



**European Participation in U.S. Federal Science & Technology
Research Funding Programmes:
Survey of Researchers and Institutions
on National Institutes of Health Grant Funding**

Appendices



February 2011

About the Link2US Project

The Link2US project facilitates easy access to relevant information on U.S. cooperation programmes through electronic communities such as a website, e-newsletter, and virtual helpdesk and designated activities such as training workshops.

Link2US is:

- Mapping opportunities of U.S. federal collaborative funding schemes and rules for participation through research and analyses.
- Raising awareness among the European scientific community by disseminating information about programmes and funding opportunities through a multi-faceted network.
- Identifying and analyzing potential obstacles to cooperation through these programmes and funding schemes so that they may be avoided and/or that solutions may be found.

Link2US is coordinated by the American Association for the Advancement of Science (AAAS) and implemented together with the Austrian Research Promotion Agency (FFG), Hungarian Science & Technology Foundation (TETALAP), and Italy's Agency for the Promotion of European Research (APRE).

Link2US is co-funded by the European Union's Capacities Programme on International Cooperation of the 7th Framework Programme on Research and Technological Cooperation under grant agreement number 244371.

For more information:

www.EuUsScienceTechnology.eu/Link2US/



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Disclaimer

The information contained within this report has been compiled from public sources and communications with U.S. funding entities. This report is not an official publication of any U.S. federal government entity nor necessarily reflects the views of the U.S. federal government or of the organizations comprising the Link2US project. The opinions and any errors within the report are entirely the responsibility of the authors.

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Appendices

Appendix 1: NIH EU-Based Researchers Questionnaire Data

Appendix 1A: Introductory Letter to Researchers

Dear Researcher,

The Link2US Project (more information below signature and attached), co-funded by the European Union (EU) Framework Programme and coordinated by the American Association for the Advancement of Science (AAAS), the world's largest general scientific society and publisher of the journal Science, seeks your assistance with its Questionnaire on EU Researcher Participation in U.S. Funding Programmes.

You are receiving this questionnaire because you have had or currently have one or more grants or other funding awards from the U.S. National Institutes of Health (NIH). If you have not received any awards from NIH, please respond to this email (Link2US@aaas.org) and we will promptly remove you from our list.

The main objective of this questionnaire is to identify barriers and other challenges that EU institutions and researchers face when applying to and participating in NIH research funding programmes. The outcomes of this questionnaire will be used in an analysis of key issues to address in improving funding programmes for international cooperation, which will be shared with stakeholders (including the European Commission and U.S. funding bodies). This questionnaire is not officially connected with any U.S. federal funding body.

Directions: The questionnaire will be implemented electronically. To complete the survey, please visit <http://www.surveymonkey.com/s/Link2US>. The questionnaire is open from 14-28 September 2010. Please submit your completed questionnaire no later than 18h00 Central European Time on 28 September.

Confidentiality: All information will be treated confidentially and will only be distributed in an anonymous format (no attribution to individuals) to any entity outside of the Link2US Project (e.g., government funding agencies).

Should you have any questions, please contact Ms. Stephanie Pals (Link2US@aaas.org; Tel: +1 (202) 326-6663), Link2US project officer.

Thank you for your time and effort in responding to this survey. You will receive a copy of the report once the analysis is completed. Your responses will contribute to improving and strengthening EU - U.S. science and technology cooperation.

Sincerely,
Dr. Tom Wang
Coordinator, Link2US Project
Director for International Cooperation,
American Association for the Advancement of Science (AAAS)
Link2US@aaas.org



www.EuUsScienceTechnology.eu/Link2US

The Link2US Project aims to enhance the understanding of U.S. collaborative research funding programmes by facilitating easy access to relevant information on U.S. cooperation programmes through electronic communities such as a website, e-newsletter, and virtual helpdesk. The Project is co-funded by the EU's Capacities Programme on International Cooperation under the 7th Framework Programme for Research and Technological Cooperation. See attached document for more information.

Appendix 1B: Questionnaire

European Union (EU) Researcher Participation in U.S. Funding

Questionnaire for Researchers: EU Researcher Participation in U.S. Funding ...

Dear Researcher,

Thank you for participating in the Link2US Project's¹ Questionnaire for Researchers: European Union (EU) Researcher Participation in U.S. Funding Programmes. You are receiving this questionnaire because you have had or currently have one or more grants or other funding awards from the U.S. National Institutes of Health (NIH). If you have not received any awards from NIH, please contact us (Link2US@aaas.org) and we will remove you from our list.

The main objective of this questionnaire is to identify barriers and other challenges that EU researchers and institutions face when applying to and participating in NIH research funding programmes. The outcomes of this questionnaire will be used in an analysis of key issues to address in improving funding programmes for international cooperation, which will be shared with stakeholders (including the European Commission and U.S. funding bodies).²

Directions: Please answer all questions in relation to your own experience with NIH funding programmes. The estimated time for completion of the questionnaire is 10-15 minutes. The questionnaire is open from 14-28 September 2010. Please submit your completed questionnaire no later than **18h00 Central European Time on 28 September**. As you are completing the questionnaire, your answers are saved when you click on the "next/save" or "submit" button at the bottom of each page. Should your session be interrupted, you may return to the system at a later time to pick up where you left off and finish, as long as you are using the same computer and browser and cookies are accepted.

Confidentiality: All information will be treated confidentially and will only be distributed in an anonymous format (no attribution to individuals) to any entity outside of the Link2US Project (e.g., government funding agencies).

Should you have any questions, please contact Ms. Stephanie Pals (Link2US@aaas.org; Tel: +1 (202) 326-6663), Link2US project officer.

Thank you for your time and effort in responding to this survey. You will receive a copy of the report once the analysis is completed. Your responses will contribute to improving and strengthening EU – U.S. science and technology cooperation.

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²This questionnaire is not officially connected with any U.S. federal funding body.

Questionnaire for Researchers: EU Researcher Participation in U.S. Funding ...

GENERAL INFORMATION/DEMOGRAPHICS

* 1. Name (Surname, Given Name)

European Union (EU) Researcher Participation in U.S. Funding

*** 2. Title**

*** 3. Name of your institution**

*** 4. Location of institution (country)**

5. Your department, center, or other organizational unit within your institution

*** 6. Which of the following best describes your organization?**

*** 7. Please indicate the number of new NIH awards that you received between 2003-2010 for each of the following categories (enter numeral; if none, enter 0):**

Direct awards (e.g., you are the principal investigator):

Research Project Grant (R01)	<input type="text"/>
Small Grant Program (R03)	<input type="text"/>
NIH Exploratory/Developmental Research Grant Program (R21)	<input type="text"/>
Research Project Cooperative Agreement (U01)	<input type="text"/>
Other (please specify using this format: type, number; type, number; etc.)	<input type="text"/>

Indirect awards (e.g., foreign component on a U.S.-based award, or subcontract):

Research Project Grant (R01)	<input type="text"/>
Small Grant Program (R03)	<input type="text"/>
NIH Exploratory/Developmental Research Grant Program (R21)	<input type="text"/>
Research Project Cooperative Agreement (U01)	<input type="text"/>
Other (please specify using this format: type, number; type, number; etc.)	<input type="text"/>

European Union (EU) Researcher Participation in U.S. Funding

*** 8. Contribution of NIH funding to your overall research programme: (please select all statements that are appropriate)**

- Provides a significant financial resource (makes up more than 25% of all your research funding in a given year)
- Provides credibility to access other funding sources
- Provides access to U.S. researchers/institutions
- None of the above
- Other (please specify)

Questionnaire for Researchers: EU Researcher Participation in U.S. Funding ...

U.S. FUNDING PROGRAMME QUESTIONS

*** 9. General challenges to participation in NIH funding programmes (for each of the following issues, rate from 0-5: where as a guide 5 is extremely important and needs priority attention; 3 is challenging but no more so than other funding programmes; 0 is not an issue).**

	Rate
Communication and information awareness of programmes	<input type="text"/>
Contractual issues and intellectual property	<input type="text"/>
Lack of administrative support from own organization	<input type="text"/>
Lack of administrative support from the U.S. funding body	<input type="text"/>
Lack of complementary funding	<input type="text"/>
Differences and/or lack of recognition between U.S. and European policy requirements on issues such as animal safety, protection of human subjects, research integrity, financial conflict of interest, etc.	<input type="text"/>
Cultural differences in management of grants	<input type="text"/>
Other (please specify and indicate rating)	
<input type="text"/>	

Information and Awareness

*** 10. Before receiving your first NIH award, had you studied or conducted research in the United States?**

European Union (EU) Researcher Participation in U.S. Funding

*** 11. Before receiving your NIH first award, had you previously collaborated with a U.S.-based researcher at: (check all that apply)**

- NIH
- Any other U.S. federal government laboratory or affiliated laboratory (e.g., U.S. national laboratory)
- Any non-governmental U.S. research institution (e.g., public or private university)
- None

*** 12. How do/did you hear about new NIH funding opportunities? (check all that apply)**

- Administrative staff at your institution
- Colleagues/collaborators at your own or other non-U.S. institution
- Commercial vendor of funding opportunities database/search
- NIH website
- NIH programme officer or other staff
- U.S. colleagues or collaborators
- Other (please specify)

*** 13. Are new NIH funding opportunities easy to find out about?**

If No, please explain.

