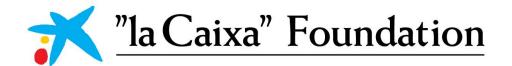
Health Research

Rules for participation

*Organoids derived from patient with luminal A breast cancer



Health Research 2021 Call for Proposals

Rules for Participation

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0. DEFINITIONS

In this call for projects, the following terms have the meaning that is defined below:

Agreement: the collaboration agreement to be signed in English by the "Ia Caixa" Foundation, the Host Institution and the Project Leader if the Proposal is awarded.

Application or Proposal: the proposal of a Project submitted within the framework of this Call.

Call: this open call for proposals (2021), which aims to allocate funds to support basic, clinical and translational biomedical research projects.

Civil Society Organizations (or "CSOs"): non-for-profit non-research performing civil society organization that carry out activities of the Project.

Host Organization: the Research Performing Institution based in Spain or Portugal that acts as a coordinating organization of the Project.

Organization: any Research Performing Organization or Civil Society Organization that carries out activities of the Project.

Organization Manager: person appointed by the Host Organization to represent it, upload and manage its accreditative documentation, and accept the submission of Proposals on its behalf on the "Ia Caixa"'s Foundation calls management online system.

Principal Investigator (or "PI"): the researcher of the Resarch Performing Organization responsible for the execution of the activities of the Project that are carried out in the organization to which he or she belongs. Each RPO can only designate one PI per proposal. In the case of the Host Organization, the Project Leader is the PI.

Project Leader (or «PL»): Principal Investigator of the Host Organization, responsible for presenting the Proposal to the Call and coordinating the overall execution of the Project.

Projects: research projects that are granted in this Call, which can be "Individual Projects" (if led by a single Research Performing Organization) or "Research Consortium Projects" (if led by a Research Consortium). In both cases proposals may also include up to three Civil Society Organizations.

Research Consortium (or "RC"): a group of Research Performing Organizations that collaborate in a Project, composed by a minimum of two Research Performing Organizations and a maximum of five (including the Host Organization).

Research Performing Organization (or "RPO"): any non-profit organization dedicated to research according to its statutes or as part of its usual activity (research centers, universities, hospitals, etc.) that carries out activities of the Project.

Selection Committee: one of the five multidisciplinary committees that will evaluate the projects pre-selected for each Thematic Area by the peer review process.

Team Members: all the members of the Research Performing Organizations or Civil Society Organizations that carry out specific activities of the Project. Members of other organizations not included in the proposal cannot be included as team members.

Thematic Area: each of the five categories detailed in section 3.3 of this Call.

1. PREAMBLE

The "la Caixa" Banking Foundation (hereinafter, "la Caixa" Foundation) firmly believes that scientific progress and excellence in research are fundamental to the advancement of our society and to find solutions to the main challenges facing humanity. These societal challenges require cutting-edge and groundbreaking research projects, in which relevance and excellence come together to contribute to the advancement of the frontiers of science and generate positive social impact.

One of the main priorities of the "la Caixa" Foundation is to consolidate the support to biomedical research aimed at facing the most serious illnesses. During this period, the strategy of the "la Caixa" Foundation in biomedical research is to support groundbreaking projects in order to increase the competitiveness of research in Spain and Portugal towards the European and international benchmarks of scientific excellence, enhancing the importance of its scientific and medical impact beyond its borders. The "la Caixa" Foundation promotes projects with both basic research and a clinical and translational perspective. The "la Caixa" Foundation supports the transfer of knowledge and technology to society, endorses the principles of Responsible Research and Innovation, and believes that international collaborations of excellence improve health research.

In this regard, the "la Caixa" Foundation launches an open call to select outstanding biomedical research projects that aim to address some of the main health challenges currently faced by our society.

2. TIMELINE

The dates and timeline included in these rules for participation are expressed in European Central Time (CET).

Opening of the online system for Applications	Deadline for Applications	Proposal Pre- selection	On site assessment by Selection Committees	Resolution announcement	Execution of Selected Projects
October 20, 2020 at 14:00h	December 03, 2020 at 14:00h	From January to May 2021	May 27 and 28, 2021	June 2021	From September - December 2021 to September - December 2024

Any of these dates may be subject to change due to organizational reasons.

<u>3.1</u>

The fundamental aim of this Call is to foster research in groundbreaking and highly relevant projects that lead the advancement of knowledge and offer solutions related to some of the most important health problems of our century. The "la Caixa" Foundation seeks research projects of scientific excellence in its field, with potential value and a high social impact. The "la Caixa" Foundation encourages projects with an innovative focus that cross the boundaries between different areas of research, aimed at new and emerging research fields and/or including unconventional approaches to problems of health.

<u>3.2</u>

Projects eligible for this call must be led by **non-profit Research Performing Organizations** (Host Organizations) based in Spain or Portugal.

