



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

## CALL FOR PROPOSALS FOR A PILOT PROJECT ON

### ESTABLISHING A REGISTRY OF RARE CONGENITAL MALFORMATIONS (AS PART OF THE RARE DISEASE REGISTRY), DRAWING ON THE STRUCTURE, ORGANISATION AND EXPERIENCE OF THE REGISTRY OF CONGENITAL MALFORMATIONS

#### 1. BACKGROUND AND PURPOSE OF THIS CALL

**Rare diseases (RD)** are diseases with a particularly low prevalence. In the European Union diseases are considered to be rare when they affect no more than 5 per 10 000 persons. Based on present scientific knowledge, there are between 6 000 and 8 000 distinct RD (currently 5 860 are described in the Orphanet database – European portal of RD and orphan drugs) that affect between 6% and 8% of the EU population in the course of their lives. In other words, between 27 and 36 million people in the European Union are affected by a rare disease.

Rare diseases are life-threatening or chronically debilitating diseases with a high level of complexity. Most of them are genetic diseases, the others being rare cancers, autoimmune diseases, **congenital malformations**, toxic and infectious diseases among other categories.

The often limited expertise in this area translates into delayed diagnosis and difficult access to care. Misdiagnosis and non-diagnosis are the main hurdles to improving life-quality of rare diseases patients, while the current fragmentation of data sources is a key obstacle to perform high-quality research and to steer policy. An approach at European level can help to share the knowledge available and to combine resources as efficiently as possible in order to tackle rare diseases across the EU as a whole.

The EU policy in the field of rare diseases is based on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on "Rare Diseases: Europe's challenges" (COMM(2008) 679 final) and the Council Recommendation on an action in the field of rare diseases (2009/C 151/02). In addition, the Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products provides incentives for bringing new drugs for rare diseases to the market, while the Directive of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare covers several aspects important for rare diseases patients including European Reference Networks.

The objective of the European Commission is to implement actions for efficient recognition, prevention, diagnosis, treatment, care and research for rare diseases in Europe, building on the benefits of the collaboration at European scale. The specificities of rare diseases – limited number of patients and scarcity of relevant knowledge and expertise – single them out as a unique domain of very high European added-value.

In line with this strategy, the Directorate-General Joint Research Centre (JRC), upon request and in close collaboration with the Directorate-General for Health and Consumers, agreed in

December 2013 on the development and maintenance of the EU Platform on Rare Diseases Registration.

1). The principal goal of the Platform is to address the fragmentation of rare diseases patient data comprised in more than 600 registries across Europe, which severely jeopardises the registries' potential and limits Europe's potential to steer health policy and facilitate research.

2). The main objective is to maximise access to patient data in Europe, both within and across many rare diseases in order to achieve a sufficient sample size for epidemiological, clinical, pharmacological, translational studies and research. In this respect the aim is to facilitate planning of clinical trials and to support the enrolment of patients knowing that their geographic dispersion is a major impediment to patient recruitment into clinical trials.

Among the objectives of the Platform there is as well the transfer of the European level coordination activities of EUROCAT to the JRC. EUROCAT is a network of population-based registries for the epidemiological surveillance of congenital anomalies, covering 1/3 of the European birth population (more than 1.7 million births/year). The EUROCAT central database contains half a million cases of children with congenital anomalies. This data enables provision of prevalence, prenatal diagnosis and perinatal mortality data, detection of teratogenic exposures among others. It develops recommendations considered for primary prevention in the Rare Diseases National Plans for medicinal drugs, food/nutrition, lifestyle, health services, environmental pollution.

It is proposed to implement the present pilot project in a close link with the activities carried out in the European Platform on rare diseases registration.

