eligible for funding.

* **Eligibility of consortium partners:**

**[ ]** I have made sure that each partner involved in the project proposal has checked its eligibility to receive funding by its funding agency (see Country-specific information here: https://www.neuron-eranet.eu/\_media/NEURONJTC2021\_All\_national\_regulations.pdf).

**Please note:**

* Proposals that **do not meet the national eligibility criteria and requirements may be declined without further review**.
* The information given in the pre-proposal is binding. Thus, **any fundamental change between pre- and full proposal stages** concerning the composition of the consortia, objectives of the project or requested budget must be communicated to the Joint Call Secretariat and their respective funding agencies with detailed justifications and will only be allowed in exceptional cases by the Call Steering Committee. Full proposal application shall not be submitted without approval by Call Steering Committee.
* All fields must be completed using **DIN-A4; font: Arial, 10pt; single-spaced, page limits.** Incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review.
* Once completed the proposal must be converted into a **single PDF document** before being uploaded to the submission website.
* Letters of commitment/intent by research partners participating with own budget can be uploaded as pdf on the submission website, if applicable.

In case of inconsistency between the information registered in the electronic submission tool 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**

Basic Project Data

**Acronym:**

**Project Title:**

**Project Coordinator:**

|  |  |
| --- | --- |
| Name |  |
| Institution/Department |  |
| Address |  |
| Country |  |
| Phone + Fax |  |
| Email |  |

**Partners:**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Country | Name of the group leader | Institution and full affiliations (*e.g.* address, phone + Fax, e-mail) |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |
| 5 |  |  |  |
| 6**[[1]](#footnote-2)\*** |  |  |  |

**Total funding applied for:** €

* **Scientific abstract of the project** (max. 1/2 page)
* **Lay Abstract** (max. 1/2 page). *Please ensure the readability for lay readers e.g. share the abstract with non-scientists.*

Detailed Information

*It is mandatory to follow the provided format. Please use the numbering and lettering in such a way that all the information can be traced in a systematic manner during the evaluation.*

**1. Background and present state of the art in the research field, and rationale *(max. 2 pages)***

**2. Work plan** *(max. 16 pages)*

1. **Objectives, hypotheses and evidence** *- primary and secondary objectives of the study and specific hypotheses being tested, background of the study, relate to relevant previous studies*
2. **Relevance** *- why is this study needed and what impact will it have:*
* *Rationale behind the study and, in case of (pre)clinical studies, the use of this/these patient group(s) for this specific study*
* *In case of clinical (trial) studies, please elaborate on the prevalence, incidence, mortality and burden of the disease, the expected improvement of the therapy or impact of the trial and patient participation*
* *In case of preclinical (animal) studies, please explain how and why the animal species and model being used can address the scientific objectives and the relevance to human biology. Elaborate on the type of animal that is the subject of study (strain, pathogen free, genetic modification status, source, age, developmental stage, weight, sex) and the housing and husbandry (type of facility, type of cage or housing, bedding material, number of cage companions, type of food, access to food and water, environmental enrichment etc.)*
1. **Methodological approach**
* *Primary and secondary (experimental) outcomes*
* *Describe the experimental and control groups and the experimental procedures and / or interventions: type, duration, frequency and time points of the measurements/interventions and the equipment that will be used*
* *Proposed sample size(s) / power calculations: Specify the N of each experiment and each condition and how this N was arrived at with* ***power calculations*** *including justification of the* ***effect size****. Where power calculations are not appropriate, explicitly explain why. Statements as ‘this N has been used in previous publications’ are not acceptable*
* *Inclusion/exclusion criteria*
* *Please specify “stopping rules” / “discontinuation criteria” for
a) the individual subject / patient,
b) participating / recruiting centres, which fail to include the estimated number of subjects / patients (in case of clinical and / or human cohort studies),
c) for the whole trial.*
* *Strategies to minimise the effects of bias (e.g. randomization, blinding, order of treatment and assessment), or an explanation why these are not relevant*
* *Feasibility of recruitment / evidence that intended recruitment rate is achievable*
* *In case of clinical (trial) studies,*
	+ *Describe inclusion/exclusion criteria*
	+ *List recruiting centres*
	+ *Please specify “stopping rules” / “discontinuation criteria” for
	a) the individual subject / patient,
	b) participating / recruiting centres, which fail to include the estimated number of subjects / patients (in case of clinical and / or human cohort studies),
	c) for the whole trial.*
	+ *Feasibility of recruitment / evidence that intended recruitment rate is achievable*
* *In case of preclinical (animal) studies, please describe the methods directed to authenticate the validity and identity of specific biological and chemical resources, such as cell and animal lines, chemicals, antibodies, biological samples and other specific reagents used in your research. Please also describe the controls you are planning to apply to validate key biological and chemical resources in the research (e.g. how you intend to confirm the genotypes of animals used, authenticate cell lines, etc.). This does not apply to common reagents or chemicals.*
1. **Statistical analysis**
* *Describe the details of the statistical methods used for each (subgroup) analysis and the methods used to assess whether the data met the assumptions of the statistical approach*
* *Describe the dataset that will be used for the analyses and the number of replications (if applicable)*
* *Details of any statistical advice sought (seeking advice is strongly recommended)*
1. **Ethical considerations, please see mandatory Annex I**
2. **Work package structure**
* *Describe the work packages, the project coordination and management, the involvement of the partners in each work package, provide a time and milestone plan*
1. **Changes between pre- and full proposal**
* *In this section changes between pre- and full proposal stage can be explained. These changes are only allowed to be minor and in response to reviewer comments and/or the inclusion of (a) widening partner(s).*
1. **Data Management Plan -DMP *(max. ½ page)***