<u>3.3</u>

The Projects must be submitted in one of the following five Thematic Areas*:

- Neuroscience.
- Infectious diseases.
- Oncology.
- Cardiovascular and associated metabolic diseases: projects in cardiovascular diseases and metabolic diseases associated with cardiovascular risks or alterations.
- Enabling technologies: projects focused on the creation and development of healthfacilitating technologies coming from fields as micro and nanoelectronics, computational science, big data, photonics, nanotechnology, biotechnology, advanced materials or advanced manufacturing, among others. Projects should also be focused to address topics of the four previous thematic areas.

*The Francisco Luzón Foundation will co-fund one project on Amyotrophic Lateral Sclerosis (ALS).

<u>3.4</u>

The Projects shall have a **duration of up to 3 years** and may be submitted as Individual or Research Consortium projects, as defined in section 0.

- Individual projects are submitted by a sole Research Performing Organization (RPO), i.e. the Host Insitution.
- **Research Consortium projects** are submitted by a Research Consortium (composed by a minimum of 2 and a maximum of 5 RPOs, including the Host Organization).

<u>3.5</u>

The Projects will be **coordinated by the Host Organization.** Additionally, both Individual and Research Consortium projects may also include **Civil Society Organizations** as described in section 0, non-research perfoming civil society organization that carry out activities of the Project). A maximum of three Civil Society Organization per proposal is allowed.

<u>3.6</u>

The Call aims to support **basic**, **clinical and translational research projects**. Although we understand the definition of the type of research is not a simple matter and can be controversial, in order to improve the evaluation (matching of project and experts), take into account the following definitions:

- **Basic research** provides knowledge to understand nature and its laws. Although it may be performed without thought of practical ends, this knowledge provides the essential means of answering a large number of important practical problems.
- Clinical research is the research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which the research team (or colleagues) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes clinical trials, epidemiological and behavioral studies, outcomes research and health services research.
- **Translational research** fosters the bidirectional integration of basic research and clinical research, with the long-term aim of improving the health of the public. It expedites the movement between basic research and clinical research that leads to:
 - / Stimulate a robust scientific understanding of human health and disease.
 - / New or improved scientific understanding or standards of care, better patient outcomes, the implementation of best practices, and improved health status in communities.

This information will only be used to better classify the proposals for the evaluation.

<u>3.7</u>

The fact that the Proposals are submitted as Individual or Research Consortium projects, and classified as Basic, Clinical or Translational **will not in any case be a selection criterion** during the evaluation process.

4. FUNDING

<u>4.1</u>

Grants may be awarded up to a maximum of **€15,000,000**^{*} to support the selected Projects. The intention is to distribute this amount approximately equitably amongst the different Thematic Areas, but the final distribution will always depend on the quality and the specific characteristics of the Projects submitted to this Call.

* This amount is subject to final approval by "la Caixa" Foundation.

<u>4.2</u>

The economic amount of the grants for the Projects is detailed below:

- Individual Projects can request a grant up to a maximum of €500,000.
- Research Consortium Projects can request a grant up to a maximum of €1,000,000.

<u>4.3</u>

The correct allocation of the **budget**, **adjusted to the activities** to be developed in the Project, **will be an evaluated criterion** during the selection process.

<u>4.4</u>

The grant will be awarded to the Host Organization, which will be responsible for distributing the budget to the other Organizations, as detailed in the Application form for this Call.

<u>4.5</u>

The grant **will be distributed** during the total duration of each Project, based on the budget submitted and the Agreement. The grant will be paid in three payments. Each payment will be made within 60 days from receipt of the corresponding payment request which shall be submitted by the Host Organization in accordance with the following schedule: (i) a first payment for a maximum of 40% following the signature of the grant agreement; (ii) a maximum of 40% after the validation of the midterm follow-up, which may include a report and meeting; and (iii) the rest of the budget after the validation of final report.

<u>4.6</u>

When **preparing the budget**, the following **criteria and requirements** must be taken into account:

a) Projects that request a grant of more than €500,000 must include in their budget the cost of an **external audit** that must be done by the Host Organization at the end of the duration of the Project, as provided in section 13.1 of these rules for participation.

b) Both Research Performing Organizations and Civil Society Organizations must carry out activities of the Project to be part of the Consortium. All Research Performing Organizations

must have an allocated budget. Having an allocated budget is not mandatory for Civil Society Organizations, however their partipation in the proposal has to be justified.

c) For-profit entities (including companies) cannot be partners of consortiums. This type of entities can **only receive Project funds if they are subcontracted** by a Research Performing Organization.

d) The **sum of the budgets** of all the Research Performing Organizations and the Civil Society Organizations **not located in Spain or Portugal cannot exceed the 30%** of the total budget of the Project.

