CALL FOR PROPOSALS FOR A PILOT PROJECT
ON CHRONIC KIDNEY DISEASES

1. BACKGROUND AND PURPOSE OF THIS CALL

Chronic diseases affect the sufferer over a long period of time and generally progress slowly. Some of them – cardiovascular diseases, cancer, chronic respiratory or kidney diseases, diabetes, mental illness – represent leading causes of mortality. To efficiently address the challenge of chronic diseases, an integrated, horizontal approach is essential – involving all the relevant levels, from communities to policy makers. The EU promotes a comprehensive approach to tackling the chronic disease burden in Europe, for example by efficiently addressing major risk factors (smoking, alcohol abuse, unhealthy diet & lack of physical activity), systematically integrating policy and action to reduce inequalities in health, or improving older people's health and quality of life and the efficiency of care systems through initiatives such as the European Innovation Partnership (EIP) on Active & Healthy Ageing. The reflection process on chronic diseases also brings together the Member States and the Commission to coordinate efforts to respond to the challenges of chronic diseases.

Among chronic diseases, chronic kidney diseases (CKD) are important diseases, often ‘silent’ but with huge costs for the patients (in terms of quality of life and life time) and for the society in general. It is estimated that one in 10 Europeans have at least one symptom of existing CKD, such as the presence of protein in the urine – an indicator of reduced kidney function. And an estimated 90% of these individuals are unaware they have early-stage CKD, as they experience few or no symptoms. Nevertheless, from its early stages onwards, CKD is associated with an increased risk of complications and death, to a large extent attributable to an ensuing cardiovascular event. Diabetes is the leading cause of kidney disease, followed by high blood pressure (hypertension). The prognosis faced by patients with CKD is linked with the effects of these other diseases. Although progress has been made in recent years, end-stage renal disease still kills more people each year than breast or prostate cancers or even road traffic accidents. Globally there was an 82% increase in the number of deaths from CKD between 1990 and 2010.

Patients who eventually reach end-stage kidney disease need renal replacement therapy (RRT) via dialysis or kidney transplantation. Data from the European Renal Association- European Dialysis and Transplant Association (ERA-EDTA) Registry shows that the prevalence of people on RRT across Europe increased by 3.3 % from 2011 to 2012 to reach 716.7 per million population. They are different types of renal replacement therapies: for dialysis hospital-based or home-based haemodialysis or peritoneal dialysis, and transplantation from a living or from a deceased donor. The type of therapy chosen will depend on the clinical status of the patient, but also of the options

1 For more information on the EU policies in the field of chronic diseases:
http://ec.europa.eu/health/major_chronic_diseases/policy/index_en.htm
http://ec.europa.eu/health/major_chronic_diseases/reflection_process/index_en.htm

2 See for example websites and recommendations of the European Kidney Health Alliance:
http://www.ekha.eu/EKHA%20Recs%20for%20Sustainable%20Kidney%20Care%2025.08.2015.pdf
available in his/her environment, as well as of orientations proposed by the treating physicians. For some patients reaching end-stage kidney disease, neither dialysis nor transplantation can be envisaged, because of the patients’ own choice or due to their poor clinical condition.

The costs for treating CKD are important. The most commonly prescribed form of dialysis in EU Member States, hospital-based haemodialysis alone costs up to €80,000 per year per patient. Moreover, this does not take into account the lost productivity caused when CKD interferes with time at work, or prevents patients from working altogether. In general, it is estimated that RRT consumes 2% of overall healthcare expenditure in Europe, for only 0.1% of the population. The total ‘direct’ cost of RRT across Europe is unknown, but one estimate puts it at up to €15 billion per year. There are additional healthcare costs of co-interventions needed to sustain RRT and to treat its complications, indirect costs associated with the time patients are absent from work while undergoing treatment, and ancillary costs such as transportation to and from the clinic. These figures also exclude the medical costs incurred before patients reach end-stage CKD – a population estimated to be around 100 times larger than the population on RRT. Moreover, choices of a type of renal replacement therapy are not always the best adapted to the patients’ needs.

Amongst renal replacement therapies, it has been demonstrated\(^3\) that kidney transplantation, in particular from living donors, offers the best results in terms of health outcomes for the transplanted patient, often avoiding dialysis (while it is also possible and necessary to ensure the best possible screening and protection of the living donors), but also in terms of cost-effectiveness; thus enabling to best treat more patients in need. Health Ministers confirmed in December 2012 in their Council Conclusions that “organ transplantation is considered to be the most cost-effective treatment for end-stage renal failure”\(^4\).

In the European Union, organ donation and transplantation\(^5\) is an issue tackled by Member States, by also at EU level. The Commission adopted in 2007 a Communication on organ donation and transplantation, and the undertaken impact assessment identified major policy challenges for organ donation and transplantation. These included 1) ensuring the quality and safety of human organs, 2) increasing organ availability and 3) enhancing the efficiency and accessibility of transplantation systems in the EU. A public consultation demonstrated wide support for EU initiatives in this field.