Adopted in September 2016, the Financing decision and its annex describing the intended scope of this pilot project are available at:

Financing decision:

[http://ec.europa.eu/dgs/health\\_food-safety/funding/docs/call\\_2016-5651-f1\\_dec.pdf](http://ec.europa.eu/dgs/health_food-safety/funding/docs/call_2016-5651-f1_dec.pdf)

Annex:

[http://ec.europa.eu/dgs/health\\_food-safety/funding/docs/call\\_2016-5651-f1\\_dec\\_annex.pdf](http://ec.europa.eu/dgs/health_food-safety/funding/docs/call_2016-5651-f1_dec_annex.pdf)

These documents set out the financing mechanisms and priority areas for action to implement this pilot project. The present call relates to this financing decision and provides for a description, here below, of the areas for funding, the eligibility, exclusion, selection and award criteria, the procedures for application and approval as well as the indicative amounts.

Interested parties active in the field of public health are invited to submit applications with accordance to the provisions of this Financing decision and its annex as well as this call text.

## **2. OBJECTIVES**

The Financing Decision<sup>1</sup> for the pilot project " registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of

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<sup>1</sup> [http://ec.europa.eu/dgs/health\\_food-safety/funding/docs/call\\_2016-5651-f1\\_dec.pdf](http://ec.europa.eu/dgs/health_food-safety/funding/docs/call_2016-5651-f1_dec.pdf)

Congenital Malformations” was adopted on 08 September 2016. Its Annex<sup>2</sup> sets out the main priority areas for this pilot project to be implemented through the present call:

- The key objective of this pilot project is to set up a registry of rare congenital malformations as a part of rare diseases national registers. The project should be implemented at a national level.
- The secondary aim of the project is to provide an example of how to extend an existing birth defects registration and surveillance system to a rare diseases registration system.
- The birth defects registration system has already been set up in several MSs as part of the EUROCAT surveillance network. The pilot project provides a model for exploring whether a birth defects registry can be extended to form a rare diseases registry.
- The pilot project should contribute to the development of an EU Platform on Rare Diseases Registration to provide a common access point to data collections on rare diseases across Europe and to be compatible with platform tools.

One call will be organized and the proposal selected shall cover the main priority areas.

### 3. TIMETABLE

The final deadline for the submission of proposals is **31 January 2017**.

	Stages	Date/period
a)	Publication of the call	October 2016
b)	Deadline for submitting applications	31/01/2017
c)	Evaluation period (indicative)	February 2017 to March 2017
d)	Information to applicants (indicative): Official letter	April 2017
e)	Signature of grant agreement (indicative)	May 2017
f)	Starting date of the action (indicative)	June 2017

### 4. BUDGET AVAILABLE

<sup>2</sup> [http://ec.europa.eu/dgs/health\\_food-safety/funding/docs/call\\_2016-5651-f1\\_dec\\_annex.pdf](http://ec.europa.eu/dgs/health_food-safety/funding/docs/call_2016-5651-f1_dec_annex.pdf)

The total budget earmarked for the co-financing of projects is estimated at EUR 100 000.

The maximum possible rate of co-financing of the eligible total costs is 80%.

## 5. ADMISSIBILITY REQUIREMENT

- Applications must be submitted online via the [participant portal](#).

<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/index.html>

- Applications must be drafted in one of the EU official languages.

Failure to comply with those requirements will lead to the rejection of the application.

Project proposals may be submitted in any official language of the European Union. However, in order to facilitate assessment by the evaluators, an English translation of the technical part (part B) should accompany any part B written in another EU official language.

Proposals received after the deadline for submission laid down in this call for proposals will not be considered for funding.

**VERY IMPORTANT:** While the call documents have been prepared for multi beneficiaries proposals, single entities can also apply. In that case, the provisions of the call relating to multi beneficiaries will apply mutatis mutandis to the single beneficiary. If successful, a single beneficiary grant agreement will be signed.

## 6. ELIGIBILITY CRITERIA

### 6.1. Eligible applicants

Grant applications are eligible if submitted by legal persons. More specifically, the applicants<sup>3</sup> must be legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

The application shall state the legal status of the applicant.

Proposals must be submitted by consortia of legal entities or a single legal entity (with or without legal personality) established in an EU Member State. Actions that have already commenced by the date on which the grant application is registered will be excluded from participation.

### 6.2. Eligible countries

Only applications from entities established in one the following countries are eligible:

- One of the 28 EU Member States;

### **Implementation period**

As a rule, the maximum duration of project is **24** months. The grant application must specify the scheduled starting date (if possible) and duration of the action. Applications for actions that have already commenced by the date on which the grant application is registered will be excluded from funding.