*Briefly outline which data will be collected, processed and/or generated and/or reused; which methodology and standards will be applied; whether data will be shared/made open access; how data will be curated and preserved.*

*A more detailed DMP* *will be requested from the consortium coordinator of each project selected for funding; with the first annual report (if not required earlier by the national funding organisation). You can already consult the extended NEURON DMP format at the* [*NEURON website*](https://www.neuron-eranet.eu/en/985.php)*, the use of this specific template is not mandatory but addresses the main points to be considered.*

**4. Justification of requested budget for each partner** *(also specifying co-funding from other sources necessary for the project, if applicable;* ***max. 1 page****)*

**5. Added value of the proposed collaboration *(max. 1 page)***

**6. Possible exploitation of expected project results** *(including data management and data sharing)* **and potential health and clinical impact *(max. 1 page)***

7. Brief CVs for each participating group leader with a list of up to five relevant publications within the last five years demonstrating the competence to carry out the project, description of patents and ongoing projects of each participating group related to the present topic, indicating funding sources and possible overlaps with proposal *(only one CV per research partner, max. 1 page each)*

**Electronic proposal submission is mandatory. It is strongly recommen­ded to meet the deadline and observe the format of the proposal structure (DIN-A4; font: Arial, 10pt; page limit). Do not add any additional attachments. All items (such as figures, tables, list of references) have to be included in the text (16 pages max., excl. Annex I). Proposals not meeting the formal criteria will be rejected.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|   | **ERA-NET NEURON Call 2021** |   |   |  |  |   |
|   | Full proposal: Budget plan of the project  |   |   |  |   |
|   | Project Acronym:     |  |   |
|   |  | Coordinator | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6**\*** |  |
|   | **Name (group leader)** |  |  |  |  |  |  |   |
|   | **Institution** |  |  |  |  |  |  |  |
|   | **Country** |  |  |  |  |  |  |   |
|  | **Funding organisation** |  |  |  |  |  |  |  |
|   | **PROJECT COSTS (€)** |   |   |   |   |   |  | **Total** |
|   | **Personnel €** |  |  |  |  |  |  |  |
|   | **Consumables €** |  |  |  |  |  |  |  |
|   | **Equipment €** |  |  |  |  |  |  |  |
|   | **Travel €1** |  |  |  |  |  |  |  |
|   | **Other direct costs €2** |  |  |  |  |  |  |  |
|   | **Overheads €3** |  |  |  |  |  |  |  |
|  | **Total budget €4** |  |  |  |  |  |  |  |
|   | **Requested budget €4, 5** |  |  |  |  |  |  |  |
|   |   |  |   |   |   |   |  |   |
|  | **We strongly recommend checking the national call texts and consulting with the national/regional contact points.** | **1 When planning the travel costs, please take into account that coordinators and PIs shall present the projects at a midterm symposium taking place during a NEURON conference (cf. call text).** **2 e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according national regulations)****3 Overhead costs: funding according to national regulations**4 **Those countries whose currency is different than €, shall include their national currency in brackets****5 PIs from countries using full cost model shall give here the proportion of their total budget requested from the funding organization; in case a research group participates by own contribution they should indicate “0” and are invited to upload a Letter of Commitment on the submission platform.** |

# Annex I : Ethical considerations

*Please fill in the requested information (mandatory form).*

|  |  |
| --- | --- |
| **Section 1: HUMAN EMBRYOS/FOETUSES**  | YES/NO |
| **Does this research involve Human Embryonic Stem Cells (hESCs)?**  |  |
| **If** **YES**: | - Will they be directly derived from embryos within this project? |  |
| - Are they previously established cells lines?  |  |
| **Does this research involve the use of human embryos?** |  |
| **If** **YES**: | - Will the research lead to their destruction? |  |
| **Does this research involve the use of human foetal tissues / cells?** |  |
| **IMPORTANT:***The following are not eligible for funding under Horizon 2020:** *Research directed at human cloning for reproductive purposes;*
* *Research intended to modify the genetic make-up of human beings that could make such changes heritable (except research related to cancer treatment of the gonads);*
* *Research activities intended to create human embryos solely for the purposes of research or stem cell procurement including somatic cell nuclear transfer;*
* *Research that leads to the destruction of human embryos.*