<u>4.7</u>

The grant will cover the costs related to the Project as long as they are **adequately justified**, **technically adapted to the needs of the project and always in accordance with the policies of the Organization**. The Proposal budget may include the following items:

a) Direct costs:

- / Personnel
- / Travel
- / Equipment
- / Consumables
- / Publications
- / Dissemination and social engagement activities
- / Other direct costs

b) **Indirect costs (overheads)**: a maximum of **10% per Organization** of the direct costs of the budget of the grant: Indirect costs_{max} = $0.1 \times \text{Direct Costs}$

c) Subcontracting

- / Subcontracting audits
- / Others subcontracting

5. ELIGIBILITY CRITERIA

<u>5.1</u>

The Host Organization must be a Research Performing Organization (a non-profit organization dedicated to research in accordance with the definition of section 0) based in Spain or Portugal. In case of Research Consortiums Projects or of Individual Projects including CSOs, the Host Organization will act as the coordinating organization. Organizations are defined by a unique identification number (NIF in Spanish Organizations or VAT number, NIPC in

Portuguese Organizations) for all purposes (e.g. submissions of proposals, constitution of Research Consortiums, etc).

<u>5.2</u>

Both Individual Projects and Research Consortium Projects proposals must include a Project Leader (PL). In the case of Research Consortium Projects, the Application must also include one Principal Investigator (PI) for each of the Research Performing Organizations (RPO) of the Research Consortium. Only one PI per RPO is allowed.

<u>5.3</u>

People who act as PL and PI must be of legal age and may be of any nationality.

<u>5.4</u>

The PL **must have a minimum of 7 years of experience in postdoctoral research.** Therefore they must have finished their doctoral degree (PhD) at least 7 years before the closing date of the Call (taking as a reference the date which appears on the doctoral degree).

<u>5.5</u>

Within the same Call, each PL can only submit a single proposal as a PL; however, they can collaborate on other Projects as PI of a RPO of the Research Consortium or as a Team Member.

<u>5.6</u>

The PLs of Projects awarded with a grant from the Health Research Call will not be allowed to submit new Proposals as PLs in the three editions following the same call.

<u>5.7</u>

The **PL** of a proposal that obtained a **score of less than 5.50** in the remote evaluation phase of the previous edition of the Call (HR20) are not allowed to submit proposals as PLs to this edition of the Call (HR21).

The **PL and the PIs** of a proposal submitted to the current Call of the Health Research Call (HR21) that obtain a **score of less than 5.50** in the remote evaluation phase, will not be able to submit proposals as PL to the next edition of the Call (HR22).

<u>5.8</u>

The **PL must be linked**, either by statute, work contract or other type of collaboration, within the framework of this Project, to the **Host Organization** when applying for the grant. The PL may also be legally linked to private foundations or non-profit organizations through which the research activities of the Host Organization are carried out or managed, in accordance with the current legislation.

<u>5.9</u>

The Project Leader needs the agreement of the Host Organization to be able to submit the Proposal. This will be done by an online check by the Organization Manager of the Host Organization on the <u>"la Caixa" Grants online system</u>. In case of a Research Consortium or individual projects with CSOs all partners must provide their acceptance through the abovementioned online system to be able to submit the Proposal. **All required acceptances must be made before the deadline for Applications.**

The Organization Manager will have access to the information of the proposals, including the evaluation reports, and will be responsible to provide and validate the information corresponding to the Host Organization.

The Host Organization must be willing to support the PL, the Team Members and the Research Consortium, if necessary, throughout the Project period and provide the appropriate scientific and administrative environment to carry out the Project.

<u>5.10</u>

The Host Organization **shall represent** all the Organizations of the Project before the "Ia Caixa" Foundation. The physical person who will act on their behalf will be the PL.

<u>5.11</u>

The PL and the Host Organization are responsible for guaranteeing the implementation of the **Project in accordance with the initial conditions** stated in the Application and the Agreement.

<u>5.12</u>

There is no limit to the number of Projects that a Host Organization can submit or for which it may receive grants as a Host Organization or as a member of a Research Consortium.

<u>5.13</u>

It is mandatory for all the Team Members to be professionally linked, either as service providers or through other professional collaborations, to any of the Research Performing Organizations or Civil Society Organizations of the Proposal.

<u>5.14</u>

The Proposal must be a **groundbreaking and innovative project related to the objectives and Thematic Areas** of the grant.

<u>5.15</u>

The activities associated with the granted Projects cannot be funded through another grant (from the "la Caixa" Foundation or from any other organization).

<u>5.16</u>

All the Organizations and Team Members of the Project must follow the **ethical principles and the highest standards of integrity in research and scientific best practices**, as described in the <u>Code of Conduct for the integrity of the research-ALLEA</u>.