14. Please describe any other issues related to awareness of NIH funding programmes and opportunities.

Questionnaire for Researchers: EU Researcher Participation in U.S. Funding ...

Legal/Policy/Administrative

European Union (EU) Researcher Participation in U.S. Funding

- * **15. Challenges to participation in NIH funding programmes (for each of the following issues, rate from 0-5: where as a guide 5 is extremely important and needs priority attention; 3 is challenging but no more so than other funding programmes; 0 is not an issue)**

	Rate
Audit requirements	<input type="text"/>
Budgeting requirements (e.g., detailed budgets required as opposed to modular budgets)	<input type="text"/>
Facilities & administrative (F&A)/indirect cost recovery limits	<input type="text"/>
Intellectual property	<input type="text"/>
Other contractual (grant) requirements	<input type="text"/>
Other (please specify and indicate rating)	<input type="text"/>

- * **According to the NIH Grants Policy Statement, proposals originating from outside the United States (but not U.S. domestic applications with foreign components) are subject to these additional review criteria: 1) Whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and, 2) Whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Center (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States.**

16. Have you experienced challenges due to these considerations?

If Yes, please explain.

17. Please describe any other issues related to administrative/policy/legal aspects of NIH funding programmes and opportunities.

General

European Union (EU) Researcher Participation in U.S. Funding

18. What recommendations could ease/improve research collaboration through NIH funding programmes?

19. What have been positive experiences/aspects/issues in applying for and/or receiving NIH awards that could be lessons for other (U.S. or European) funding bodies?

Appendix 1C: Member State of Current Institution

Member State of Current Institution	
<u>Country</u>	<u>Response Amount</u>
Austria	1
Belgium	2
Croatia	1
Denmark	2
Estonia	1
Finland	1
France	4
Germany	7
Greece	1
Ireland	3
Italy	7
Netherlands	3
Poland	1
Spain	2
Sweden	10
United Kingdom	32
Total Responses	78

Appendix 1D: Breakdown of Organization Type

Breakdown of Organization Type	
<u>Organization Type</u>	<u>Response Amount</u>
Higher Education institution	58
Research organization - public or private	20
Industry	0
Total Responses	78

Appendix 1E: Number of New NIH Grants Awarded

Number of New NIH Grants Awarded Between Fiscal Year 2003-2010		
<u>Award Name</u>	<u>Direct Award Total Amount</u>	<u>Indirect Award Total Amount</u>
Research Project Grant (R01)	58	13
Small Grant Program (R03)	2	0
NIH Exploratory /Developmental Research Grant Program (R21)	11	0
Research Project Cooperative Agreement (U01)	8	2
Other	3	6
Total Award Amount	82	21

*Researchers were able to insert data for all that apply (a total of 78 individual researchers responded)

Appendix 1F: Did Researchers Study in the U.S. Prior to First NIH Grant

Did Researchers Study in the U.S. Prior to Receiving their First NIH Grant	
<u>Response</u>	<u>Response Amount</u>
Yes	56
No	22
Total Responses	78

Appendix 1G: Type of U.S. Based Institution Previously Collaborated With

Type of U.S. Based Institution Previously Collaborated with Before First NIH Grant was Awarded

<u>Type of Institution</u>	<u>Response Amount</u>
Non-governmental U.S. research institution	55
U.S. National Institutes of Health	24
Other U.S. federal government or affiliated laboratory	14
None	13
Total Responses	106

*Researchers were able to check all that apply (a total of 78 individual researchers responded)

Appendix 1H: General Challenges to Participation in NIH Funding Programmes

General Challenges to Participation in NIH Funding Programmes

<u>Challenge</u>		<u>Response</u>	<u>Amount</u>
Communication and information awareness of programmes	Low	0	5
		1	11
	Medium	2	8
		3	24
		4	12
	High	5	18
		Total Responses	78
Contractual issues and intellectual property	Low	0	19
		1	10
	Medium	2	12
		3	24
		4	11
	High	5	2
		Total Responses	78
Cultural differences in management of grants	Low	0	18
		1	9
	Medium	2	13
		3	18
		4	7
	High	5	13
		Total Responses	78
Differences and/or lack of recognition between U.S. and European policy requirements on issues such as animal safety, protection of human subjects, research integrity, financial conflict of interest, etc.	Low	0	15
		1	16
	Medium	2	13
		3	16
		4	15
	High	5	3
		Total Responses	78

		0	9
Lack of administrative support from own organization	Low	1	7
		2	8
	Medium	3	17
	High	4	25
		5	12
Total Responses			78

		0	20
Lack of administrative support from U.S. funding body	Low	1	19
		2	12
	Medium	3	18
	High	4	7
		5	2
Total Responses			78

		0	20
Lack of complementary funding	Low	1	8
		2	6
	Medium	3	23
	High	4	14
		5	7
Total Responses			78

Other (All information below are direct quotes from researchers)

Almost all administrative issues of grant application and management due to cultural and administrative differences between US and Germany (rate 5).
Budgeting allowances - indirect cost recovery.
Extremely competitive for non-US applicants.
Have been a lot of changes to NIH funding. Difficult for non-US bodies to keep up to date as they do not have the staff dedicated to US funding. NIH could perhaps provide a clear guide to what schemes are open to non-US based researchers.
Indirect cost provision is insufficient therefore obtaining a grant from NIH actually costs money to the department so there is an incentive AGAINST obtaining these grants.
Low indirect costs for foreign institutions.
Low overheads for non-us institutions leads to institutions devaluing NIH as a source of funds.

Many regard that EU researchers shouldn't be applying because it would take funding away from US researchers.

One has to argue that the proposed research is not being done or cannot be done in the US. This is a major hurdle in most cases. - The maximum overhead (F&A) for foreign institutions is 8%. The actual institutional overhead is more than 8%, for which the department is charged. This means that one loses money on having an NIH grant.

One issue relates to the need for all collaborating institutions to be registered for Grants.gov. Although this is not a problem for my own institution, it has blocked progress on collaborative projects with other European Partners who do not have the same awareness of the NIH and its administrative requirements (Rating 5).

Technical facilities needed for a first class competitive research.

There are major differences in grant writing and what is expected of a research grant application between USA and most European countries.

There is an understandable bias of study section reviewers against European applicants. This limits enthusiasm for making applications, and it reduces the willingness of US researchers to include European investigators in teams/ consortia. Added to this, US researchers generally under-value European scientists without justification. In the worst cases, there are US-based cliques which act to exclude European participation.

Uniqueness criteria (you must propose something that is not being pursued by US residents).

Appendix 1I: Are New NIH Funding Opportunities Easy to Find Out About

Are New NIH Funding Opportunities Easy to Find Out About?

<u>Response</u>	<u>Response Amount</u>
Yes	59
No	19
Total Responses	78

If No, please explain (All information below are direct quotes from researchers)

Because I do not routinely check for US funding, I am outside the loop of information, a tendency that increases with the years.
But only when you are in the system.
Competitive renewal was difficult since there was no RFA supported by the NEI and consequently a dedicated study section with specific expertise and interested on the topic was lacking.
Even if new opportunities are posted by Email or so, it is difficult to find out, whether non-US scientists are eligible.
However, the conditions and transparent openness regarding the eligibility of European applicants is often hard to decode.
I have not heard of any new funding opportunities now.
I now get emails updating me about NIH funding opportunities but prior to this was largely unaware of them.
It does not come to the attention of our research office.
It is very difficult for me to find an orientation in the NIH program "jungle".
It was straightforward to find out about opportunities with the Human Brain Project but more difficult now as different initiatives and calls have to be followed and their relevance assessed.
It would be good to have a simple guide to NIH funding; what types there are, what the criteria are etc. The website is not easy to navigate. Lots of info!!!
Lots of emails (listservers), not well organized into different fields of research.

NIH Webpage is too large and hard to navigate. As non administrative person you normally apply for grant 1-2 times a year and have to find your way back through every time.

Not routinely advertised/announced in our scientific environment.

Not so easy, because they are not mentioned in my own institutiosn funding opportunities. So in other words it is up to yourself to find out, whereas EU programs are "pre-digested".

So complex a system I do not bother checking regularly to see what is available.

The newsletters that I receive contained too much information.

There are so many funding opportunities it is hard to find the ones that are most relevant to you.

Websites are complicated.

Appendix 1J: How Researchers Hear About New NIH Opportunities

How Researchers Hear About New NIH Opportunities

<u>Method of Hearing About New Awards</u>	<u>Response Amount*</u>
Administrative staff at your institution	5
Commercial vendor of funding opportunities database/search	5
NIH programme officer or other staff	22
NIH website	39
Colleagues/collaborators at your own or other non-U.S. institution	23
U.S. colleagues or collaborators	43
Other	10

*Researchers were able to check all that apply (a total of 78 individual researchers responded)

Other (All information below are direct quotes from researchers)

Article about the Human Brain project.
Discussion at scientific meeting in the US on inauguration of the new programme.
E-mail messages from Columbia University e-mailing list.
Email newsletter from NIH.
Had my lab in the US.
I heard about a specific opportunity at a strategic PIs conference.
I transferred an NIH grant that had been awarded but not yet started.
My first R=1 dates back to 1980. It was awarded to a research institute in
NIH e-mail updates on funding opportunities.
Research newsletter.
The model organisms database website.
Vision of Children Foundation, San Diego, CA, a US based foundation promoting research on albinism that let me know about a specific RFA on the topic.
Web research alerts.

