Call title: HEALTH 2011: TWO-STAGE

Call identifier: FP7-HEALTH-2011-two-stage

Proposal submission and evaluation: two-stage procedure.

Date of publication: 20 July 2010

Deadline for stage 1 proposals: 13 October 2010 at 17:00:00 (Brussels local time)¹

Indicative budget: EUR 498 million from the 2011 budget²

The budget for this call is indicative. The final budget awarded to actions implemented through calls for proposals may vary:

the final budget of the call may vary by up to 10% of the total value of the indicated budget for each call; and

any repartition of the call budget may also vary by up to 10% of the total value of the indicated budget for the call.

Table 1: Indicative budget lines

ACTIVITY/AREA	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN H	EALTH
1.1 HIGH-THROUGHPUT RESEARCH	50
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS	90
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY	33
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT ANI	D AGEING
2.2.1 BRAIN AND RELATED DISEASES	79
2.2.2 HUMAN DEVELOPMENT AND AGEING	30
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT M PUBLIC HEALTH	AJOR THREATS TO
2.3.1 ANTIMICROBIAL DRUG RESISTANCE	31
2.3.3 EMERGING EPIDEMICS	15
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	
2.4.1 CANCER	42
2.4.2 CARDIOVASCULAR DISEASES	44
2.4.3 DIABETES AND OBESITY	63
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS	
3.3 HEALTH PROMOTION	21

Table 2: Topics called:

¹ The Director-General responsible for this call may delay this deadline by up to two months.

² Under the condition that the draft budget for 2011 is adopted without modifications by the budgetary authority.

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Activity/Area	Topics called	Funding Schemes and particular requirements
1.BIOTECHNOL	OGY, GENERIC TOOLS AND MEDICAL 1	FECHNOLOGIES FOR HUMAN HEALTH
1.1 HIGH-THROUG	HPUT RESEARCH	
1.1	HEALTH.2011.1.1-1: SME-targeted research for developing tools and technologies for high-throughput research	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded
1.1	HEALTH.2011.1.1-2: Genome-based biomarkers for patient stratification and pharmacogenomic strategies	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded
1.4 INNOVATIVE T	HERAPEUTIC APPROACHES AND INTERVENTIO	NS
1.4	HEALTH.2011.1.4-1: Regenerative medicine clinical trials ³	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
1.4	HEALTH.2011.1.4-2: Tools, technologies and devices for application in regenerative medicine.	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded

³ <u>http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/</u> Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

1.4	HEALTH.2011.1.4-3: Development and production of new, high-affinity protein scaffolds for therapeutic use.	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.
2. TRANSLATING	G RESEARCH FOR HUMAN HEALTH	
2.1. INTEGRATIN SYSTEMS BIOLO	IG BIOLOGICAL DATA AND PROCESSE: DGY	S: LARGE-SCALE DATA GATHERING,
2.1.1 Large-scale d	lata gathering	
2.1.1	HEALTH.2011.2.1.1-2: Proteins and their interactions in health and disease.	Collaborative Project (large-scale integrating project). Requested EU contribution per project: Maximum EUR 12 000 000. One or more proposals can be selected.
2.1.1	HEALTH.2011.2.1.1-3: Large-scale genomics approaches to identify host determinants of infectious diseases.	Collaborative Project (large-scale integrating project). Requested EU contribution per project: Maximum EUR 12 000 000. Only up to one proposal can be selected.
2.2. RESEARCH ON	THE BRAIN AND RELATED DISEASES, HUMAN I	DEVELOPMENT AND AGEING
2.2.1. Brain and br	ain-related diseases	
2.2.1	HEALTH.2011.2.2.1-1: Investigator- driven clinical trials ⁴ for childhood-onset neurodegenerative diseases.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.2.1	HEALTH.2011.2.2.1-2: Understanding the role of neuroinflammation in neurodegenerative diseases.	Collaborative Project (large scale integrating project). Requested EU contribution per project: Maximum EUR 12 000 000. One or more proposals can be selected.
2.2.1	HEALTH.2011.2.2.1-3: Addictive and/or compulsive behaviour in children and adolescents: translating pre-clinical results into therapies.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.2.2. Human deve	lopment and ageing	
2.2.2	HEALTH.2011.2.2.2-1: Investigator- driven clinical trials ⁵ for therapeutic interventions in elderly populations.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.