<u>5.17</u>

Projects whose results are **subject to rights**, of any nature, **held by for-profit organizations** before the submission of the Proposal (including without limitation assignments, licenses, first-refusal rights, distribution agreements, etc.) are not eligible.

The "la Caixa" Foundation reserves the right to reject other proposals with a clear benefit for for-profit organizations.

<u>5.18</u>

Any other condition or instruction indicated in any of the clauses of these Rules for Participation (including but not limited to the "Definitions" and "Application submission" sections), or the <u>"la Caixa" Grants online system</u> will be considered a criterion of eligibility, since full compliance with them is mandatory for all participants.

<u>5.19</u>

Any incomplete, mistaken and/or ambigous information will also be deemed as a breach of the elegibility requirements and may lead to the inadmission of the proposal, at "la Caixa" Foundation's sole criterion.

6. APPLICATION SUBMISSION

<u>6.1</u>

The Application must be submitted electronically through the "la Caixa" Grants online system.

<u>6.2</u>

The Proposals must be completed with all the information requested (either in the "laCaixa" Grants online system and/or in the rules for participation) and submitted before the closing date of the Call (see clause 6.7). Incomplete Proposals will be declared ineligible to participate in this Call.

<u>6.3</u>

The whole process of submission and selection of Applications, including the interview, will be carried out in English. All information must be submitted in English.

<u>6.4</u>

On the Application form, applicants must **select the Thematic Area** (described in point 3.3) in which they prefer their Proposals to be evaluated.

<u>6.5</u>

The following information will also need to be provided for the best assignment of the evaluators to each project:

- Basic/Clinical/Translational nature of the project (more than one option may be selected)
- **Keywords**: a minimum of two and a maximum of four main keywords will be selected for the best description of the Project. A minimum of 6 and a maximum of 8 other important keywords will complete the description of your proposal.

<u>6.6</u>

The Proposal application must include all the information requested in the <u>"la Caixa" Grants</u> online system (including but not limited to: the following aspects:

- General data and project information: classification of the Host Organization, classification of the application, acronym, title, scientific abstract and lay summary.
- Scientific excellence and impact: State of the art; preliminary data; project aims and objectives; transformative approach and expected results; methodology and scientific approach; work plan and Gantt; timeline and budget; study limitations and contingency plan; scientific and social relevance; ethical, social, legal and environmental project implications; dissemination, social engagement and knowledge transfer. Graphics and additional figures to support the Proposal description may be uploaded as a pdf file of maximum 3 pages in this section.

At the end of this section you can add a maximum of 30 references related to the scientific excellence and impact of the proposal.

- Project Team:
 - **Project Leader**: relevance and research experience in relation with the proposal.
 - **Research Consortium (if applicable)**: description of the contribution of each member of the Research Consortium.
 - **Principal Investigators (in the case of Research Consortiums):** relevance and research experience in relation with the proposal.
 - **Research team**: brief description of the relevance, experience and contributions of the Team Members of the Host Organization and each Research Performing Organization (where applicable).
 - **Civil Society Organizations**: brief description of the role and relevance of the CSOs involved in the Project, if any.
 - Publications: at the end of the section Project Team you must add a minumum of 1 and maximum of 5 publications for the PL and each PI correctly related with the information in the Project Team section. Any proposal including publication(s) incompletely or incorrectly quoted may be considered as non-eligible.

• **Budget**: detail and justification of the Project budget. In the case of Research Consortiums, detail of the budget distribution among partners must also be included (this also applies to Individual Projects including CSOs with allocated budget).

<u>6.7</u>

The online system will be open for **Applications** from **October 20, 2020 at 14:00h Central European Time (CET)** until **December 3, 2020 at 14:00h, CET**. Instructions and/or information requested on the <u>"la Caixa" Grants online system</u> will prevail over any templates available out of the system. All instructions on the "la Caixa" Grants online system must be strictly followed; non-compliance with any such instructions may be deemed a breach of these Rules for Participation.

<u>6.8</u>

All users of the "la Caixa" Grants online system must strictly comply with its terms of use. Among other aspects, all information introduced in the system must be truthful and accurate. The identification of the different organizational and personal roles within an Application, as well as the accuracy of the information associated to each party and role will serve as the basis for the grant agreement in case the project is awarded. Changes in this information may not be accepted so participants are strongly encouraged to verify and confirm every organizational role and the associated information before submitting the Application.

Each user can **only register once** in the online system with their email and ID number. The main responsabilities of the users during the application are reminded below:

- Project Leader (PL): is the only person with permission to complete and submit the Application and is also a signatory to the grant agreement, together with the Host Organization, if the Application is awarded.
- Organization Manager (OM): must complete and validate the information of the Host Organization. OM has access to view the proposals and must accept the submission of the Application on behalf of the Host Organization in the "la Caixa"'s Foundation calls management online system.
- Principal Investigator (PI) and Civil Society Organizations (CSO): have access to view the Application of which they are members through the invitation from the PL.