Appendix 1K: Other Issues Related To Awareness of NIH Programmes

Other Issues Related to Awareness of NIH Funding Programmes and Opportunities

Responses (All information below are direct quotes from researchers)

The NIH web site is excellent. Funding programs are advertised during international conferences and meetings. Management of funding is absolutely friendly and leaves to the investigator freedom in budget changes.
Most people at my institution do not have NIH funding, so are not talking about programmes and other opportunities from NIH, and, as above, because overheads are low the institution does not encourage seeking nih funding as much as seeking other sources.
Lack of confidence in own possibilities due to misinformation (people are "afraid" of applying, because they are convince they do not have a chance).
Not always clear which are open to non-US based researchers.
The scope of NIH funding is poorly recognized in Europe. Colleagues view the application process as cumbersome and complicated.
Moreover, it became more and more difficult as a non-US scientist outside the US to participate in NIH funding.
I think that most EU-based researchers just don't know that they are eligible to apply.
Once the NIH information tools are detected it is easy to get access to any new development.
The amount of information to digest is considerable and the website may be daunting to the uninitiated.
Maybe it was because China was no longer considered "developing" because our R21 was so successful we couldn't understand not getting R01.
Hearing from our US colleagues that success rates are down to 10% does not encourage to go through the whole process.
It is challenging - and is becoming more so - to obtain NIH funding as foreign applicant.

Appendix 1L: Legal, Policy, & Administrative Challenges to NIH Participation

Legal, Policy, & Administrative Challenges to Participation in NIH Funding Programmes

<u>Challenge</u>		<u>Response</u>	<u>Amount</u>
Audit requirements	Low	0	8
		1	14
	Medium	2	9
		3	28
		4	12
	High	5	6
Total Responses			77
Budgeting requirements (e.g., detailed budgets required as opposed to modular budgets)	Low	0	6
		1	12
	Medium	2	11
		3	30
		4	7
	High	5	11
Total Responses			77
Facilities & administrative (F&A)/indirect cost recovery limits	Low	0	7
		1	6
	Medium	2	8
		3	25
		4	17
	High	5	14
Total Responses			77
Intellectual property	Low	0	21
		1	23
	Medium	2	9
		3	19
		4	4
	High	5	0
Total Responses			76

		0	21
Other contractual (grants) requirements	Low	1	11
		2	12
	Medium	3	20
	High	4	7
		5	1
Total Responses			72

Other (All information below are direct quotes from researchers)

Again, any problems seem more related to lack of expertise on NIH policy within my institution, rather than the policies being overly burdensome.
Different requirements with regard to Select Agents.
Due to cultural difference, the overall administrative issues are rather tricky to overcome as a non-US scientist outside the US (e.g. it took me a long time to understand what a DUNS no is, for example...).
EU funding is MUCH worse in all these respects.
Exchange rate considerations.
In many ways, obtaining funding from the NIH was a joy compared with getting that from the BBSRC.
Just general awareness.
Lack of knowledge of NIH rules/procedures by my Institution. Fluctuations in exchange rate are problematic given the detailed budgets.
My experience is limited to an award in 2001 when budgets were modular and as far as I recall there were no complex auditing requirements. I have therefore given ratings of 3, in the absence of a 'don't know' option.
My RO1 had a modular budget which was easy to admister and report.
Requirments for annual reports.
See comment on previous topic.
The feeling non-us PI's are having extra difficulties in obtaining grants despite competetive research programs.

To a UK researcher the NIH funding process is rather confusing compared to those of UK Government funding and Wellcome Trust funding. It can be difficult to be sure that all the relevant forms have been found and filled out correctly. In addition, the effort required for non-competing renewals/ annual reports and annual re-budgeting is considerable and is something unfamiliar when previous experience was only of UK funding. (Rating 5) A major problem for UK participants in NIH-funded projects is the time delay between unofficial notification of an award and official notification. Likewise the delay between official notification and subcontract award. US partners seem able to initiate hiring and even pre-award expenditure as soon as the unofficial notification is received. At least at the University of Cambridge (and I believe at other Universities) we can only start advertising for hiring once the subcontract is awarded. This led to a considerable (>6 month) delay in starting up our component of the project relative to the US partners.

On grants such as the U41 the need for an annual subcontract means that my department has had, in effect, to provide a bridging loan each year while waiting for the subcontract to arrive. This has made me rather unpopular with my Department, which is not at all happy about this kind of arrangement! Such delays cause a further problem in that budgets have to be adjusted and applications made to carry forward funds from one year to the next. Again, my University will not allow such carry-forwards to be spent until official permission has arrived from the NIH, while in contrast US Universities seem to allow immediate expenditure. In one case official permission to spend the carry-forward arrived so late in the grant year that I was unable to spend it and had to carry it forward again! (Rating 4) Improved guidance for non-US central administration: we had difficulty in submitting the most recent application as there was confusion over who was the Authorised Official for submission purposes. The problem is that foreign Universities may only submit NIH applications rarely and therefore are unfamiliar with the process.

With my U01 - the NIH would only guarantee funding on an annual basis - consequently my university would only offer single year contracts to my Post Doc. This was a deterrent to most applicants and it became difficult to recruit.

Appendix 1M: NIH Grants Policy

According to the NIH Grants Policy Statement, proposals originating from outside the United States (but not U.S. domestic applications with foreign components) are subject to these additional review criteria:

- 1) Whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and,**
- 2) Whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Center (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States.**

Have researchers experienced challenges due to these considerations?

Response

Yes
No

Response Amount

27
50

If Yes, please explain

(All information below are direct quotes from researchers)

Because of the potential competition from US scientists who have priority on the same research subjects.

Comment of one reviewer in a proposal that was not funded.

Competing research in important topics is done internationally, the extra justification that the research is that unique that it is not done in the U.S., is sometimes difficult to justify. If your research is competitive, you will have competitors all over, including the U.S.

Criticisms concerning unique resources not available in USA with respect to the foreign country, and conduction of the research in any of the major research center in the USA have been raised in a recent summary statement of a submitted proposal.

Given the competition in biomedical research, these review criteria are often difficult to demonstrate.

However, we have had to received US State department clearance to ensure that the project does not compromise US-UK relations which, while not problematic in the end, did lead to a time delay in commencing the research.

I feel strongly that I was awarded a grant because of both these reasons (I was asked to apply).

I had to justify that the reserach proposed could not be performed in the US. It was quite difficult.

I included a statement (1/2 page) in applications exp,kainign why I felt that foreign grant requirements were met. Requirement 1 is the most difficult but experience has been favourable if the project is sufficiently innovative and builds on investigator experience with novel methods and approaches to a problem: that seems to meet the requirement for 'unusual talent or resources'.

In clinical pharmacological research in special target groups - eg women, pregnancy-an important value on knowledge from european legal aspects (EMEA is equivalent to FDA) can be introduced to US; different insurance policies, different approaches.

In my case you have to argue that the research is not being done in the US or even cannot be done in the US. This is not an easy criterion to meet.

In principle, all work could be undertaken in the US as all of the facilities and expertise are present. The issue relates to whether anyone in the US has conceived the proposed line of investigation.

It is rather difficult to define what "unusual talents, resources, populations, or environmental conditions" are, or in other words: it is easy to state that a non-US scientist outside the US has nothing "superior" to his US competitors. Thus, it will happen pretty easily that a non-US scientist outside the US will be rejected with a grant proposal by the use of the aforementioned pre-requesites - since they are rather ill defined.

It is very difficult to get a grant from NIH without US partner, if not having, e.g. very large unique patient cohorts.

Most reserach can be carried out in the USA so it is difficult to say that you have a unique set of experiments or even technologies.

Necessitates an application of very high standards.

No, on the contrary.

Not really a challenge but we have, quite reasonably, had to demonstrate that we can contribute something to the research which cannot as easily be done in the US. We have not had to go to great lengths to do this however, simply we have had to make the case. There is undoubtedly a benefit to having a very close collaboration with a US partner and it definitely helps if the US partner is the lead institution.

Only in the sense of having to provide extra information to justify our 'unusual expertise/knowledge' - has always worked out fine.

Project related to activities of NIH scientific committee.

The resubmission of the pre-2003 grant was not succesfull, in part due to item 1 which is difficult to judge.

There are problems with human populations as control groups in life science experiments that do not exist in individual countries. Legal differences between US and EU in definitions of children/adults also as control groups in life science experiments.

There is always a fine line to define what is "not readily available in the United States".

These statements nearly excludes foreign institutions to get NIH grants. I got my NIH grant since I applied when i worked in the US and thereafter transfered the grant. Currently the opinion is that at the critical US funding situation no money will go outside the USA and thus, it is not worth for foreigners to apply for NIH grants.

This issue was not a real problem 10 years ago, as long as one could demonstrate to perform unique research within the mission of the NIH Institute. However, given the present shortage of funding, the challenge has increased considerably.

Transformative Roadmap large application was "not considered" in spite of strong scientific case; no reason given.

We didn't answer these questions as appropriately and effectively as we could have done in our application, but fortunately the reviewers provided helpful supplementary comment.