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<sup>3</sup> Wherever "applicants" is written this means the coordinator and the co-applicants.

The compliance with the eligibility criteria will be assessed based on the application content.

## **7. EXCLUSION CRITERIA**

### **7.1. Exclusion from participation:**

Applicants will be excluded from participation in an award procedure if they are in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

Applicants will be excluded from participating in the call for proposals procedure if they are in any of the following situations:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- (b) they or persons having powers of representation, decision making or control over them have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;
- (c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify including by decisions of the EIB and international organisations;
- (d) they are not in compliance with their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the grant agreement is to be performed;
- (e) they or persons having powers of representation, decision making or control over them have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such an illegal activity is detrimental to the Union's financial interests;
- (f) they are currently subject to an administrative penalty referred to in Article 109(1) of the EU Financial Regulation.

### **7.2. Exclusion from award:**

Applicants will not be awarded co-funding, in the course of the grant award procedure, if they:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresenting the information required by the contracting authority as a condition of participation in the grant procedure or fail to supply this information;
- (c) find themselves in one of the situations of exclusion, referred to in the above section.

In order to demonstrate compliance with the exclusion criteria, the coordinator has to check the relevant box in online application. If selected for co-funding, all beneficiaries have to submit a declaration on their honour certifying that they are not in one of the situations referred to in articles 106(1) and 107 to 109 of the

Financial Regulation<sup>4,5</sup>. The applicants should follow the instructions in the participant portal.

## **8. SELECTION CRITERIA**

Only proposals which meet the exclusion and eligibility criteria will be assessed on the basis of the selection criteria.

### **SELECTION CRITERIA.**

#### **8.1. Financial viability**

Applicants must have stable and sufficient sources of funding to maintain their activity throughout the period during which the activity is being carried out and to participate in its co-financing.

The verification of financial capacity will not apply to public bodies and to international public organisations.

The financial viability of all beneficiaries will be assessed, except if:

- a) the EU-contribution for the coordinator / other beneficiary is < EUR 60 000;
- b) the beneficiary is a public body.

The documents that will be requested when assessing the financial viability include:

- the annual accounts (including the balance sheet and the profit and loss statement) for the past financial year for which the accounts were closed (for newly created entities, the business plan shall be submitted to replace the accounts);

In addition for a coordinator or other beneficiary requesting an EU-contribution of > EUR 750 000 (threshold applicable per beneficiary) an audit report produced by an approved external auditor certifying the accounts for the last financial year available. This provision shall not apply to public bodies.

#### **8.2. Operational capacity**

Applicants must have the professional resources, competencies and qualifications required to complete the proposed action.

As evidence the general profiles (qualifications and experiences) of all relevant staff in all organisations involved in the proposed action must be provided.

## **9. AWARD CRITERIA**

Part B of the information to be included in the application serves to evaluate the proposal against the award criteria.

Generally, it is expected that projects have a good technical quality and an efficient management structure and budget, clear evaluation and communication strategies, a precise description of expected results and a high added-value for as many EU Member States as possible. They should include a plan for using and disseminating results at EU level to appropriate target audiences.

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<sup>4</sup> [REGULATION \(EU, EURATOM\) NO 966/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation \(EC, Euratom\) No 1605/2002](#)

<sup>5</sup> [Commission Delegated Regulation \(EU\) No 1268/2012 of 29 October 2012 on the rules of application of Regulation \(EU, Euratom\) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union](#)

As regards the award criteria, each proposal will be assessed according to criteria below. Only proposals which meet the eligibility, exclusion and selection criteria will be further assessed on the basis of the following award criteria:

<b>Criteria</b>	<b>Maximum points</b>	<b>Threshold</b>	<b>Threshold in % of max. points</b>
1- Policy and contextual relevance	40	20	50%
2- Technical quality	30	15	50%
3- Management quality and budget	30	15	50%
<b>TOTAL</b>	<b>100</b>	<b>50</b>	