⁴ http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/

Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

⁵ <u>http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/</u> Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

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2.2.2	HEALTH.2011.2.2.2-2: Linking human development and ageing.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected.
2.3. TRANSLATION HEALTH	AL RESEARCH IN MAJOR INFECTIOUS DISEASE	S: TO CONFRONT MAJOR THREATS TO PUBLIC
2.3.1. Anti-microb	vial drug resistance	
2.3.1	HEALTH.2011.2.3.1-1: Investigator- driven clinical trials ⁶ of off-patent antibiotics.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.3.1	HEALTH.2011.2.3.1-4: Development of multi-analyte diagnostic tests.	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded
2.3.1	HEALTH.2011.2.3.1-5: Development of tools to control microbial biofilms with relevance to clinical drug resistance.	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded
2.3.3. Potentially r	new and re-emerging epidemics	
2.3.3	HEALTH.2011.2.3.3-1: Identification of factors promoting the emergence of pathogens with human pandemic potential from pathogens with a zoonotic background and related prevention strategies.	Collaborative Project (large-scale integrating project). Requested EU contribution per project: Maximum EUR 12 000 000. Only up to one proposal can be selected.
2.3.3	HEALTH.2011.2.3.3-3: Development of an evidence-based behavioural and communication package to respond to major epidemic outbreaks.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 2 000 000. One or more proposals can be selected

⁶ <u>http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/</u> Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

2.4. TRANSLA	TIONAL RESEARCH IN OTHER MAJOR DISEASES	
2.4.1. Cancer		
2.4.1	HEALTH.2011.2.4.1-1: Investigator- driven treatment trials ⁷ for rare cancers.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.4.1	HEALTH.2011.2.4.1-2: Translational research on cancers with poor prognosis.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected.
2.4.2. Cardiov	/ascular diseases	
2.4.2	HEALTH.2011.2.4.2-1: Investigator- driven clinical trials ⁸ for the management of cardiovascular diseases.	Collaborative Project (large-scale integrating project). Requested EU contribution per project: Maximum EUR 12 000 000. One or more proposals can be selected.
2.4.2	HEALTH.2011.2.4.2-2: Evaluation and validation studies of clinically useful biomarkers in prevention and management of cardiovascular diseases.	SME-targeted Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected. Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded
2.4.3. Diabete	es and obesity	
2.4.3	HEALTH.2011.2.4.3-1: Investigator- driven clinical trials ⁹ to reduce diabetes complications.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.4.3	HEALTH.2011.2.4.3-2: Development of novel treatment strategies based on knowledge of cellular dysfunction.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.
2.4.3	HEALTH.2011.2.4.3-3: Molecular and physiological effects of lifestyle factors on diabetes/obesity.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 6 000 000. One or more proposals can be selected.

⁷ <u>http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/</u> Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

⁹ http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/

⁸ <u>http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/</u> Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 17/18

2.4.3	HEALTH.2011.2.4.3-4: Genetic and environmental factors in obesity and/or diabetes in specific populations.	Specific International Cooperation Action (SICA), Collaborative Project (small or medium-scale focused research project) target regions: Mediterranean countries, Africa, Asia Latin-America). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected.
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3.3 HEALTH PROMO	DTION	
3.3	HEALTH.2011.3.3-1: Developing methodologies to reduce inequities in the determinants of health.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected.
3.3	HEALTH.2011.3.3-2: Analysis of integrated strategies for sustainable behaviour change.	Collaborative Project (small or medium-scale focused research project). Requested EU contribution per project: Maximum EUR 3 000 000. One or more proposals can be selected.