When money is tight in US, I think these considerations become very strict.

You have to be very careful to find your niche. I found better to collaborate, rather than compete, with colleagues in the US. Of course this is a big limitation on what you can do.

Appendix 1N: Other Issues Related to Legal, Policy & Administrative Challenges

Other Issues Related to Legal, Policy, & Administrative Challenges of NIH Funding Programmes and Opportunities

Responses (All information below are direct quotes from researchers)

Astonishing level of support from the staff at the NIH.
Because our R21 was with China, we had difficulties with their financial aspects since it was difficult to get proper receipts from them and we were administering the budget from London.
Colleagues in UK and Europe usually consider direct access to NIH funding to be out of reach.
Difficulties in writing the grant without experience/administrative support at our University.
Great help from administrative personnel for e.g. financial reports.
I always found it counter-intuitive to calculate indirect costs for the U01 I had. Sometimes techniques/resources may not differ between USA and non-USA countries - but good research ideas may originate from outside the USA or the level of thinking in a particular area may be more advanced. It would be great if the NIH could see fit to support such ideas and the groups from where they originated. Similarly, I feel that the EU should do so also for ideas that originate from the USA - only fair. Science is funded at a national level but scientific ideas have no national boundaries. Also reviewers in the USA understandably probably resent applications coming in from overseas - not certain that the playing field is always level. Consequently, good applications may sink based on the study section score (by one or two reviewers), and never be given proper consideration. Applicants put a lot of effort into their applications - something that is often forgotten by those who are reviewing.
I could transfer my NIH grant when I moved my lab from the US to Germany so the above points were not a major hurdle but I do not plan to renew it because of these requirements.
I experienced - despite the tricky discussions due to cultural differences in administration - very nice, helpful and patient NIH supervisors, at all levels and offices at the NIH (in my instance at the NINDS). This was a great experience!
I find the online form for submitting annual reports extremely difficult to use. Exchange rate fluctuations can be problematic.
I had one grant that was awarded to me and my colleague Dr. A Bianco (TGR5), but given that it was part of the stimulus package, only he could get money. We were excluded on an administrative basis. 2. Administrative clearance by the Dept of Foreign Affairs is challenging.

I have participated in several NINDS workshops (also as a member of the organizing committee) that search ideas from investigators, what should be studied in that particular field (e.g., epilepsy). The ideas in these workshops often turn to funding opportunities. We completely lack such direct interaction between investigators and representatives of funding organizations in Europe, which is a true pity.

In general, the procedures for application are well organized and now with online applications are rather easy to manage. Was more difficult previously with submitting of hard copies.

It is not clear if foreign institutions are treated on par with US based institutions in accessing NIH funding. The "stimulus" funds, for example, were not open for example. There are different views held by many different people I've spoken to on the perceived eligibility of foreign institutions that may need clarification publicly.

It would help if NIH recognised local ethics approvals and other regulatory bodies.

Non-competing renewal process during the grant is unnecessary and should be stopped (for both US and non-US grants). It generates more work for both NIH and the grantee. End of grant reporting system and the multitude of forms is over-complicated and too proscriptive. The forms are very difficult to find in the NIH site which is difficult to navigate.

None. I believe our admin department deals with most of the "behind the scenes" stuff.

Overheads are considered too low by my institution.

Poor/lack of communication between NIH and my institution. Administrative mistakes on both sides were not resolved in a reasonable manner, resulting in adverse effects on the research and staff involved. Hopefully, improved training has eliminated the chances of similar errors happening again.

Precise definition of human subjects research has been difficult to get right.

Significant differences in salaries & wages for PhD and lab technicians.

Simplified time reports would be beneficial, instead of having to specify for each day how many hours are devoted to specific NIH-funded tasks. But perhaps this is already the new simplified requirements?

Smooth running of the grant is helped by having a good NIH programme official, sometimes not clear how to get information if that person is non-responsive.

The first grant I applied for as a PI, was really a challenge because I simply had no support from the administration. This has improved a lot when I moved to the CRG-- my current institute. As a Bioinformatician, my research does not involve animal models, and I guess that this has simplified the application process

The major problem in moving from the US to Europe has been to find competent grant administrators.

The new formats for grant application have reduced considerably the space allocated for research description. This is a real challenge for people who are outside the USA because they have limited access to courses designed for NIH grant writing and find hard to meet the requirements based on unwritten rules that are otherwise easy to perceive for American investigators. Also, it is often said that NIH funds projects already at advanced stages: this seems to be true, as the requirement of preliminary data for all the points included in a proposal needs to be met but it is not always available.

The NIH requirements may require the recipient organization to adjust their regulations accordingly and it can be difficult to make the administrators aware of these requirements.

Under the GO RC2 award scheme which was rushed in as part of the stimulus package for the US economy some of the rules were not clear at the time of submission. Although our part of the budget for this grant was nearly \$200,000 by the time it was awarded the legislature had put a limit of \$50,000 on any funds going to non-US institutions. This clearly had a big impact on us. Another, actually more major problem not just for us but also for our US partners in our GO RC2 grant was that it was a clinical trial. We carefully costed the proposal that was submitted but after the grant was awarded, NIH appointed a Clinical Trials Management Company (Rho) to manage the study for them. They introduced many changes to the protocol and insisted on lots of new procedural arrangements that have meant the clinical trial will now be much more costly than was allowed for in the original budget. Despite this NIH have not indicated that they will provide the extra funds for all the extra work the Trials Management company have imposed on us.

Understanding financial management issues completely different in the US and Germany Exclusive use of checks in financial transactions that additionally are send by normal mail.

Virtually no knowledge on procedures etc. locally available in own research institution.

We had no comprehension of some aspects of the award process, so that when we received our initial rating (which turned out to be excellent) we had no idea what it meant - but were delighted when we eventually found out! We did submit a subsequent grant application, which was not funded but for which we received extensive reviewers' comments. It was only some time later that I was told by a NIDA staff member, who I met in a different context, that it is normal to resubmit in light of such feedback - whereas our experience with similar funding organisations in the UK is that there is little point in a resubmission unless one is explicitly invited. Such differences in expectation reflect local custom and practice, and it would be helpful to explain to articulate to overseas applicants some procedures which are likely to be highly familiar to US applicants. It transpired that there was also more flexibility in expenditure from a NIH grant than expected based on experience with UK grants - that is, there were fewer administrative hoops to jump through, and this made it much easier for us to be somewhat versatile in how we achieved the project objectives. This relatively light touch administration was much appreciated, and in our view contributed to excellent outcomes from the project.

Appendix 10: Contribution of NIH Funding to Overall Research Programme

Contribution of NIH Funding to Overall Research Programme	
<u>Type of Contribution</u>	<u>Response Amount*</u>
Provides access to U.S. researchers/institutions	27
Provides credibility to access other funding	46
Provides a significant financial resource	56
None of the options listed	5
Other	5

Other (All information below are direct quotes from researchers)

Allows participation in major US-led international project; allows technology transfer from my group to US projects.
I had NIH grants prior to 2003.
Our R21 project, awarded in 2001, yielded a large database from which we continue to publish - most recent output this year.
Significant financial resource-<20%- in previous years.
Was response to brain disorders in developing countries but despite doing very well we didn't get the R01 to continue.

*Researchers were able to check all that apply (a total of 78 individual researchers responded)

Appendix 1P: Positive Experiences in Applying to NIH

Positive Experiences/Aspects/Issues in Applying for and/or Receiving NIH Awards That Could be Lessons for Other (U.S. or European) Funding Bodies

<u>Themes*</u>	<u>Response Amount</u>
NIH General Administration	17
NIH Review Process	22
NIH Staff	10
Transparency	4
Other	12

Responses (All information below are direct quotes from researchers)

Note: some comments are double-counted within categories

NIH General Policy Administration
Applying for an NIH grant from outside the US would be completely impossible without the extensive NIH guides that are most informative and exemplary for any application system. The most helpful people from the management who solved all the problems arising from cultural differences to actual financial problems. Completely different from what we are used in university administrations in Germany.
Efficacy and relatively simple procedure for administering NIH grants.
I find the NIH system excellent, far less burdensome than EU funding which can fairly be described as a nightmare. It is only lack of familiarity that makes the NIH system look difficult. Program staff are normally very helpful (though this makes it even more noticeable when you find yourself dealing with someone who is less so). There is flexibility in how budgets are used (ie whether on pay or consumables etc) and more focus on the scientific output which is as it should be.
I found less bureaucracy attached to the grant application and grant management. This could definitely be a lesson for the EU.
I got an R21 grant from the NIGMS. It was a great experience. I liked obtaining a grant score that was available on the web prior to a funding decision being made as it let me see early whether or not my grant was going to be competitive. I had a modular budget so did not have to waste excessive administrative time on putting together a detailed budget. I had regular contact with the program director who was very encouraging. The NIH approach to IP was refreshingly simple. In short, I felt the organisation was very much geared to "can do" science which is not true of all funding agencies.
I have found NIH staff and processes to be the epitome of professionalism that other European Funding agencies could learn a lot from. Also, the facility to resubmit grants after they have been reviewed (but scored below the payline) is an excellent idea.
I liked on the NIH review system that it is much less political driven than the EU system. The EU grants have only very little to do with science but much more with industry, dissemination, etc.

