



**EUROPEAN COMMISSION**  
CONSUMERS, HEALTH, AGRICULTURE AND FOOD EXECUTIVE AGENCY  
Health Unit

Luxembourg,  
Chafea JR/GM/Ares (2016)

## **CALL for PROPOSALS for PROJECT Rare diseases - Support for New Registries**

### **APPROVED ERNs (European Reference Networks)**

#### **THIRD PROGRAMME FOR THE UNION 'S ACTION IN THE FIELD OF HEALTH (2014-2020). Annual Work Plan 2016**

#### **1. BACKGROUND AND PURPOSE OF THIS CALL FOR PROPOSALS**

On 11 March 2014, the European Parliament and the Council adopted a Regulation establishing the third programme for the Union's action in the field of health (2014-2020)<sup>1</sup>. This programme entered into force retroactively from the 1 January 2014.

The Consumer, Health, Agriculture and Food Executive Agency (Chafea) is entrusted with the implementation of the above programme, the Third Health Programme (hereinafter referred to as "the Programme").

The general objectives of the Programme shall be to complement, support and add value to the policies of the Member States aimed at improving the health of Union citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

The specific objectives of the Programme are:

1. In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles: identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the added value for the Union.
2. In order to protect Union citizens from serious cross-border health threats: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.
3. In order to support public health capacity-building and contribute to innovative, efficient and sustainable health systems: identify and develop tools and mechanisms at Union level to address

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<sup>1</sup> Regulation No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC. OJ L86, volume 57; 21 March 2014.

shortages of resources, both human and financial, and to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies.

4. In order to facilitate access to better and safer healthcare for Union citizens: increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to the improvement of health literacy.

The 2016 work plan<sup>2</sup> sets out details of the financing mechanisms and priority areas for action to implement the programme and is available at [http://ec.europa.eu/health/programme/events/adoption\\_workplan\\_2016\\_en.htm](http://ec.europa.eu/health/programme/events/adoption_workplan_2016_en.htm)

The present call relates to the financing mechanism "project grants"<sup>3</sup>.

Interested parties meeting the conditions stipulated in the annual work programme 2016 are invited to submit applications with accordance to the provisions of Annex I, Annex II and Annex VII of the 2016 work plan and this call text, in order to pursue the objectives of the third Health Programme.

The areas for funding, the eligibility, exclusion, selection and award criteria, the procedures for application and approval and the indicative amounts are described below.

## 2. OBJECTIVES

Chapter 2.1, point 2.1.4.2, of Annex I of the 2016 work programme sets out the priority area for the project to be implemented through the present call. Only project proposals that directly correspond to the topic and description given will be considered for funding.

It is not possible to submit project applications covering other topics or priorities than that for which the call is launched.

## 3. TIMETABLE

The final deadline for the submission of proposals is 21 March 2017.

	Stages	Indicative timeline
a)	Publication of the call	22/12/2016
b)	Deadline for submitting applications	21/03/2017
c)	Evaluation period	02/04 – 15/05/2017
d)	Information to applicants (official letter)	≤ 20/05/2017
e)	Signature of grant agreement	≤ 31/07/2017

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<sup>2</sup> Commission Implementing Decision C(2016) 1158 of 01 March 2016.

<sup>3</sup> The provisions of the 2016 work plan and those of the present call for proposals are complementary and mutually explanatory. Nevertheless, in case of ambiguities or discrepancies between the provisions of the 2016 work plan and those of the call for proposals the former will take precedence over the latter.

f)	Starting date of the action	≥ 01/08/2017
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#### 4. BUDGET AVAILABLE

The total indicative amount of the present call is EUR 1.200.000. In line with the text of the funding decision (Annual Work Programme 2016) which foresees the creation of 3-4 new registries, the indicative budgetary ceiling per grant to be awarded in 2017 is EUR 400.000.

#### 5. ADMISSIBILITY REQUIREMENTS

- Applications must be submitted online via the [Participant Portal](#).

The closing date (deadline) for the submission of applications is indicated in section 3 above. Incomplete applications or applications submitted via the electronic submission system after the deadline will be disqualified and considered as non-admissible.