In December 2008, the Commission adopted a proposal for a Directive that defines quality and safety requirements for human organs, and an Action Plan\(^6\) for improving co-operation between Member States in this field. The directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation\(^7\) was adopted by the European Parliament and the Council on 7 July 2010. It provides for the appointment of Competent Authorities in all Member States, for authorisation of procurement and transplantation centers and activities, for traceability systems, as well as for the reporting of serious adverse events and reactions. The deadline for Member States to transpose the requirements of the Directive was 27 August 2012.

While Directive 2010/53/EU applies a generic approach for all types of human organs intended for transplantation (no specific considerations for kidneys, or livers, or lungs etc.), the Article 15 on

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\(^5\) For more information on the EU policies in the field of organ donation and transplantation: [http://ec.europa.eu/health/blood_tissues_organisms/organisms/index_en.htm](http://ec.europa.eu/health/blood_tissues_organisms/organisms/index_en.htm)


quality and safety aspects of living donation deserves to be mentioned in this call, as it is particularly relevant for kidney transplants from living donors: “1. Member States shall take all necessary measures to ensure the highest possible protection of living donors […]. 2. Member States shall ensure that living donors are selected on the basis of their health and medical history, by suitably qualified and trained or competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks […]. 3. Member States shall ensure that a register or record of the living donors is kept […; 4. They] shall endeavour to carry out the follow-up of living donors and shall have a system in place […] in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.” In addition to this quality and safety aspects in the EU legislation, the EU Action Plan on organ donation and transplantation states that EU “Member States should to increase organ availability, promote living donation programme following best practices” (objective 2) and therefore “support registers of living donors” (priority action 3). The development of such registers, and of methodologies to apply for such registers, has been supporting by a Working group of national experts on Living Donation and has also been co-funded, via the EU Health Programme and other EU funding mechanisms, in several projects, for example EU-LID8, ELIPSY9, the LIDOBS10 and the ELPAT11 Conferences and most recently the Joint Action ACCORD12 (Work package 4, building upon previous projects). In addition, EU-funded Research projects relating to kidney diseases or transplantation will be valuable for this pilot project, for example POSAT, COPE, DIREKT; Kidney Injury, Technology, OLDIAS and SCOPE.

Another important aspect of organ transplantation in general and of kidney transplantation in particular is the follow-up of transplanted patients. Indeed, it is not worth transplanting patients if they do not survive the transplant procedures and also if they do not have a good, or at least improved quality of life after transplantation. In addition, the collection of post-transplant results can offer findings on the mid- and long-term only if done in a consistent and comprehensive manner, via commonly defined methodologies. In its recital 24, Directive 2010/53/EU mentions that “the collection of relevant post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union.” Under its Objective 5 (improving quality and safety), the EU Action Plan on organ donation and transplantation also recognises the need for the “evaluation of post-transplant results”, its Priority Action 9, with two actions: action 9.1. “develop common guidelines of terms and methodology to evaluate the results of transplantation”, and action 9.2. “develop a register or network of registers to follow up organ recipients”. Action 9.1. has been implemented via the EU funding of the international collaborative project EFRETOS13 (European Framework for the Evaluation of Organ Transplants). It is proposed to implement Action 9.2. via the present pilot project, building upon the results, methodologies and terms delivered in the EFRETOS project.

Adopted and published in July 2015, the Financing decision and its annex describing the intended scope of this pilot project are available at:

http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3

8 http://www.eulivingdonor.eu/eulid/index.html
9 http://www.eulivingdonor.eu/elipsy/index.html
10 http://www.eulivingdonor.eu/lidobs/index.html
11 http://www.esot.org/ELPAT/home
12 http://www.accord-ja.eu/living-donor-registries
13 http://www.efretos.org/
Financing decision:


Annex:


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\(^{14}\) for the pilot project “The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes” was adopted and published\(^{15}\) on 10 July 2015. Its Annex\(^{16}\) sets out three main priority areas for this pilot project on chronic kidney diseases to be implemented through the present call:

1) a **study to assess the different treatment modalities for chronic kidney diseases** (haemodialysis, peritoneal dialysis (hospital-based or home-based), transplantation from deceased donors and living donors, conservative management) used currently in the different EU Member States and associated countries; the frequency of choice of each of the available options, the factors influencing the treatment choice, the impacts in terms of health and costs, both at patient’s level and societal level;

2) the establishment by EU Member States of **registries to follow-up living donors**\(^{17}\), as required under Article 15 of Directive 2010/53/EU, following the methodology and data set already defined in the EU-funded Joint Action ACCORD; solutions should be proposed for each Member State to fulfill its legal obligation, while international data sharing should also be put in place for Member States interested;

3) the establishment of **follow-up registers for transplant recipients**, at minima at national levels and possibly also at European level, following the methodologies and recommendations already formulated and tested, for example via the EU-funded project EFRETOS.