In general, I consider that the application to NIH-sponsored programs is much easier than those sponsored by the European Union.

Limited bureaucracy, freedom to adapt the project according to novel findings or issues.

Long-term (5-year) grant.

Positive experiences are 1. writing the grant (once into it) 2. annual follow-up and meetings/discussions/interactions at NIH with other scientists on the same program 3. substantial financial support over several years.

Reasonably quick decisions and to be honest NIH and EU grants suffer from exactly the same problems ie far too much paperwork and not easy to apply without professional input.

Scientific quality of the proposal (in relation to the mission of the funding agency) is more important than where you happen to live.

Simplicity in preparing all paper work. Very strict rules how to write a grant proposal. Minimum bureaucracy.

The EU has nothing that is equivalent to the NIH. The ERC advanced grants only fund the top 2% of European scientists, while FP7 funding requires elaborate collaborations with other EU partners on very specific programme calls. There is nothing really equivalent to the NIH RO1.

The experience has been extremely positive. Compared to EU grants, NIH funds are easier to manage, due to the large rebudgeting authority of the principal investigator and the minimum requirement for administrative work. Also, scientifically, NIH funds single researchers-based initiatives, so that even good scientists who are not part of a network can find a funding opportunity.

The modular budgeting was great - we felt that NIDA got excellent value for money for our project, which was conducted very economically, and it hugely cut down on the minutiae of costing the application from our point of view. It seems a pity that this system has now been abolished.

NIH Review Process

Being able to re-submit following reviewers' comments.

Excellent scientific review of application and possibility to re-submit.

Experience has generally been very positive with regard to reviewing and funding.

For me the process was very smooth, although I think that might be unusual. It took quite a while to navigate the complex application procedure, but I had good help from a UK-based American scientist who has an RO1 grant in the UK and knew the system well.

Having a report from the panel discussion (as well as referees comments) is very helpful. Often that stage of grant review is a "black box".

High quality of the review process that is not matched by most European funding agencies. I have had experience from several on the granting side and as an applicant.

I believe the NIH grant review system is still the best existing because it gives the possibility to PIs to answer a new application to criticisms received during the review process. I have never seen this in the review process of European agencies.

I have found NIH staff and processes to be the epitome of professionalism that other European Funding agencies could learn a lot from. Also, the facility to resubmit grants after they have been reviewed (but scored below the payline) is an excellent idea.

I liked on the NIH review system that it is much less political driven than the EU system. The EU grants have only very little to do with science but much more with industry, dissemination, etc...

Important that NIH supports "bottom-up" research and is so much less bureaucratic than the EU funding.

One of the more rewarding experiences is the written critiques provided by the study section and the possibility to work with them to improve the rating. A most important aspect where Europe has a lot to learn is the complete coverage of research costs to complete a project.

Peer- reviews by scientists competent in your area. Transparency and meritocracy.

Really good research with excellent partners/collaborators in the US. The prestige of NIH funding. I think the organisation into different institutes for different disease areas is a definite bonus and ensures that research funds are spread across different areas of research in a fairer manner, that reviewers no more about the subject under review and that research funding strategies are better targetted to specific disease areas by the individual institutes. My research is primarily related to dentistry. It is almost impossible for dental research to get a fair hearing within the broaded scope of medical research in Europe but in the US the existence of the National Institute for Dental and Craniofacial Research ensures that all the best oral and dental research in the world happens in the US. I also feel the NIH system of grant submission, review etc is somewhat simpler and more open and transparent than is often the case in Europe. It is also extremely helpful that they only have one system and so researchers quickly become familiar with how to submit an NIH grant (the forms are pretty much the same whatever grant you submit) and the process/ scoring system involved. In Europe there are so many differnet funding schemes all with their own systems and idiosyncroses that researchers have to go through a major learning process each time they submit a grant.

Streamlined application process, very detailed and helpful comments from the study section.

Stringent review of proposals.

The capacity to submit a revision of an original application.

The level of support from the scientitfc contact has always been excellent, the the degree of feedback incredibly useful for developing the ides/concepts further. It is very common in the UK (especially with charitable bodies) not to receive feedback and this is most unhelpful and counterproductive for the development of successful research programmes. This is especailly so for the more novel and innovative projects, from which the most exciting data are more likely to arise. The UK is far more conservative with regards to funding more speculative programmes that the NIH.

The most relevant advantage of the NIH reviewing system is that the Applicant and not the Funding agency decided the scientific subject of his research proposal. Then the review Committee decides the relevance and importance of the research project for the scientific community. Moreover, a crucial feature of the NIH Funding System is represented by an extremely fair review process with a final score for both funded and unfunded project and an accurate and useful review summary.

The NIH has an excellent peer review system. I feel like NIH proposals are judged more on merit and referee recommendations compared to UK research councils.

The peer review mechanism of NIH grants is a model for any funding agency. In addition, NIH grants do not have the bureaucracy for reporting and cost claiming associated to current EU grants, that make the workload for administrative offices unbearable.

The review process is very good indeed.

Very fair, clear and efficient scientific evaluation. Possibility to apply as 1 scientist 1 project on basic research (like ERC grants).

NIH Staff

Close collaboration with their scientific staff after the grant was awarded.

Direct interactions with administrators of funding instruments, and their receptiveness to ideas directly from researchers.

Excellent support from NIH and a reasonably user friendly reporting system; links into other NIH opportunities and resources.

I find the NIH system excellent, far less burdensome than EU funding which can fairly be described as a nightmare. It is only lack of familiarity that makes the NIH system look difficult. Program staff are normally very helpful (though this makes it even more noticeable when you find yourself dealing with someone who is less so). There is flexibility in how budgets are used (ie whether on pay or consumables etc) and more focus on the scientific output which is as it should be.

In my particular case, one strong difference has been the implication of the program directors on the developing of the grant. They follow closely the development of the grant, and provide very useful input.

My initial programme officer was very helpful. However, variability in POs is already a known concern.

Positive experiences are 1. writing the grant (once into it) 2. annual follow-up and meetings/discussions/interactions at NIH with other scientists on the same program 3. substantial financial support over several years.

The NIH personnel are generally very helpful and accommodating but the online submissions are set up for US institutions.

The organisation of the program and communication with the program manager were excellent (all the problems encountered later related to the administration of the funds).

The professional and efficient way in which NIH deals with problems rising during the project period.

Transparency

A more transparent and balanced review process. More willingness to consider risky science.

I got an R21 grant from the NIGMS. It was a great experience. I liked obtaining a grant score that was available on the web prior to a funding decision being made as it let me see early whether or not my grant was going to be competitive. I had a modular budget so did not have to waste excessive administrative time on putting together a detailed budget. I had regular contact with the program director who was very encouraging. The NIH approach to IP was refreshingly simple. In short, I felt the organisation was very much geared to "can do" science which is not true of all funding agencies.

In general the process is 1) easy; 2) transparent, which is not always the case in the EU.

Really good research with excellent partners/collaborators in the US. The prestige of NIH funding. I think the organisation into different institutes for different disease areas is a definite bonus and ensures that research funds are spread across different areas of research in a fairer manner, that reviewers no more about the subject under review and that research funding strategies are better targetted to specific disease areas by the individual institutes. My research is primarily related to dentistry. It is almost impossible for dental research to get a fair hearing within the broaded scope of medical research in Europe but in the US the existence of the National Institute for Dental and Craniofacial Research ensures that all the best oral and dental research in the world happens in the US. I also feel the NIH system of grant submission, review etc is somewhat simpler and more open and transparent than is often the case in Europe. It is also extremely helpful that they only have one system and so researchers quickly become familiar with how to submit an NIH grant (the forms are pretty much the same whatever grant you submit) and the process/scoring system involved. In Europe there are so many different funding schemes all with their own systems and idiosyncroses that researchers have to go through a major learning process each time they submit a grant.

Other

A switchboard / information desk / helpline specifically decoted to non-US researchers outside the US, which mediates all administrative issues (and tell you why non-US researchers outside the US - in contrast to their US colleagues - couldn't submit yearly progress reports onlie through the Era, but had to go for paper submission, thus getting into conflict with the deadlines.

Exciting bringing an international team together - UK, USA, Canada, China.

Grantee meetings are excellent opportunities to meet with peers. Policy officer is always available for advice and is extremely supportive.

Increasing collaboration US/UK.

Nothing is as bad as applying for, getting and running a grant funded by the EU. Although NIH provides very few grants originating in Europe (which is probably appropriate), it is excellent that they do so at all.

One should always give priority to the highest quality research programs and not to hesitate to start new lines of research, provided that pilot experiments may convince the reviewers that the planed studies are feasible.

Really good research with excellent partners/collaborators in the US. The prestige of NIH funding. I think the organisation into different institutes for different disease areas is a definite bonus and ensures that research funds are spread across different areas of research in a fairer manner, that reviewers no more about the subject under review and that research funding strategies are better targetted to specific disease areas by the individual institutes. My research is primarily related to dentistry. It is almost impossible for dental research to get a fair hearing within the broaded scope of medical research in Europe but in the US the existence of the National Institute for Dental and Craniofacial Research ensures that all the best oral and dental research in the world happens in the US. I also feel the NIH system of grant submission, review etc is somewhat simpler and more open and transparent than is often the case in Europe. It is also extremely helpful that they only have one system and so researchers quickly become familiar with how to submit an NIH grant (the forms are pretty much the same whatever grant you submit) and the process/scorring system involved. In Europe there are so many different funding schemes all with their own systems and idiosyncroses that researchers have to go through a major learning process each time they submit a grant.