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

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

#### 6. ELIGIBILITY CRITERIA

##### 6.1. Eligible applicants

As laid down in Article 12 of the Directive on the application of patients' rights in cross-border healthcare<sup>4</sup> registries will be one of the objectives of the European Reference Networks to be set up. The present call and the proposed EU co-funding is therefore limited to proposals coming from such **approved ERNs**. More specifically, are eligible under this call, whether as coordinators or associated partners, applicant organisations which are members of official European Reference Networks and which fall under the scope of Directive 2011/24/EU<sup>5</sup>, i.e. which have been positively assessed and approved by the Board<sup>5</sup> of the Member States.

Grant applications are eligible if submitted by legal persons. More specifically, the applicants<sup>6</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.

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<sup>4</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L88, 4.4.2011, P. 45-65.

<sup>5</sup> Articles 5 and 6 of the Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

<sup>6</sup> Wherever "applicants" is written this means the coordinator and the co-applicants.

Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other) from at least 3 countries participating in the Health Programme. Proposals which involve fewer applicants will be rejected.

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

## 6.2. Eligible activities

Project proposals may be submitted for the topic.

TITLE	INDICATIVE AMOUNT, EUR	Ref. in Work Plan 2016	Grants foreseen
Rare diseases - Support for new registries	1.200.000	2.1.4.2	3-4

For a more detailed description of the objectives pursued and results expected please check the Work Programme 2016. Proposals should match the specific description of the given action.

## 6.3. Implementation period

The maximum duration of a project is 36 months. The grant application must specify the scheduled starting date (if possible) and the duration of the action.

Applications for actions that have already commenced by the date on which the grant application is registered shall be excluded from funding from the Health Programme.

## 7. EXCLUSION CRITERIA AND ADMINISTRATIVE SANCTIONS

### 7.1. Exclusion from participation:

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

(a) is bankrupt, subject to insolvency or winding-up procedures, where its assets are being administered by a liquidator or by a court, where it is in an arrangement with creditors, where its business activities are suspended, or where it is in any analogous situation arising from a similar procedure provided for under national laws or regulations;

(b) it has been established by a final judgment or a final administrative decision that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the granting authority is located or those of the country of the performance of the grant agreement.;

(c) it has been established by a final judgment or a final administrative decision that the applicant is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the applicant belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

- (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract/grant agreement;
  - (ii) entering into agreement with other economic operators with the aim of distorting competition;
  - (iii) violating intellectual property rights;
  - (iv) attempting to influence the decision-making process of the contracting authority during the procurement / grant award procedure;
  - (v) attempting to obtain confidential information that may confer upon it undue advantages in the procurement / grant award procedure;
- (d) it has been established by a final judgment that the applicant is guilty of any of the following:
- (i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;
  - (ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the law of the country where the contracting authority is located, the country in which the economic operator is established or the country of the performance of the contract;
  - (iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
  - (iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
  - (v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
  - (vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;
- (e) the applicant has shown significant deficiencies in complying with main obligations in the performance of a contract / a grant agreement financed by the budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an authorising officer, OLAF or the Court of Auditors;
- (f) it has been established by a final judgment or final administrative decision that the applicant has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95.

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

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

- (a) are in an exclusion situation established in accordance with Article 106 and 107 of the EU Financial Regulation;

- (b) have misrepresented the information required as a condition for participating in the procedure or have failed to supply that information;
- (c) were previously involved in the preparation of documents where this entails a distortion of competition that cannot be remedied otherwise.

In order to demonstrate compliance with the non-exclusion requirements, the coordinator has to check the relevant box in the online application. If selected for co-funding, all beneficiaries have to submit a declaration of honour certifying that they are not in one of the situations referred to in articles 106 and 107 of the Financial Regulation<sup>7,8</sup>. The applicants should follow the instructions in the participant portal. Where requested by the granting authority, successful applicants shall supply such evidence, unless there is a material impossibility recognised by the granting authority or such evidence has already been submitted to the granting authority for the purposes of another grant or procurement procedure, provided that the documents are not more than one year old counting from their date of issue and that they are still valid.

## 8. 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 financial viability of all beneficiaries will be verified, except if:

- a) the EU-contribution for the coordinator / other beneficiary is  $\leq$  EUR 60.000:
- b) the beneficiary is a public body

For all applicants except for public bodies, the following supporting documents will be submitted with the application::

- the annual accounts (including the balance sheet and the profit and loss statement) for the last 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  $\geq$  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.