<u>6.9</u>

IMPORTANT NOTICE: Applications must be submitted through the <u>"la Caixa" Grants online</u> <u>system</u> (without any other channel being allowed). For the submission, it is mandatory to have the registration and acceptance (all of them to be made before the closing date) of the Project Leader, the Organization Manager of the Host Organization, the CSOs (if applicable), and the PIs of the Research Consortiums (if applicable).

We strongly reccomend that invitations for acceptance are not sent until the general data and proposal information, and the composition of the consortiums (where applicable) are filled in,

as changes to this information/composition will require the re-approval of all other members in the proposal.

A validation button is available during the application process to check that the data provided is correct without submitting the proposal. We recommend this validation be used throughout the process to ensure submission prior to the deadline for applications.

7. EVALUATION CRITERIA

<u>7.1</u>

The evaluation criteria used for this Call are the following:

7.1.1. Scientific excellence and impact (Weight: 75%): *7.1.1.1. Project Quality (30%)*

- Potential of the proposal to go beyond the state of the art and generate groundbreaking results, novelty and high relevance.
- Soundness of the hypothesis, support of the preliminary results and coherence of the objectives.

7.1.1.2. Scientific approach and work plan (20%)

- Feasibility and rigor of the methodology and the work plan in accordance with the objectives.
- Proper justification of the timescales, resources and budget necessary to carry out the proposal.
- Definition of the limitations of the study and contingency plan.

7.1.1.3. Impact (Weight: 25%)

- Scientific impact and social relevance: the extent to which the results of the Project can make a positive, relevant and innovative difference to the scientific field and/or the society.
- Responsible research: detailed analysis of the ethical, legal, social and environmental implications of the execution of the Project and/or the potential implantation of its results in the society.
- Dissemination and transfer: suitable description of the mechanisms, actions and activities of dissemination, communication, social implication, valorization and transfer of the results of the Project.

7.1.2. Project Leader and Team (Weight: 25%):

Individual projects: 25% PL, Team and CSO, if applicable Research Consortium projects: 12.5% PL, Team and CSO, if applicable / 12.5 % PI's and Teams

- · Professional trajectory and research potential of the PL.
- Adequacy of the role and capacity of the research team members to support the Project execution.
- Suitability and contributions of the Civil Society Organizations of the Project.

Research Consortium, if applicable

- Professional trajectory and research potential of the PIs of each Research Performing Organization of the Research Consortium.
- Adequacy of the role and capacity of the Team Members of the Research Performing Organizations of the Research Consortium.

Evaluation criteria are the same for both remote evaluation and selection committees. Nevertheless, peer reviewers will score each section (4 scores from 1 to 8) while panel reviewers will score by block (2 scores from 1 to 5).

8. EVALUATION PROCEDURE

<u>8.1</u>

The Project evaluation procedure will consist of the following phases:

- Phase of eligibility Analysis of eligibility criteria: All applications received will be reviewed to ensure the fulfilment of the criteria published in the rules for participation of this Call. In the event that an Application is dismissed, the "la Caixa" Foundation will send an email notification to the applicant explaining the reasons.
- Peer review pre-selection process: All applications that pass the eligibility phase will enter the peer review pre-selection process formed by three or four international experts with extensive experience in the Thematic Area of the application. The evaluation criteria (see Section 7) will be applied to each Project. The applications that obtain the best scores of each Thematic Area of the Call will pass to the next phase. The "la Caixa" Foundation will notify the applicants if they have been shortlisted by email.
- Selection Committees: There will be five Selection Committees, one for each Thematic Area
 of this Call. Each Selection Committee will be composed by 8 to 12 internationally renowned
 experts with extensive experience in the Thematic Area of the Application, as well as in
 evaluation and selection processes.

If the Application is pre-selected, the applicants will be called for a face-to-face interview before the corresponding Selection Committee.

The interviews will be held in Barcelona. All the interviews will take place in person and will be carried out in English. They cannot be carried out on the phone or using other audiovisual and/or telecommunication media.

The presentation of the Proposal will be carried out by the PL. If needed, they may be accompanied by up to 2 Team Members or PIs that they deem necessary. However, if attendance at the interview entails travel or accommodation expenses, applicants may receive **compensation limited solely to the PL**. The reimbursement policy will be sent to these applicants for clarity.

At the end of this phase, each Selection Committee will rank the pre-selected Proposals based on the criteria of evaluation of this Call (see section 7). **The scientific evaluation of the Projects is not subject to appeals.**

<u>8.2</u>

Under no circumstances may the applicant contact the evaluators involved in the selection process in order to obtain information on any aspect related to the Call. If this happens, the applicant may be excluded from the call or any other future call of the "Ia Caixa" Foundation.