Reasonably quick decisions and to be honest NIH and EU grants suffer from exactly the same problems ie far too much paperwork and not easy to apply without professional input.

Synthetic project body.

The collaborative experience in the exchange of research ideas and questions with investigators within the US.

To worked jointly with USA researchers and also to consider cultural differences in the study population despite identical protocols; an enrichment for both sites; great administrative staff at NIDA!

U01 mechanism can be difficult to implement but my experience of this type of cooperative research was very positive. There needs to be greater flexibility in how research is delivered - adherence to strict milestones can be counter-productive - science doesn't work like that.

*Themes were identified from the responses; they were not indicated in the question.

Appendix 1Q: Recommendations for NIH Funding Programmes

Recommendations That Could Ease/Improve Research Collaboration Through NIH Funding Programmes

<u>Themes*</u>	<u>Response Amount</u>
Awareness of NIH Programmes	3
Home Institution Administration	6
Increased Funding Collaboration	16
NIH Administration	19
Other	8

Responses (All information below are direct quotes from researchers)

Note: some comments are double-counted within categories

<i>Awareness of NIH Programmes</i>
Announcements through European scientific bodies.
Better vehicles to make us aware about NIH funding opportunities and NIH policies would be helpful. Also clear information as whether we as EU labs are eligible to get funding, which was not the case for the stimulus money.
Better visibility of funding opportunities. Joint funding activities.
<i>Home Institution Administration</i>
A better understanding of and adaptation to the rules of an NIH from our University.
A clearer application process for non-US applicants will be helpful. F&A cost recovery needs negotiations. Admin staff in non-US organizations need better training in budgeting and admin issues.
Better internal administrative awareness and communication of NIH policy, grantsmanship, etc.
Communication with NIH administration was a big problem. In most cases I didn't get a response to my emails. Over the phone it was OK but due to the different timezones quick responses to questions/problems by email would be better. Many institutes in Europe don't have much knowledge about NIH administration such as filing the final financial reports and therefore help from NIH is often required.
Establishment of (in)formal collaboration between EU/NIH on specific research topics. local expertise on administrative aspects in EU.
Increased awareness of rules at the local university. This has meanwhile become a priority and is rapidly improving.
<i>Increased Funding Collaboration</i>
Allowing a single coordinating center to administer a collaborative project on behalf of others.

Availability of joint funding between European and US research groups funded by EU and NIH.
Better collaboration between research groups working in the same field; better opportunities for applying the obtained results in clinical practice.
Collaborative Program projects with multiple PIs from US and EU countries.NIH grants.
Development of a co-funding structure in Europe.
Encourage US investigators to include a non-US partner in their applications and provide for a budget for such option.
Establishment of (in)formal collaboration between EU/NIH on specific research topics. local expertise on administrative aspects in EU.
Grant funding initiatives requiring collaborations between European and US scientists.
In general, it should be better communication between European and US funding bodies, and a larger degree of reciprocity. I think that it makes little sense that i can be a PI on an NIH grant, but american researcher can not be in similar European grants. This benefits nobody.
Joint funding programmes in specific areas - fostering links between EU and USA universities/institutes. To make this work there has to be a simplified method of grant management/auditing - the EU go overboard on this but I guess some institutes in certain EU countries in the past just took the money and didn't deliver.
Joint funding ventures in critical areas between the EU and the US.
linking up with EU bodies for strategic initiatives. We live in a small world and there are not enough resources for real step change research. There is much complementarity between US and UK researchers.
Make researchers aware of the opportunities. Start a series of grants that require EU-based collaborators.
Making clearer which are collaborative research funding programs, special RFA ?, program projects for international collaboration?
more joint funding opportunities from the NIH and UK/EU Research Councils to support US/European collaborations.
Participation of NIH in EU collaborative programs (i.e. 7. Framework, EraNet, etc.).
NIH Administration
A clearer application process for non-US applicants will be helpful. F&A cost recovery needs negotiations. Admin staff in non-US organizations need better training in budgeting and admin issues.

A web page titled something like "An introduction to NIH funding for foreign applicants" could be useful to paint a broad overview of the process. For instance covering points like: - Foreign researchers quite often provide subcontracts to NIH grants. It is possible, but much rarer, for foreign applicants to be the lead applicant on NIH applications. In both cases there must be a compelling benefit to the US for the foreign researcher to receive funds. - Budgets: an outline of the application stage, award-stage and annual re-budgeting process and an overview of the differences between different types of grant. (For UK grants, there is usually a single budget at application stage, and then no further re-budgeting for the duration of the grant) - The fact that one may need to apply to carry-forward underspend from one year to the next (rarely necessary for UK grants) - Annual reports/ non-competing renewals (rare in the UK).

Communication with NIH administration was a big problem. In most cases I didn't get a response to my emails. Over the phone it was OK but due to the different timezones quick responses to questions/problems by email would be better. Many institutes in Europe don't have much knowledge about NIH administration such as filing the final financial reports and therefore help from NIH is often required.

Eliminate prejudice against foreign researchers.

Ensure that administrative issues/problems are identified and dealt with in a timely manner.

EU information on financial management differences between the US and the European countries. - Information on administrative differences on the cultural and legal level between the EU and the US that are important for the audits of foreign universities/institutions receiving NIH grants - Information from the EU on the type and culture of the decision finding system at the NIH and if funded on the possibilities to extend grants, if money is not used etc. Although explained in the guides, cultural differences often lead to misunderstandings.

Fairness in review. An announcement, e.g. via the web, that US researchers are actively encouraged to find the very best research talents to participate in their grants, even if those individuals reside outside the US.

Greater clarity over what funding mechanisms are open to overseas researchers. Greater familiarity within overseas organisations of the NIH system. The constant updates to the application process are difficult to keep up with (when there are no dedicated admin' staff doing the job) and so every application takes a long time to prepare from an admin perspective.

If good scores from grant review panels would be taken seriously into account and not overruled by other research priorities.

Information received by email is perhaps not always understandable. Forms are also complex and difficult to complete compared with other funding bodies and could be simplified.

More appreciation at the NIH that administering grants is different in Europe.

More explicit about why no move from R21 to R01.

More help in mediating administrative issues for people outside the US - if we "outsiders" happen to overcome the difficulty hurdle of presenting "unusual talents, resources, populations, or environmental conditions".

Not require foreign justification.

Simpler forms and more in house advice on annual financial form filling.

To have study sections experienced in reviewing grants from foreign Institutions and therefore capable of understanding some cultural differences.

The first strategy to increase the interaction would be to strengthen the participation in multiple PI RO1s. The second is to identify research that is not carried out in the US to strengthen competitiveness in the study section.

The most awkward single difficulty with operation of these grants has been the confirmation of funding only a week or two before start date. This applies to the initial startup in year one, where 3-4 months are required to recruit staff. Also the annual renewals of funding create major difficulties with employment contracts; staff are legally entitled to be informed that their post will end at least 3 months before its closing date, at which time staff start looking for other jobs.

Unfortunately most of what would need to be done revolves around institutional support for NIH grants. Given the small numbers of grants awarded to any one EU institution it is unrealistic to expect the same familiarity with NIH processes as with US institutions. Perhaps a separate programme officer for EU awards who understands this challenge might help?

Other

A reduction in regulatory constraints and the expectation that we will include a range of specific populations that are not relevant to all clinical research projects. For instance my project was on the immunology of alcoholic liver disease but i had to explain why we were not studying children and native american groups.

I do think it works very good!

It was 12 months from grant submission to grant award, which is 6 months slower than the BBSRC.

No suggestions for improvements.

See 19.

Sorting out direct negotiations between UK institutions an NIH on various aspect of the grant (administrtrion of grant, overheads, locl issues particularly with ethics etc).

To extend the NIH approach to European Funding Agencies.

UK government should provide QR (additional indirect costs) for NIH (and other non-UK) funding of grants to make them comparable to charity funded research from within the UK and thus remove the negative incentives to apply to NIH.

*Themes were identified from the responses; they were not indicated in the question.

Appendix 2: NIH EU-Based Grants Administrators Questionnaire Data

Appendix 2A: Introductory Letter to Grants Administrators

Dear Grants Administrator,

The Link2US Project (more information below signature and attached), co-funded by the European Union (EU) Framework Programme and coordinated by the American Association for the Advancement of Science (AAAS), the world's largest general scientific society and publisher of the journal Science, seeks your assistance with its Questionnaire on EU Researcher Participation in U.S. Funding Programmes.

You are receiving this questionnaire because your institution had or currently has one or more grants or other funding awards from the U.S. National Institutes of Health (NIH). If your institution has not received any awards from NIH, please respond to this email (Link2US@aaas.org) and we will remove you from our list. If you believe another colleague in the grants office or equivalent is more appropriate for this survey, please also contact us. A separate questionnaire is being sent to relevant researchers.