*Any proposed research involving hESC's or human embryos/foetuses must be submitted to REA for mandatory evaluation prior to the commencement of any research activities.* |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 2: HUMAN SUBJECTS** | YES/NO |
| **Does this research involve human participants?** |  |
| **If YES**: | - Are they volunteers for social or human sciences research? |  |
| - Are they persons unable to give informed consent? |  |
| - Are they vulnerable individuals or groups? |  |
| - Are they children/minors? |  |
| - Are they patients? |  |
| - Are they healthy volunteers for medical studies? |  |
| **Does this research involve physical interventions on the study participants?** |  |
| **If YES**: | - Does it involve invasive techniques? |  |
| - Does it involve collection of biological samples? |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 3: HUMAN CELLS / TISSUES** | YES/NO |
| **Does this research involve human cells or tissues?** (o*ther than from Human Embryos/Foetuses, see section 1)* |  |
| **If YES:** | - Are they available commercially? |  |
| - Are they obtained within this project? |  |
| - Are they obtained from another project, laboratory or institution? |  |
|  | - Are they obtained from a biobank? |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 4: PERSONAL DATA** | YES/NO |
| **Does this research involve personal data collection and/or processing?** |  |
| **If YES:** | - Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*? |  |
| - Does it involve processing of genetic information? |  |
| - Does it involve tracking or observation of participants? |  |
| **Does this research involve further processing of previously collected personal data (secondary use)?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 5: ANIMALS** | YES/NO |
| **Does this research involve animals?** |  |
| **If YES:** | - Are they vertebrates? |  |
| - Are they non-human primates (NHPs)? |  |
| - Are they genetically modified? |  |
| - Are they cloned farm animals? |  |
| - Are they endangered species? |  |
| *Please indicate the species involved* |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
|  **Section 6: Non-EU COUNTRIES** | YES/NO |
| **In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?***Specify the countries involved:*  |  |
| **Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?** |  |
| **Is it planned to import any material – including personal data – from non-EU countries into the EU?** |  |
| **If Yes**: | *Specify material and countries involved*  |  |
| **Is it planned to export any material – including personal data –from the EU to non-EU countries?** |  |
| **If Yes**: | *Specify material and countries involved*  |  |
| **In case this research involves** [**low and/or lower-middle income countries**](http://data.worldbank.org/about/country-classifications/country-and-lending-groups)**, are any benefit-sharing actions planned?**  |  |
| **Could the situation in the country put the individuals taking part in the research at risk?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 7: ENVIRONMENT & HEALTH AND SAFETY** | YES/NO |
| **Does this research involve the use of elements that may cause harm to the environment, to animals or plants?** |  |
| **Does this research deal with endangered fauna and/or flora/protected areas?** |  |
| **Does this research involve the use of elements that may cause harm to humans, including research staff?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 8: DUAL USE[[2]](#footnote-3)** | YES/NO |
| **Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS[[3]](#footnote-4)** | YES/NO |
| **Could this research raise concerns regarding the exclusive focus on civil applications?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 10: MISUSE[[4]](#footnote-5)** | YES/NO |
| **Does this research have the potential for misuse of research results?** |  |
| **Compliance (incl. any authorisations, approvals or notifications):** |
| **Section 11: OTHER ETHICS ISSUES**  | YES/NO |
| **Are there any other ethics issues that should be taken into consideration?** *If yes, please specify:* |  |

**Legal references which should be used during the ethics evaluation process**

Clinical Trials

Regulation 536/2014 of the European Parliament

Commission Directive 2005/28/EC

Human genetic material and biological samples

Directive 2004/23/EC

Use of animals

Directive 2010/63; Council Directive 98/58/EC; Council Directive 2008/120/EC; Council Directive 2008/119; Council Directive 2007/43; Council Regulation (EC) 1/2005; Council Regulation 1099/2009

Data Protection

Directive 95/46/EC is repealed with effect from 25 May 2018

Regulation (EU) 2016/679 on the protection of natural persons and processing personal data and its free movement (as from 25/05/2018)

Developing countries and politically sensitive issues

Declaration/Charter (EU Fundamental Rights; UN Rights of Child, UNESCO Universal Declaration

Environmental Protection and safety

Directive 2001/18/EC; Directive 2009/41/EC; Regulation EC No 1946/2003; Directive 2008/56/EC; Council Directive 92/43/EEC; Council Directive 79/409/EEC and Council Regulation EC No 338/97

Dual use in the context of security/dissemination

Council Regulation (EC) 428/2009

Access to Genetic Resources

The Nagoya Protocol, Secretary-General of the United Nations (2010)

1. **\*The total number of research groups in a consortium is limited to five. Only consortia including partners from Latvia, Hungary, Romania, Turkey, and Slovakia may increase the total number of partners to six. For further regulations concerning the composition of the consortia please refer to the call text.** [↑](#footnote-ref-2)
2. Guidance note – Research involving dual use items: <http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf> [↑](#footnote-ref-3)
3. Guidance note- Research focussing exclusively on civil applications:

<http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf> [↑](#footnote-ref-4)
4. Guidance note – Potential misuse of research results:

<http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf> [↑](#footnote-ref-5)