1. Policy and contextual relevance (40 points, threshold: 20 points) :

(a) Project's contribution to meeting the objectives and priorities defined in the financing decision (8 points);

(b) Strategic relevance with regard to the EU Health Strategy (COM (2007) 630 final; [http://ec.europa.eu/health/ph\\_overview/strategy/health\\_strategy\\_en.htm](http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm) ) and with regard to expected contribution to existing knowledge and implications for health (8 points);

(c) Added value at EU level in the field of public health (8 points):  
 — impact on target groups, long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,  
 — contribution to complementarity, synergy and compatibility with relevant EU policies and programmes;

(d) Pertinence of geographical coverage (8 points):  
 Applicants must ensure that the geographical coverage of the project is commensurate with its objectives, and explain the role of eligible countries as partners and the relevance of project resources or the target populations they represent;

(e) Social, cultural and political context (8 points):  
 Applicants must explain how the project relates to the situation of the countries or specific areas involved, ensuring the compatibility of envisaged actions with the culture and views of the target groups.

2. Technical quality (30 points, threshold: 15 points):

(a) Evidence base (6 points):  
 Applicants must include a problem analysis and clearly describe the factors, impact, effectiveness and applicability of the proposed measures;

(b) Content specification (6 points):  
 Applicants must clearly describe aims and objectives, target groups, including relevant geographical factors, methods, anticipated effects and outcomes;

(c) Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level (6 points):

Applicants must clearly identify the progress that is expected to result from the project within a given field in relation to the state of the art and ensure that there will be neither inappropriate duplication nor overlap, whether partial or total, between projects and activities already carried out at EU and international level;

(d) Evaluation strategy (6 points):

Applicants must clearly explain the methods proposed and indicators chosen and their adequacy;

(e) Dissemination strategy (6 points):

Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology to ensure transferability of results and sustainability of dissemination.

3. Management quality and budget (30 points, threshold: 15 points):

(a) Planning and organisation (5 points):

Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, and provide a risk analysis;

(b) Organisational capacity (5 points):

Applicants must clearly demonstrate the quality level of the structure of the project by describing its management structure, competence of staff, responsibilities, internal communication, decision-making, monitoring and supervision.

(c) Quality of partnership (5 points):

Applicants must clearly describe the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between the partners, and the synergy and complementarity of partners and network structure;

(d) Communication strategy (5 points):

Applicants must clearly describe the communication strategy in terms of planning, target groups, adequacy of channels used, and visibility of EU co-financing;

(e) Overall and detailed budget, including financial management (10 points, threshold: 5 points):

Applicants must ensure that the budget is relevant, appropriate, balanced and consistent in itself, between partners and in relation to the specific objectives of the project. The budget should be distributed between partners at a minimum reasonable level, avoiding excessive fragmentation.

Applicants must clearly describe financial circuits, responsibilities, reporting procedures and controls.

Any proposal which does not reach all the thresholds will be rejected.

Following the evaluation, a list is drawn up containing proposals reaching all the thresholds and ranked according to the total number of points awarded. Only the highest ranked proposal will be awarded co-financing.

## **10. LEGAL COMMITMENTS**



Following the evaluation, the Commission establishes a list of proposals recommended for funding, ranked according to the total number of points awarded. Depending on the budget availability, the highest ranked proposal will be awarded co-financing.

In the event of a grant awarded by the Commission, a grant agreement, drawn up in euro and detailing the conditions and level of funding, will be sent to the beneficiary, as well as the procedure in view to formalise the obligations of the parties.

## 11. FINANCIAL PROVISIONS

The Financial Regulation and the Rules of Application<sup>6</sup> are the reference documents for the implementation of this pilot project.

### 11.1. General Principles

Grants must comply with the following principles:

a) Non-cumulative award

An action may only receive one grant from the EU budget.

In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, applicants shall indicate the sources and amounts of Union funding received or applied for the same action or part of the action or for its functioning during the same financial year as well as any other funding received or applied for the same action.

b) Non-retroactivity

No grant may be awarded retrospectively for actions already completed.

A grant may be awarded for an action, which has already begun only where the applicant can demonstrate the need to start the action before the grant agreement is signed.