The main objective of this questionnaire is to identify barriers and other challenges that EU institutions and researchers face when applying to and participating in NIH research funding programmes. The outcomes of this questionnaire will be used in an analysis of key issues to address in improving funding programmes for international cooperation, which will be shared with stakeholders (including the European Commission and U.S. funding bodies). This questionnaire is not officially connected with any U.S. federal funding body.

Directions: The questionnaire will be implemented electronically. To complete the survey, please visit http://www.surveymonkey.com/s/Link2US_grants. The questionnaire is open from 14-28 September 2010. Please submit your completed questionnaire no later than 18h00 Central European Time on 28 September.

Confidentiality: All information will be treated confidentially and will only be distributed in an anonymous format (no attribution to individuals) to any entity outside of the Link2US Project (e.g., government funding agencies).

Should you have any questions, please contact Ms. Stephanie Pals (Link2US@aaas.org; Tel: +1 (202) 326-6663), Link2US project officer.

Thank you for your time and effort in responding to this survey. You will receive a copy of the report once the analysis is completed. Your responses will contribute to improving and strengthening EU - U.S. science and technology cooperation.

Sincerely,
Dr. Tom Wang
Coordinator, Link2US Project
Director for International Cooperation,
American Association for the Advancement of Science (AAAS)



Link2US@aaas.org

www.EuUsScienceTechnology.eu/Link2US

The Link2US Project aims to enhance the understanding of U.S. collaborative research funding programmes by facilitating easy access to relevant information on U.S. cooperation programmes through electronic communities such as a website, e-newsletter, and virtual helpdesk. The Project is co-funded by the EU's Capacities Programme on International Cooperation under the 7th Framework Programme for Research and Technological Cooperation. See attached document for more information.

Appendix 2B: Questionnaire

European Union (EU) Researcher Participation in U.S. Funding

Questionnaire for Grants Administrators: EU Researcher Participation in U.S...

Dear Grants Administrator,

Thank you for participating in the Link2US Project's¹ Questionnaire for Grants Administrators: European Union (EU) Researcher Participation in U.S. Funding Programmes. You are receiving this questionnaire because your institution had or currently has one or more grants or other funding awards from the U.S. National Institutes of Health (NIH). If your institution has not received any awards from NIH, please contact us (Link2US@aaas.org) and we will remove you from our list. If you believe another colleague in the grants office or equivalent is more appropriate for this survey, please also contact us. A separate questionnaire is being sent to relevant researchers.

The main objective of this questionnaire is to identify barriers and other challenges that EU institutions and researchers face when applying to and participating in NIH research funding programmes. The outcomes of this questionnaire will be used in an analysis of key issues to address in improving funding programmes for international cooperation, which will be shared with stakeholders (including the European Commission and U.S. funding bodies).²

Directions: Please answer all questions in relation to your institutional experience with NIH funding programmes. The estimated time for completion of the questionnaire is 15-20 minutes. The questionnaire is open from 14-28 September 2010. Please complete the questionnaire no later than **18h00 Central European Time on 28 September**. As you are completing the questionnaire, your answers are saved when you click on the "next/save" or "submit" button at the bottom of each page. Should your session be interrupted, you may return to the system at a later time to pick up where you left off and finish, as long as you are using the same computer and browser and cookies are accepted.

Confidentiality: All information will be treated confidentially and will only be distributed in an anonymous format (no attribution to individuals) to any entity outside of the Link2US Project (e.g., government funding agencies).

Should you have any questions, please contact Ms. Stephanie Pals (Link2US@aaas.org; Tel: +1 (202) 326-6663), Link2US project officer.

Thank you for your time and effort in responding to this survey. You will receive a copy of the report once the analysis is completed. Your responses will contribute to improving and strengthening EU – U.S. science and technology cooperation.

Sincerely,

Dr. Tom Wang
 Coordinator, Link2US Project
 Director for International Cooperation,
 American Association for the Advancement of Science (AAAS)
Link2US@aaas.org
www.EuUsScienceTechnology.eu/Link2US

¹The Link2US Project aims to enhance the understanding of U.S. collaborative research funding programmes by facilitating easy access to relevant information on U.S. cooperation programmes through electronic communities such as a website, e-newsletter, and virtual helpdesk. The Project is co-funded by the EU's Capacities Programme on International Cooperation under the 7th Framework Programme for Research and Technological Cooperation.

²This questionnaire is not officially connected with any U.S. federal funding body.

Questionnaire for Grants Administrators: EU Researcher Participation in U.S...

GENERAL INFORMATION/DEMOGRAPHICS

*** 1. Name (Surname, Given Name)**

European Union (EU) Researcher Participation in U.S. Funding

*** 2. Title**

*** 3. Name of your institution**

*** 4. Location of institution (country)**

5. Your department, center, or other organizational unit within your institution

*** 6. Which of the following best describes your organization?**

Questionnaire for Grants Administrators: EU Researcher Participation in U.S...

*** 7. Please indicate the number of new NIH awards your institution received between 2003-2010 for each of the following instruments (enter 0 if no awards):**

Direct awards (e.g., researchers at your institution are the principal investigators):

Research Project Grant (R01)	<input type="text"/>
Small Grant Program (R03)	<input type="text"/>
NIH Exploratory/Developmental Research Grant Program (R21)	<input type="text"/>
Research Project Cooperative Agreement (U01)	<input type="text"/>
Other (please specify using this format: type, number; type, number; etc.)	<input type="text"/>

Indirect awards (e.g., foreign components on a U.S.-based award, subcontracts, etc.):

Research Project Grant (R01)	<input type="text"/>
Small Grant Program (R03)	<input type="text"/>
NIH Exploratory/Developmental Research Grant Program (R21)	<input type="text"/>
Research Project Cooperative Agreement (U01)	<input type="text"/>
Other (please specify using this format: type, number; type, number; etc.)	<input type="text"/>

Questionnaire for Grants Administrators: EU Researcher Participation in U.S...

U.S. FUNDING PROGRAMME QUESTIONS

European Union (EU) Researcher Participation in U.S. Funding

*** 8. General challenges to researcher participation in NIH programmes (for each of the following issues, rate from 0-5: where as a guide, 5 is extremely important and needs priority attention; 3 is challenging but no more so than other funding programmes; 0 is not important at all).**

	Rate
Communication and information awareness of programmes	<input type="text"/>
Contractual issues and intellectual property	<input type="text"/>
Lack of complementary funding	<input type="text"/>
Lack of administrative support from own organization	<input type="text"/>
Lack of administrative support from the U.S. funding body	<input type="text"/>
Differences and/or lack of recognition between U.S. and European policy requirements on issues such as animal safety, protection of human subjects, research integrity, financial conflict of interest, etc.	<input type="text"/>
Cultural differences in management of grants	<input type="text"/>
Other (please specify and indicate rating)	
<input type="text"/>	

Information and Awareness

*** 9. How do/did researchers in your institution hear about new NIH funding opportunities? (check all that apply)**

- Administrative staff at your institution
- Colleagues/collaborators at your own or other non- U.S. institutions
- Commercial vendor of funding opportunities database/search
- NIH website
- NIH programme officer or other staff
- U.S. colleagues or collaborators
- Other (please specify)

*** 10. Are new NIH funding opportunities easy to find out about?**

If No, please explain

European Union (EU) Researcher Participation in U.S. Funding

11. Please describe any other issues related to awareness of NIH funding programmes and opportunities.

Legal/Policy/Administrative

*** 12. Challenges to participation in NIH programmes (for each of the following issues, rate from 0-5: where as a guide, 5 is extremely important and needs priority attention; 3 is challenging but no more so than other funding programmes; 0 is not important at all)**

	Rate
Audit requirements	<input type="text"/>
Budgeting requirement (detailed budgets as opposed to modular budgets)	<input type="text"/>
Facilities & administrative (F&A)/indirect cost recovery limits	<input type="text"/>
Intellectual property	<input type="text"/>
Other contractual (grant) requirements	<input type="text"/>
Other (please specify and indicate rating)	
<input type="text"/>	

*** According to the NIH Grants Policy Statement, proposals originating from outside the United States (but not U.S. domestic applications with foreign components) are subject to these additional review criteria: 1) Whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and, 2) Whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Center (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States.**

13. Have the researchers at your institution experienced challenges due to these considerations?

If yes, please explain

European Union (EU) Researcher Participation in U.S. Funding

14. Please describe any other issues related to administrative/policy/legal aspects of NIH funding programmes and opportunities.

Questionnaire for Grants Administrators: EU Researcher Participation in U.S...

General

*** 15. In approaching challenges to participation in NIH programmes, your institution: (please select all statements that apply)**

- Assumes that existing/national policies already cover all requirements of U.S. policies
- States inability to certify compliance in certain areas in the application
- Adapts your own university/institution/national policies to reach compliance
- Asserts that university/institution/national policies need to be followed rather than U.S. policies
- None of the above
- Other (please describe)

16. What recommendations could ease/improve research collaboration through NIH funding programmes?

17. What have been positive experiences/aspects/issues in applying for and/or receiving NIH awards that could be lessons for other (U.S. or European) funding bodies?

Appendix 2C: Member State of Current Institution

Member State of Current Institution	
<u>Country</u>	<u>Response Amount</u>
Czech Republic	1
Finland	1
France*	1
Germany*	2
Ireland	1
Italy*	1
Spain	2
Sweden	3
United Kingdom*	9
Total Responses	21

*Indicates that a single GA self identified as being from all four countries.