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<sup>7</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 and REGULATION \(EU, EURATOM\) NO 2015/1929 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 October 2015 amending Regulation \(EU, Euratom\) No 966/2012 on the financial rules applicable to the general budget of the Union.](#)

<sup>8</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 and COMMISSION DELEGATED REGULATION \(EU\) 2015/2462 of 30 October 2015 amending Delegated Regulation \(EU\) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.](#)

## 8.2. Operational capacity<sup>9</sup>

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

In this respect, applicants have to submit a declaration of honour. 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<sup>10</sup>

Part B of the application form, available in the online submission system, provides the information enabling to evaluate the proposal against the award criteria.

It is expected that the proposed projects present an efficient management structure, a clear evaluation strategy and a precise description of expected results. In addition, they should include a plan for use and dissemination of results at EU level to appropriate target audiences.

Each proposal will be assessed according to the award criteria listed below.

As regards the award criteria, each proposal will be assessed according to criteria below, published in the Work Programme 2016.

<b>Criteria</b>	<b>Maximum score (in points)</b>	<b>Threshold (pass-mark)</b>
1 – Policy and contextual relevance	10	7
2 – Technical quality	10	6
3 – Management quality	10	6
4 – Overall and detailed budget	10	6
<b>TOTAL</b>	<b>40</b>	<b>25</b>

comprising the following sub-criteria:

### 1. Policy and contextual relevance

Sub-criteria that are taken into account in the assessment:

- Relevance of the contribution to meeting the objectives and priorities defined in the annual work plan of the 3<sup>rd</sup> Health Programme, under which the call for proposals is published,
- Added value at EU level in the field of public health,
- Pertinence of the geographical coverage of the proposals,
- Consideration of the social, cultural and political context.

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<sup>9</sup> Article 131 FR, Article 202 RAP.

<sup>10</sup> Article 132 of the Financial Regulation, Article 203 of the Rules of Application

## **2. Technical quality**

Sub-criteria that are taken into account in the assessment:

- Quality of the evidence base,
- Quality of the content,
- Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

## **3. Management quality**

Sub-criteria that are taken into account in the assessment:

- Quality of the planning and appropriate task distribution to implement the project,
- Relevance of the organisational arrangements, including financial management,
- Quality of the partnership

## **4. Overall and detailed budget**

Sub-criteria that are taken into account in the assessment:

- Relevance and appropriateness of the budget,
- Consistency of the estimated cost per applicant and the corresponding activities,
- Realistic estimation of person days / deliverable and per work package,
- The budget allocated for evaluation and dissemination is reasonable.

Following the evaluation, all eligible proposals are ranked according to the total number of points awarded. Only proposals meeting all thresholds are eligible for co-funding. Meeting the threshold does not imply automatic co-funding. Actual co-funding depends on the specifications in the annual work plan and budget availability.

## **10. LEGAL COMMITMENTS<sup>11</sup>**

Following the evaluation, Chafea establishes a list of proposals recommended for funding, ranked according to the total number of points awarded. Depending on the specifications in the annual work plan and budget availability, the highest ranked proposal(s) will be awarded co-financing.

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<sup>11</sup> Article 121 of the Financial Regulation, Article 174 of the Rules of Application.



In the event of a grant award, the coordinator of the applicant consortium is invited to enter into a grant agreement preparation period via an on-line system (SYGMA). If successful, this should result in the signature of a grant agreement, drawn up in euro and detailing the conditions and level of funding.

The grant agreement must be signed electronically first by the coordinator on behalf of the consortium and then by Chafea, the latter being the last party to sign the agreement. All co-beneficiaries must accede to the grant agreement by signing electronically the accession form to the grant.

Please note that the award of a grant does not establish an entitlement for further support after the end of the project.

## **11. FINANCIAL PROVISIONS**

The Financial Regulation and the Rules of Application<sup>12</sup> are the reference documents for the implementation of the third Health Programme.

### **11.1. General Principles**

Grants must comply with the following principles:

a) Non-cumulative award<sup>13</sup>

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<sup>14</sup>

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<sup>15</sup>

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 and affiliated entities' own resources,
- income generated by the action,
- financial contributions from third parties.