<u>8.3</u>

In the event that a Proposal is dismissed at any stage of the avaluation process, no redress or appeal procedure will be admitted. The avalulation/selection process will not be subject to redress nor will the technical and scientific assessment of the evaluators be called into question. The evaluation and selection processes in themselves guarantee the independence and objectivity of the evaluation.

9. SELECTED PROJECTS

<u>9.1</u>

The Executive Committee of the "la Caixa" Foundation will collect the Proposals selected by the Selection Committees and will approve and announce the final list of awarded Projects.

<u>9.2</u>

The outcome of the decision will be published on the website of the "la Caixa" Foundation and the applicants will be previously notified through the email address provided by the PL in the online application. The publication of the decision may include the identification of the Host Organization, any other RPOs and COs involved (if any), the name and professional bio of the Project Leader and Team Members, and information on the Project (including without limitation the lay summary, etc). The status of the proposal will also be updated on the "la Caixa" Foundation's calls management online system.

<u>9.3</u>

Eligible applicants may receive more information on the evaluation of their Proposal at the end of the selection process of the Call.

<u>9.4</u>

In the event that a selected Project waives the grant, it will be offered to the applicants in the reserve list in the corresponding order.

<u>9.5</u>

The Projects must follow the internal rules of their Organizations regarding the requirements of the ethics committees. The approval of the corresponding ethics committees must be obtained before signing the Agreement. The awarded Projects will also have to receive the **approval of an external ethics committee** under the responsibility of the "la Caixa" Foundation.

10. CONSIDERATIONS FOR THE PROJECT IMPLEMENTATION

<u>10.1</u>

The "la Caixa" Foundation fosters the **principles of Responsible Research and Innovation** (RRI). These principles take into account gender equality in research and innovation (R&I), as well as other inclusion issues; open access to scientific results, ethics and research integrity and the engagement of social stakeholders in the design and performance of R&I.

<u>10.2</u>

Cases of **scientific misconduct** that may arise during the evaluation of a Proposal and throughout execution of the awarded Project or once completed, must be communicated immediately by the Institution to the "la Caixa" Foundation.

<u>10.3</u>

The selected Projects must comply with the "la Caixa" principles of responsible research and innovation, the "la Caixa" research integrity policy and <u>research results management and open access policy of "la Caixa" Foundation and any other policies applicable to research projects receiving support by "la Caixa" Foundation as published on its website (https://obrasociallacaixa.org/en/investigacion-y-becas/politicas-de-investigacion), and for all results derived from this Project to be made available following the parameters described therein, except when justified circumstances exist. Awarded projects must include a **management plan for the research data** within the six months following the start of the project; a data management plan describes the management of the data collected, processed and/or generated by the Project.</u>

If human genotype and/or phenotype data are generated in the framework of the Project, the Organization is obliged to deposit them as a priority in the European Genome-phenome Archive (EGA) https://ega-archive.org/ repository.

11. DISSEMINATION RULES

<u>11.1</u>

The Organizations are obliged to explicitly acknowledge that their activity has received support from the "la Caixa" Foundation, meaning that in all dissemination and communication of the Project, the "la Caixa" Foundation shall be stated as funding organization of the Project.

This shall be done, if possible and unless the "la Caixa" Foundation asks otherwise, in all communications, disclosures and activities, as well as in all equipment, infrastructure and main results funded by the grant. These communication and disclosure materials shall be submitted to "la Caixa" Foundation for prior review and approval.

<u>11.2</u>

The logo of the "la Caixa" Foundation and the reference to the contribution of the "la Caixa" Foundation must appear in a way that is easily visible to the public and is sufficiently prominent (taking into account also the nature of the activity or the object), always subject to the previous revision and approval of the "la Caixa" Foundation.

<u>11.3</u>

Scientific articles and any other scientific communication published as a result of these research grants must include the following text "*The project leading to these results has received funding from "la Caixa" Foundation under the project code <CODE ASIGNED TO AWARDED PROJECTS>"*. The selected applicants must notify the "la Caixa" Foundation in advance of the publication of any of these articles.

<u>11.4</u>

Should there be results that are protected or protectable and/or registered or registrable as intellectual/industrial property or other types or modes, as a result of the research carried out in the awarded Project within the framework of this call, the Host Organizations agree to inform the "la Caixa" Foundation.

<u>11.5</u>

"la Caixa" Foundation may also promote the collaboration regarding the Project which may include disclosing certain details (current or future) of the Project where relevant, in international, national, and/or regional media and/or any other means deemed suitable. For this purpose, the general characteristics of the Applications (including but not limited to the title of the Project, a brief description of it, the Host Organization name, and the name and professional bio of the Project Leader (and/or other team members) may be published through, without limitation, press releases, emails, brochures, and websites.