In such cases, costs eligible for financing may not have been incurred prior to the date of submission of the grant application.

c) Co-financing

Co-financing means that the resources, which are necessary to carry out the action, may not be entirely provided by the EU grant.

Co-financing of the action may take the form of:

- the beneficiary's own resources,
- income generated by the action,
- financial contributions from third parties.

d) Balanced budget

The estimated budget of the action is to be attached to the application form. It must have revenue and expenditure in balance.

The budget must be drawn up in euros.

e) Implementation contracts/subcontracting

Where the implementation of the action requires the award of procurement contracts (implementation contracts), the beneficiary must award the contract to the bid offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests and retain the documentation for the event of an audit.

For public bodies: entities acting in their capacity of contracting authorities in the meaning of

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<sup>6</sup> Please refer to footnotes 27 and 28 above

Directive 2004/18/EC or contracting entities in the meaning of Directive 2004/17/EC shall abide by the applicable national public procurement rules.

Sub-contracting, i.e. the externalisation of specific tasks or activities which form part of the action as described in the proposal must satisfy the conditions applicable to any implementation contract (as specified above) and in addition to them the following conditions:

- it may only cover the implementation of a limited part of the action;
- it must be justified having regard to the nature of the action and what is necessary for its implementation;
- it must be clearly stated in the proposal.

## **11.2. Funding form: mixed financing**

Mixed financing grants are calculated on the basis of a detailed estimated budget indicating clearly the costs that are eligible for EU funding. The grant amount may neither exceed the eligible costs nor the amount requested. Amounts are indicated in euros.

### **Maximum amount requested**

The EU grant is limited to a maximum co-funding rate of **80%** of **eligible costs**.

Consequently, part of the total eligible expenses entered in the estimative budget must be financed from sources other than the EU grant.

- Eligible costs are actually incurred by the beneficiary of a grant and meet all the criteria indicated in Article 6 of the model grant agreement. Eligible (direct and indirect) costs are indicated in the grant agreement (see Articles 6.1., 6.2. and 6.3.);

- Ineligible costs are indicated in the grant agreement (see Article 6.4.). Please note that contributions in kind are not considered eligible cost.

### **Calculation of the final grant amount**

The Commission establishes the final amount of the grant to the coordinator and the other beneficiaries after completion of the action, upon approval of the request for payment containing the documents indicated in the grant agreement.

The final grant amount is calculated as indicated in the grant agreement (see Article 5).

EU grants may not have the purpose or effect of producing a profit within the framework of the action of the beneficiary. **Profit shall be defined as a surplus of the receipts over the eligible costs incurred by the beneficiary**, when the request is made for payment of the balance. In this respect, where a profit is made, the Commission shall be entitled to recover the percentage of the profit corresponding to the Union contribution. A partner (coordinator or other beneficiary) requesting an EU-contribution of EUR < 60 000, is exempted from this provision.

## **11.3. Payment arrangements**

The payments generally consist of the following:

The Commission will execute a pre-financing payment of 50 % (see Article 16.2 of the model grant agreement) to the coordinator within 30 days of the date when the last of the two parties signs the agreement, provided all requested guarantees have been received. All other beneficiaries have to accede to the grant agreement before the coordinator can transfer to them their share of the pre-financing.

The Commission will establish the amount of the final payment to be made to the coordinator on the basis of the calculation of the final grant amount (see section 11.2 above). If the total of earlier payments is higher

than the final grant amount, the coordinator will be required to reimburse the amount paid in excess by the Commission through a recovery order (see Article 28 of the grant agreement).

For more details, please see Article 16 of the grant agreement.

#### **11.4. Pre-financing guarantee**

In the event that the applicant's financial capacity is not satisfactory, measures may be taken in order to limit the financial risks linked to the pre-financing payment. These may include a financial guarantee for an amount up to that of the pre-financing payment or the inclusion of several reporting periods, leading to interim payments, subject to the approval of the periodic report.