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

3. TIMETABLE


\(^{15}\) http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3


\(^{17}\) Kidney living donors (who represent the huge majority of living donors), but also liver living donors, as they might be more at risk than kidney donors and because results of previous projects are also defined and therefore available (e.g. data set to be collected in a register for such donors).
The final deadline for the submission of proposals is **16 June 2016**.

<table>
<thead>
<tr>
<th>Stages</th>
<th>Date/period</th>
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<tr>
<td>a) Publication of the call</td>
<td>31/03/2016</td>
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<tr>
<td>b) Deadline for submitting applications</td>
<td>16/06/2016</td>
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<tr>
<td>c) Evaluation period (indicative)</td>
<td>mid-June to end of July 2016</td>
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<tr>
<td>d) Information to applicants (indicative): Official letter</td>
<td>July – August 2016</td>
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<td>e) Signature of grant agreement (indicative)</td>
<td>August-September 2016</td>
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<tr>
<td>f) Starting date of the action (indicative)</td>
<td>October 2016</td>
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4. **Budget available**

The total budget earmarked for the co-financing of projects is estimated at EUR 1,000,000. The maximum possible rate of co-financing of the eligible total costs is 80%.

5. **Admissibility requirement**


- 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.

6. **Eligibility criteria**

6.1. Eligible applicants

Grant applications are eligible if submitted by legal persons. More specifically, the applicants\(^{18}\) must be legally established organisations, public authorities, public sector bodies, in particular research organisations.

\(^{18}\) Wherever "applicants" is written this means the coordinator and the co-applicants.
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 (with or without legal personality) established in at least five different EU Member States. Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other). Proposals which do not involve at least 5 applicants from 5 different countries fulfilling the above conditions will be rejected.

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 of the following countries are eligible:

- One of the 28 EU Member States;

Implementation period

As a rule, the maximum duration of project is 36 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.

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 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;
7.2. Exclusion from award:

Applicants will not be awarded co-funding, in the course of the grant award procedure, 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. The applicants should follow the instructions in the participant portal.

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 action is being carried out or the year for which the grant is awarded and to participate in its funding.

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.

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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.

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:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Maximum points</th>
<th>Threshold</th>
<th>Threshold in % of max. points</th>
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<tbody>
<tr>
<td>1- Policy and contextual relevance</td>
<td>40</td>
<td>20</td>
<td>50%</td>
</tr>
<tr>
<td>2- Technical quality</td>
<td>30</td>
<td>15</td>
<td>50%</td>
</tr>
<tr>
<td>3- Management quality and budget</td>
<td>30</td>
<td>15</td>
<td>50%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100</td>
<td>50</td>
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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 activities in the field of chronic kidney diseases and organ transplantation such as Directive 2010/53/EU and to the EU Action Plan on Organ Donation & Transplantation, also with regards 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 (health authorities, healthcare professionals and patients), long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,
– contribution to complementarity, synergy and compatibility with relevant EU policies, programmes and specific EU-funded projects;

(d) Pertinence of geographical coverage (8 points):
Applicants must ensure that the geographical coverage of the project is commensurate with its objectives, explain the role of eligible countries as partners, the location of different activities, and the relevance of project resources or the target populations they represent. A sufficient variety of Member States must be covered reflecting different situations in EU Member States;

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

(b) Content specification (5 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 (5 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, national and international level;

(d) Evaluation strategy (5 points):
Applicants must clearly explain the methods proposed and indicators chosen and their adequacy;

(e) Dissemination, implementation and sustainability strategy (10 points, threshold: 5 points):
Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology to ensure not only a large dissemination of the projects’ results, but also their transferability and self-sustainability into the different healthcare systems of European countries. These aspects are particularly important for the IT components of the project and critical for its success. They should be taken into account in all work packages and over the whole timeline of the project.

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

(a) Planning, organisation and implementation (5 points):
Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks to be implemented by all partners to achieve results self-sustainable within national healthcare systems even after the end of the project, 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; The quality of partnerships is critical also in terms of implementation within national healthcare systems;

(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; Communication is understood here both as internal communication (amongst partners involved in the project and related stakeholders to be involved for a successful implementation of the project) as well as external communication (to disseminate project’s results);
(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 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:

21 Please refer to footnotes 27 and 28 above
- 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 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 (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 make an interim payment (see Article 16.3) to reimburse the eligible costs incurred in implementing the action during a given reporting period. The Commission will execute the payment within 60 days from receiving the periodic report.

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 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\textsuperscript{22} 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 Commission and the Chafea. Details concerning the processing of personal data are available on:


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\textsuperscript{23}. For more information, see the Privacy Statement on 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:


2. Create an account to submit a proposal:

\textsuperscript{22} European Union Official Journal L 39, of 10 February 2007.


3. Register all partners via the beneficiary registry:

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

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:

- Guide for applicants
- Model grant agreement