The Host Organization and the Project Leader shall make their best efforts to enhance dissemination of the Project and of the collaboration with "la Caixa" Foundation, which includes providing information and documentation for developing dissemination materials as well as availability for interviews and other press events/materials.

<u>11.6</u>

If any Project on amyotrophic lateral sclerosis (ALS) is partially funded by the Francisco Luzón Foundation, the obligations that the Organizations must meet before the "la Caixa" Foundation in accordance with clauses 11.1 to 11.4, 12.6 and 13.1, must also be met before the Francisco Luzón Foundation.

<u>11.7</u>

The Host Organization and the PL shall ensure that all Organizations and Team Members, as well as their successors and assignees (to the extent possible), apply the terms established in this rules for participation to its activities and publications.

12. GRANT MANAGEMENT AND OTHER OBLIGATIONS OF THE HOST ORGANIZATION AND OF THE PROJECT LEADER (PL)

<u>12.1</u>

The Host Organization will manage and administer the amounts that the "la Caixa" Foundation allocates for the grant and will be responsible for the distribution of the budget to the other Organizations, where applicable. To this end, the "la Caixa" Foundation:

(a) will request Host Organizations with a Project with a budget greater than €500,000 to provide an external audit report (agreed-upon-procedures report) on their justifying account detailing the expenses incurred during the Project and the procedures applied by the auditor to validate the correct allocation of them according to the approved budget; all of the above in order to justify the costs of the activities of the Project carried out by the Host Organization as well as by any other Organization of the Project receiving funds in accordance with the budget (with respect to the part of the audit on the expenses of such Organizations, such audit may be commissioned to the external auditor of the Host Organization or to another auditor with experience in the field).

The report must be submitted at the end of the Project period and the cost of the same must be included and allocated to the Project budget, as indicated in clause 4.6. of this Call.

(b) may request Host Organizations with a Project with a budget equal to or less than €500,000 to provide an audit report and/or statement, as well as any additional information,

documentation and/or clarification that the "la Caixa" Foundation may deem pertinent to allow its auditors and/or advisors to evaluate the correct allocation of the grants awarded. The cost of this audit report and/or statement will be paid by the "la Caixa" Foundation, subject to prior approval of the corresponding budget, unless irregularities are detected as a result of it, in which case the Host Organization would bear the cost.

The request mentioned in paragraph (b) above may take place at any moment and may also apply to projects with budgets over $\leq 500,000$ in addition to the audit report indicated in paragraph (a) above.

<u>12.2</u>

Two follow up meeting will take place during the Project: a midterm follow-up (18 months following the beginning of the execution of the Project) and a final meeting (at the end of the Project). "Ia Caixa" Foundation might ask the PL to provide a scientific-technical summary as well as any other information that the "Ia Caixa" Foundation deems necessary, or he/she must authorize the Host Organization to provide it before each of the meetings.

<u>12.3</u>

At the request of the "la Caixa" Foundation, the selected applicants must certify, with original or certified documents, the files and information included in the Application. Likewise, the "la Caixa" Foundation may request the original certificates of any data mentioned in the Application.

<u>12.4</u>

The Project must comply with the ethical principles of the European Union, the Spanish, Portuguese and international laws applicable in this field, as well as the Charter of Fundamental Rights of the European Union. All applicants (including, but not limited to, awarded applicants) warrant that the Projects comply with and will continue to comply with the applicable regulations and that the Projects (including, but not limited to, their Proposal and eventual execution) do not infringe nor will infringe any rights of third parties, including, but not limited to, intellectual/industrial property rights and/or prior commitments or agreements. In this regard, all the applicants will hold the "la Caixa" Foundation harmless from and against any damages resulting from a breach of this warranty.

<u>12.5</u>

The awarded Projects will be carried out as described in the proposal submitted to the Call, with no substantial modifications being allowed. Should any substantial modifications be required, these must be communicated to the "la Caixa" Foundation, and the "la Caixa" Foundation reserves the right to cancel or claim reimbursement of the grant depending on the nature and impact of the change at issue. Any budgetary changes shall also be communicated to the "la Caixa" Foundation, duly justified and subject to its prior approval in writing.

<u>12.6</u>

All awarded Projects will be regulated in an Agreement to be signed in English between the Host Organization and the "la Caixa" Foundation. The signature of the Agreement is a mandatory requirement to receive the grant. For the entities subject to that regime, the Agreement constitutes a business collaboration agreement in activities of general interest under article 25 of Law 49/2002, of 23 December, on the tax regime for not-for-profit organisations and tax incentives for patronage.