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<sup>12</sup> Please refer to footnotes 7 and 8 above

<sup>13</sup> Art 129 of the Financial Regulation

<sup>14</sup> Art. 130 of the Financial Regulation

<sup>15</sup> Art. 125 (3) of the Financial Regulation, Article 183 of the Rules of Application

d) Balanced budget<sup>16</sup>

The estimated budget of the action is to be attached to the application form. It must have revenue and expenditure in balance. A model of the budget overview can be found in Part A of the application form, available in the online submission system.

The budget must be drawn up in euros.

e) Implementation contracts/subcontracting<sup>17</sup>

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 Directive 2014/24/EU or contracting entities in the meaning of Directive 2014/23/EU 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<sup>18</sup>

The funding takes the form of mixed funding.

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 60% of **eligible costs** per each applicant. In case of exceptional utility up to 80% per applicant can be granted (see Annex VII of the Work Programme for 2016).

Consequently, part of the total eligible expenses entered in the estimative budget must be financed from sources other than the EU grant (see section 11.1 (c) above).

### ➤ **Eligible costs**

Eligible costs are actually incurred by the beneficiary of a grant and meet all the criteria indicated in Article 6 of the grant agreement.

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<sup>16</sup> Article 196 (2) of the Rules of Application.

<sup>17</sup> Article 137 of the Financial Regulation, Art. 209 of the Rules of Application.

<sup>18</sup> Article 123 of the Financial Regulation, Art. 181 of the Rules of Application.

- 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**

Chafea 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, Chafea 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 Chafea will execute a pre-financing payment (see Article 16.2 of the 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 Chafea will make an interim payment (see Article 16.3) to reimburse the eligible costs incurred in implementing the action during a given reporting period. Chafea will execute the payment within 60 days from receiving the periodic report.

The Chafea 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 Chafea through a recovery order (see Article 28 of the Model Grant Agreement).

For more details, please see Article 16 of the Model 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.

In order to limit the financial risks connected with the payment of pre-financing on the basis of a risk assessment the beneficiary may be required to lodge a guarantee in advance, for up to the same amount as the pre-financing, except for low value grants (EU contribution of EUR ≤60.000), or the payment may be split into several instalments.

The guarantee shall be denominated in euro and 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.

## **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.

To do this they must use the text, the emblem and the disclaimer available at [http://ec.europa.eu/chafea/management/visual\\_identity.html](http://ec.europa.eu/chafea/management/visual_identity.html).

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 Executive Agency / 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>19</sup> if he/she is domiciled within EU or equivalent if domiciled outside EU,
- subject of the grant,
- amount awarded.

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 Executive Agency / the Commission. Details concerning the processing of personal data are available on the privacy statement at the participants' portal:

[http://ec.europa.eu/research/participants/portal/desktop/en/support/legal\\_notices.html](http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html)

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) established and managed by the European Commission; the new system replaced the Early Warning System and the Central Exclusion Database as of 1 January 2016. The purpose of the EDES is the protection of the Union's financial interests against unreliable economic operators. This is ensured via the following two components:

- Early detection of risks threatening the Union Financial Interests via the inclusion of relevant markings (in case of suspicion or presumption);
- Exclusion of entities/ natural persons, imposition of financial penalties (administrative sanctions) in case of situations provided for by the law.

Situations that may give rise to an Early Detection/Exclusion are provided for in article 108 par. 2 and article 106 of the Financial Regulation respectively. An economic operator can only be subject to early detection/exclusion following his/her notification by the responsible service.

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.

### 14. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

Before submitting a proposal:

1. Find a call on the participant portal:

<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.**

#### ➤ 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 a helpdesk at the Chafea is available at: [CHAFEA-HP-CALLS@ec.europa.eu](mailto:CHAFEA-HP-CALLS@ec.europa.eu) weekdays between 9.30–12.00 and 14.00–17.00. The helpdesk is unavailable on weekends and public holidays.

Frequently asked questions are published on the website of Chafea:  
<http://ec.europa.eu/chafea/health/faq.html>

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 proposal ID, the applicant must use this number in all subsequent correspondence.

After the deadline for submission modifications to the application are impossible.

➤ **Annexes:**

- a) Guide for Applicants
- b) Model Grant Agreement