If requested, the financial guarantee, in euro, shall be provided by an approved bank or financial institution established in one of the Member State of the European Union. When the beneficiary is established in a third country, the authorising officer responsible may agree that a bank or financial institution established in that third country may provide the guarantee if he considers that the bank or financial institution offers equivalent security and characteristics as those offered by a bank or financial institution established in a Member State. Amounts blocked in bank accounts shall not be accepted as financial guarantees.

The guarantee may be replaced by a joint and several guarantee by a third party or by a joint guarantee of the beneficiaries of an action who are parties to the same grant agreement.

The guarantee shall be released as the pre-financing is gradually cleared against interim payments or payments of the balance to the beneficiary, in accordance with the conditions laid down in the grant agreement.

No financial guarantee will be requested for a beneficiary receiving an EU contribution of EUR <60. 000 (low value grants).

## **12. PUBLICITY**

### **12.1. By the beneficiaries**

Beneficiaries must clearly acknowledge the European Union's contribution in all publications or in conjunction with activities for which the grant is used in line with Article 38 of the grant agreement.

In this respect, beneficiaries are required to give prominence to the name and emblem of the European Union on all their publications, posters, programmes and other products realised under the co-financed project.

If this requirement is not fully complied with, the beneficiary's grant may be reduced in accordance with the provisions of the grant agreement.

### **12.2. By the Commission**

With the exception of scholarships paid to natural persons and other direct support paid to natural persons in most need, all information relating to grants awarded in the course of a financial year shall be published on an internet site of the European Union institutions no later than the 30 June of the year following the financial year in which the grants were awarded.

The following information will be published:

- name of the beneficiary,
- address of the beneficiary when the latter is a legal person, region when the beneficiary is a natural person, as defined on NUTS 2 level<sup>7</sup> if he/she is domiciled within EU or equivalent if domiciled outside EU,
- subject of the grant,
- amount awarded.

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<sup>7</sup> European Union Official Journal L 39, of 10 February 2007.

Upon a reasoned and duly substantiated request by the beneficiary, the publication shall be waived if such disclosure risks threatening the rights and freedoms of individuals concerned as protected by the Charter of Fundamental Rights of the European Union or harm the commercial interests of the beneficiaries.

### 13. DATA PROTECTION

The reply to any call for proposals involves the recording and processing of personal data (such as name, address and CV). Such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the call for proposal will be processed solely for that purpose by the Commission and the Chafea. Details concerning the processing of personal data are available on:

[http://ec.europa.eu/dataprotectionofficer/privacystatement\\_publicprocurement\\_en.pdf](http://ec.europa.eu/dataprotectionofficer/privacystatement_publicprocurement_en.pdf)

Applicants are invited to check this website at regular intervals so as to be duly informed on possible updates that may occur by the deadline for submission of their proposals.

Personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 106 of the Financial Regulation<sup>8</sup>. For more information, see the Privacy Statement on [http://ec.europa.eu/budget/explained/management/protecting/protect\\_en.cfm](http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm)

### 14. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

Proposals must be submitted via the participant portal.

Before submitting a proposal:

1. Find a call:

<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/index.html>

2. Create an account to submit a proposal:

<http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html>

3. Register all partners via the beneficiary registry:

<http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html>

Applicants will be informed in writing about the results of the selection process.

**In submitting a proposal, the applicant accepts the procedures and conditions as described in this call and in the documents to which it refers. Applications that do not comply with these requirements will be rejected.**

#### > Contacts

For problems with the online submission tools please contact the IT helpdesk set-up for this purpose via the participant portal website: <http://ec.europa.eu/research/index.cfm?pg=enquiries>

For non-IT related questions, please contact DG SANTE helpdesk at the European Commission email: [SANTE-PP-CALLS@ec.europa.eu](mailto:SANTE-PP-CALLS@ec.europa.eu)

In all correspondence relating to this call (e.g. when requesting information, or submitting an application), reference must be clearly made to this specific call. Once the electronic exchange system allocated a

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<sup>8</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298 of 26.10.2012, p. 1) as amended.

proposal ID, the applicant must use this number in all subsequent correspondence.  
After the deadline for submission modifications to the application are impossible.

**> Annexes:**

- Guide for applicants
- Model grant agreement