<u>12.7</u>

The Projects that receive the grant will have to submit the following complementary documentation **before the signature of the Agreement**:

- Keep and make available to la Caixa" Foundation all documentation required by "la Caixa" Foundation in order to comply with the provisions outlined in regulations on preventing money laundering and financing terrorism, which includes:
 - / Legal documents proving that the legal representative is entitled to act on behalf of the organization and copy of his/her ID, passport, residence permit or ID valid in the country of origin including a photograph.
 - / Copy of the deeds evidencing the name, legal form, address and legal purpose of the Organization
 - / Beneficial owner deed or certificate executed by the legal representative of the Organization including the full name, National Identity Card Number (DNI) and, optionally the positions, of the persons who directly or indirectly hold more than 25% of the voting rights of the Organization. If no one holds more than 25% of the voting rights, the full name, National Identity Card Number (DNI) and, optionally the position, of all the members of the Executive Board (for associations), members of the Board of Trustees (for foundations) and directors or members of the organization's governing body must be specified.

Regarding CSOs with allocated budget and RPOs belonging to Research Consortiums, information detailing the members of the governing bodies will be required. The Organization Manager will be the one responsible for uploading all the above-mentioned documentation/information in the system, including partners'.

Complementary information and/or documentation may be required, especially for those Organizations located in high risk countries pursuant to the list of high risk third countries identified by the European Commission at any given time and/or equivalent lists.

Checks against the international lists of sanctioned persons will be performed on the basis of internacional economic and financial sanctions imposed by the United Nations, the European Union, Spain and/or the U.S. Department of the Treasury's Office of Foreign Assets Control ("Sanctions"). Organizations based in countries or territories or whose government is subject to Sanctions, including without limitation, North Norea, Iran, Siria, Sudan and South Sudan cannot be part of the proposals.

Signature of the Agreement and award of the grant will be subject to successful verification of the requirements applicable in the field of prevention of money laundering and financing terrorism including successful verification via the above-mentioned checks against the list of sanctioned persons. This is mandatory for receiving the grant throughout the whole term of the Agreement.

- Certificate from the Spanish Tax Agency or the equivalent Portuguese authority that certifies that the Host Organization fulfills its tax obligations and, for Portuguese Institutions, that it is resident for tax purposes in Portugal.
- Certificate of the Spanish Social Security or the equivalent Portuguese authority that certifies that the Host Institution fulfills its obligations in accordance with current labor regulations.

13. CONFIDENTIALITY. PRIVACY AND DATA PROTECTION POLICY

<u>13.1</u>

The Institutions authorize the "la Caixa" Foundation to access, use and share the information of the Proposals, including any and all documents referred to therein, whether submitted at the time of the Application or at a later stage, for the purposes of this Call and to the extent necessary, including, but not limited to, the evaluation, selection and monitoring of the Projects. The Institutions warrant that the "la Caixa" Foundation that such information and documentation can be shared and used for these purposes. To the extent that the identifying and/or professional information of natural persons linked to the Projects (including the PLs, the PIs, the other Team Members and representatives), the Institutions, when submitting the Proposals, warrant having informed those persons on the information indicated in clasue 13.3 below and, where applicable, having obtained the necessary consent of those persons for their inclusion in the Proposals.

<u>13.2</u>

The "la Caixa" Foundation fully complies with the legislation in force in the field of personal data protection. All Institutions must also comply with the regulations applicable in this field.

<u>13.3</u>

Any and all personal data collected within the framework of this Call (including the ones submitted in the Proposal) will be processed for the purpose of managing the participation of Institutions in it, being the basis of such processing the performance of the resulting

relationship, and such data will be stored until the end of the applicable statutory limitation periods.

Personal data will only be communicated if needed to comply with legal obligations. The "la Caixa" Foundation hires service providers (of technological and evaluation services) located outside the European Economic Space, with all guarantees required by applicable regulations. The data subjects can ask for more information and/or exercise their rights of access, rectification, erasure, restriction, portability and objection before the Data Protection Officer of the "la Caixa" Foundation at the post address Avinguda Diagonal 621 – 629, 08028 Barcelona, or at the e-mail address dpd@fundacionlacaixa.org. Data subjects are also entitled to lodge a complaint before the Spanish Data Protection Agency.

14. ADDITIONAL COMMENTS

<u>14.1</u>

The submission of an Application for this Call entails all the applicants' express acceptance of these rules for participation as well as the criteria and decisions that may be made by the "la Caixa" Foundation if questions arise on how to interpret the requirements and the terms and conditions of this document.

<u>14.2</u>

The detection of non-compliance of these rules for participation, regardless of when they occur and the status in which the Application is found within the grant awarding process or the execution of an awarded project will entitle the "la Caixa" Foundation to reject the application or cancel the awarded grant.

Should the grantee not comply with the obligations mentioned above, or with any other obligation included in these rules for participation of the Call, the "la Caixa" Foundation reserves the right to act as it deems appropriate, including requesting the return of the received amounts.

<u>14.3</u>

Further detailed information and documents regarding this Call for Proposals can be found at the <u>website of the "la Caixa" Foundation</u>.