It is important to note that once the basic conditions for eligibility are met – such as the minimum number of participants (in most cases 3) or the ceiling for the maximum requested EU contribution to the budget – it is entirely up to the applicants to propose a number of partners, a duration of the project or the financial contribution requested from the EU. The quality, feasibility, implementation and impact of the proposed work as well as the match between the expertise of the consortium and the project goals are subject to the evaluation carried out by independent experts.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation.

Eligibility conditions (stage 1 and stage 2):

The general eligibility criteria are set out in Annex 2 to this work programme, and in the guide for applicants for each funding scheme. Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.

Table3: Standard minimum number of participating legal entities for all funding schemes used in the call, in line with the Rules for Participation and in the below format, unless otherwise specified in the work programme and/or table 2.

Funding scheme	Minimum participation conditions
Collaborative project	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.
Collaborative project for specific cooperation Action (SICA) dedicated to international cooperation partner countries	At least 4 independent legal entities. Of these, 2 must be established in different MS or AC. The other 2 must be established in different international cooperation partner countries

¹⁰ The list of international cooperation partner countries (ICPC) is provided in Annex I of the Cooperation Programme <u>ftp://ftp.cordis.europa.eu/pub/fp7/docs/icpc-list.pdf</u>

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The eligibility criteria apply to both first and second stage proposals. At stage 1, only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds, while part B will be used to check the number of eligible participants. At stage 2, part A will be used alone to determine these eligibility conditions.

The following additional eligibility criteria apply in this call:

- It is important to note that the upper limits for the Requested EU contribution given per topic in table 2 of this call fiche will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible.
- At stage 2, for topics HEALTH.2011.1.1-1, HEALTH.2011.1.1-2, HEALTH.2011.1.4-2, HEALTH.2011.2.3.1-4, HEALTH.2011.2.3.1-5 and HEALTH.2011.2.4.2-2, the following additional eligibility criterion will be applied: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30-50% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*
- At stage 2, for topic HEALTH.2011.1.4-3 the following additional eligibility criterion will be applied: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Evaluation procedure:

- The evaluation criteria and scoring scheme are set out in annex 2 to the work programme.
- Proposal page limits: Applicants must ensure that proposals conform to the page limits and layout given in the Guide for Applicants, and in the proposal part B template available through the EPSS.

The Commission will instruct the experts to disregard any pages exceeding these limits.

The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

- A two-stage submission and evaluation procedure will be used.
- Experts will carry out the individual evaluation of proposals remotely.

Additional information regarding criteria and procedures:

- For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Successful proposals must pass the following minimum thresholds.
- In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme.
- The following aspects will be considered for SME-targeted Collaborative Projects under the evaluation criterion relating to 'implementation':
 - Proposals are expected to have a substantial involvement of SMEs. As an indication of the expected level of involvement, evaluators should note that only proposals which fulfil the conditions as set out in the topic for the percentage of the estimated EU contribution going to SMEs will be eventually selected. This will be checked definitively at the end of any negotiation.
 - The leading role of SMEs with R&D capacities: the coordinator does not need to be an SME, but the participating SMEs should have a decision making power in the project management, and the output should be for the benefit of the participating SMEs and the targeted SME-dominated industrial communities.
- **Proposal ranking:** The series of priority lists will be prepared by the panels of external experts, per indicative budget line as set out in this call fiche. The aspects taken into account for establishing a priority order for ranking of proposals are set out in annex 2 of the work programme.

Stage 1 proposals

- Stage 1 proposals must be submitted by the deadline mentioned above.
- Stage 1 proposals should follow the instructions set out in the guide for applicants and in the proposal part B template available through EPSS. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones to be reached (intended results), their intended use and the expected impact (scientific, economic, social, environmental, etc.) in a maximum of 5 pages (excluding the cover page and the required tables). Applicants should also provide an additional 1 page (maximum) to describe the consortium and the estimated financial resources involved. The maximum page limits of each section must be respected. The Commission will instruct the independent external experts (evaluators of proposals) to disregard any pages in excess of these limits. A minimum font size of 11 is required.
- Stage 1 proposals will be individually evaluated remotely by independent external experts and discussed in consensus meetings.
- Stage 1 proposals will be evaluated on the basis of the following two criteria: Scientific/technological quality and Impact. For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. Proposals must pass the minimum thresholds as follows:

Table 4:	Threshold	s for evaluation	criteria for t	first stage
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Criterion	Minimum threshold
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S/T quality	4/5
Impact	3/5
Overall threshold	8/10

- Coordinators of proposals retained at stage 1 (proposals passing the evaluation thresholds) will be invited to submit a complete proposal (stage 2 proposal) that will then be evaluated against the entire set of evaluation criteria. In line with the objectives of each topic, additional eligibility criteria may be indicated in the work programme.
- Proposals will be retained at stage 1 (proposals passing the evaluation thresholds) to a total budgetary value of maximum 3 times the indicative budget for this call.

Stage 2 proposals

- The deadline for submission for stage 2 proposals will be specified in the invitation to submit. The *indicative deadline* for stage 2 proposals is: February 2011.
- Stage 2 proposals are evaluated on the basis of the following three criteria: *Scientific/technological quality* and *Implementation* and *Impact*.
- For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. Proposals must pass the minimum thresholds as follows:

Criterion	Minimum threshold
S/T quality	4/5
Implementation	3/5
Impact	3/5
Overall threshold	12/15

Table 5: Thresholds for evaluation criteria for second stage

- In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme.
- The following aspects will be considered for SME-targeted Collaborative Projects under the evaluation criterion relating to 'implementation':
 - Proposals are expected to have a substantial involvement of SMEs. As an indication of the expected level of involvement, evaluators should note that only proposals which fulfil the conditions as set out in the topic for the percentage of the estimated EU contribution going to SMEs will be eventually selected. This will be checked definitively at the end of any negotiation.

• The leading role of SMEs with R&D capacities: the coordinator does not need to be an SME, but the participating SMEs should have a decision making power in the project management, and the output should be for the benefit of the participating SMEs and the targeted SME-dominated industrial communities.

Proposal ranking at stage 2:

- *For stage 2:* There will be differing numbers of proposals short-listed according to the funding scheme and topic:
 - For Large-scale Integrating Projects, Coordination and Support Actions, only up to one proposal can be funded per topic, unless otherwise stated in the topic description in table 2 (particular requirements for specific topics).
 - For small and medium-scale Focused Research Projects, one or more proposals can be funded per topic, unless otherwise stated in table 2 (particular requirements for specific topics)..

However, there may be topics for which no proposals are of sufficient quality to be selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals.

- **For stage 2:** The Commission ranked lists of proposals to be retained for negotiation will be based on the priority list established by the panel of independent external experts taking into account the budget available for each budget line (as indicated in this call for proposals). For each budget line, a number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.

Indicative timetable for Stage 1 and 2: The stage 1 evaluation should be finalised at the end of December 2010. The evaluation of the stage 2 is expected to take place in March/April 2011. Overall evaluation results: estimated to be available within 3 months after the closure date for stage 2 proposals. It is expected that grant agreement negotiations for short-listed proposals would begin in June 2011.

Consortium agreements: Participants in collaborative projects or networks of excellence with a requested **EU-contribution higher than EUR 3 000 000** are required to conclude a consortium agreement. For collaborative projects with a requested **EU-contribution up to EUR 3 000 000** a consortium agreement is not mandatory but recommended. For **coordination and support actions** a consortium agreement is not mandatory.

Forms of grant and maximum reimbursement rates for projects funded through the Cooperation work programme are given in Annex 3.

Flat rates to cover subsistence costs: In accordance with Annex 3 to this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant Guides for Applicants for this call. The applicable flat rates are available at the following website: <u>http://cordis.europa.eu/fp7/find-doc_en.html</u> under 'Guidance documents/Flat rates for daily allowances'.

Dissemination. Grant agreements of projects financed under this call for proposals will include the special clause 39 on the "Open Access Pilot in FP7". Under this clause, beneficiaries are required to make their best efforts to ensure free access to peer-reviewed articles resulting from projects via an institutional or subject-based repository.