Appendix 2D: Breakdown of Organization Type

Breakdown of Organization Type	
<u>Organization Type</u>	<u>Response Amount</u>
Higher Education institution	13
Research organization - public or private	5
Industry	0
Total Responses	18

Appendix 2E: Number of New NIH Grants Awarded

Number of New NIH Grants Awarded Between Fiscal Year 2003-2010		
<u>Award Name</u>	<u>Direct Award Total Amount</u>	<u>Indirect Award Total Amount</u>
Research Project Grant (R01)	87	231
Small Grant Program (R03)	8	4
NIH Exploratory /Developmental Research Grant Program (R21)	19	17
Research Project Cooperative Agreement (U01)	11	13
Other	4	9
Total Award Amount	129	274

*Researchers were able to insert data for all that apply (a total of 18 individual GA responded)

Appendix 2F: General Challenges to Participation in NIH Funding Programmes

General Challenges to Participation in NIH Funding Programmes

<u>Challenge</u>		<u>Response</u>	<u>Amount</u>
Communication and information awareness of programmes	Low	0	0
		1	0
	Medium	2	0
		3	6
		4	1
	High	5	5
		Total Responses	12
Contractual issues and intellectual property	Low	0	1
		1	0
	Medium	2	0
		3	5
		4	4
	High	5	2
		Total Responses	12
Cultural differences in management of grants	Low	0	2
		1	0
	Medium	2	4
		3	2
		4	3
	High	5	1
		Total Responses	12
Differences and/or lack of recognition between U.S. and European policy requirements on issues such as animal safety, protection of human subjects, research integrity, financial conflict of interest, etc.	Low	0	1
		1	0
	Medium	2	2
		3	1
		4	3
	High	5	5
		Total Responses	12



		0	3
Lack of administrative support from own organization	Low	1	1
		2	1
	Medium	3	4
		4	1
	High	5	2
Total Responses			12

		0	1
Lack of administrative support from U.S. funding body	Low	1	0
		2	1
	Medium	3	4
		4	4
	High	5	2
Total Responses			12

		0	0
Lack of complementary funding	Low	1	1
		2	2
	Medium	3	6
		4	1
	High	5	2
Total Responses			12

Other (All information below are direct quotes from GA)

Obscurity of language used by NIH - 4
 Lack of clarity of application and renewal processes - 4

Appendix 2G: How GA's Approach Challenges to NIH Participation

How GA's Approach Challenges to NIH Participation	
<u>Response</u>	<u>Response Amount</u>
Adapts your own university/institution/national policies to reach compliance	10
Asserts that university/institution/national policies need to be followed rather than U.S. policies	4
Assumes that existing/national policies already cover all requirements of U.S. policies	4
States inability to certify compliance in certain areas in the application	3
None of the Above	0
Other	0

Appendix 2H: Approach to Challenges by Organization Type

In approaching challenges to participation in NIH programmes, your institution: (please select all statements that apply)	Which of the following best describes your organization?				Response Count
	Higher Education Institution	Research organization (public/private)	Industry (including SMEs)	Other (please specify)	
Assumes that existing/national policies already cover all requirements of U.S. policies	3	1	0	0	4
States inability to certify compliance in certain areas in the application	2	1	0	0	3
Adapts your own university/institution/national policies to reach compliance	4	5	0	0	9
Asserts that university/institution/national policies need to be followed rather than U.S. policies	3	1	0	0	4
None of the above	0	0	0	0	0
Response Count	12	8	0	0	

Appendix 2I: Are New NIH Funding Opportunities Easy to Find Out About

Are New NIH Funding Opportunities Easy to Find Out About?	
<u>Response</u>	<u>Response Amount</u>
Yes	6
No	6
Total Responses	12
<u>If No, please explain (All information below are direct quotes from GA)</u>	
All seems very very complicated but the bottom line is that there aren't any at the moment available.	
Complexity of websites; difference between EU funding procedures related to the calls.	
If an announcement is of interest, it can be difficult to drill down and find the appropriate information on the website.	
Schemes for European participation are not easy to find. There should be a newsletter for foreign institutions.	
There are a lot different types and programmes, and it is not clear enough that foreign researchers can apply.	
They are not always easy to find in the application system.	

Appendix 2J: Hearing About New Funding Opportunities by Organization Type

Are new NIH funding opportunities easy to find out about?	Which of the following best describes your organization?				Response Amount
	Higher Education Institution	Research organization (public/private)	Industry (including SMEs)	Other (please specify)	
Yes	5	1	0	0	6
No	2	4	0	0	6
Response Count	7	5	0	0	12

Appendix 2K: How GA's Hear About New NIH Opportunities

How GA's Hear About New NIH Opportunities

<u>Method of Hearing About New Awards</u>	<u>Response Number</u>
Administrative staff at your institution	7
Colleagues/collaborators at your own or other non-U.S. institution	8
Commercial vendor of funding opportunities database/search	4
NIH programme officer or other staff	7
NIH website	3
U.S. colleagues or collaborators	10
Other	1
Total Responses	40

*Researchers were able to check all that apply (a total of 18 individual GA responded)

Other (All information below are direct quotes from GA)

Our NIH grants were transferred from US institutions when the the PIs (Spanish researchers) moved to the CNIO.

Appendix 2L: Other Issues Related to Awareness of NIH Programmes

Other Issues Related to Awareness of NIH Funding Programmes and Opportunities

Responses (All information below are direct quotes from GA)

The actual criteria when foreign applicants could be financed by NIH.

Appendix 2M: Legal, Policy, & Administrative Challenges to Participation

Legal, Policy, & Administrative Challenges to Participation in NIH Funding Programmes			
<u>Challenge</u>		<u>Response</u>	<u>Amount</u>
Audit requirements		0	1
	Low	1	0
		2	1
	Medium	3	3
		4	0
	High	5	7
Total Responses			12
Budgeting requirements (e.g., detailed budgets required as opposed to modular budgets)		0	1
	Low	1	0
		2	2
	Medium	3	5
		4	3
	High	5	1
Total Responses			12
Facilities & administrative (F&A)/indirect cost recovery limits		0	1
	Low	1	0
		2	2
	Medium	3	0
		4	1
	High	5	8
Total Responses			12
Intellectual property		0	1
	Low	1	1
		2	0
	Medium	3	3
		4	4
	High	5	3
Total Responses			12
Other contractual (grants) requirements		0	2
	Low	1	0
		2	0
	Medium	3	4
		4	4
	High	5	2
Total Responses			12

Appendix 2N: NIH Grants Policy

According to the NIH Grants Policy Statement, proposals originating from outside the United States (but not U.S. domestic applications with foreign components) are subject to these additional review criteria:

- 1) Whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and,
- 2) Whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Center (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States.

Have researchers at your institution experienced challenges due to these considerations?

Response

Yes
No

Response Number

6
6

If Yes, please explain

(All information below are direct quotes from GA)

Difficult to predict the actual possibilities.
Different NIH institutes are perceived as more or less open to international awards, i.e. this requirement is more important for overall judgement.
I have selected 'no' because there is no 'unknown' option - I do not know the answer to this question.
I've answered 'yes' simply in order to be able to state that this is probably better addressed by the principal investigators themselves. Perhaps an "N/A" or "unknown" option on the survey might have been appropriate here.
I am the only one receiving an NIH grant over many years (if not the first one at all) and it was not an issue for me.
Participation as partner organization often required further information about IPR and contractual regulations.
The additional information required is not always described well, so that it's difficult to fulfil the obligations.

Appendix 2O: Other Issues Related to Administrative, Policy, & Legal Challenges

Other Issues Related to Legal, Policy & Administrative Challenges of NIH Funding Programmes and Opportunities.

Responses (All information below are direct quotes from GA)

Navigating the internal administrative set-up at the NIH is challenging.

Appendix 2P: Positive Experiences in Applying to NIH

Postive Experiences/Aspects/Issues in Applying for and/or Receiving NIH awards That Could be Lessons for Other (U.S. or European) Funding Bodies.

Response Amount

2

Responses (All information below are direct quotes from GA)

Note: some comments are double-counted within categories

Detailed summary statements and very competent peer review process which improves project for other applications.
 Very helpful and knowledgeable program officers with strategic outlook and mission.
 Adaptive funding mechanisms.

Group of direct NIH contacts identified in award letter.
 Consistent advice and interpretation by direct NIH contacts.

Appendix 2Q: Recommendations for NIH Funding Programmes

What Recommendations Could Ease/Improve Research Collaboration Through NIH Funding Programmes?

<u>Theme*</u>	<u>Response Number</u>
Application Process	3
NIH Regulations	2

Responses (All information below are direct quotes from GA)

Note: some comments are double-counted within categories

Acceptance of our national policies or legislation as sufficient. Explanation/Summary rather than a reference to Federal regulations that require legal knowledge of US legal system and its application.
Clearer information on opportunities and clear guidance on funding schemes open to foreign applicants.
Make NIH/US Universities aware of EU FP7 open calls for US investigators which provide full F&A. Harmonizing compliance requirements between EU and US. Allow foreign applicants possibility to negotiate full F&A rates.
Simplicity and transparency of the offered programs (if there are any).
The language used for the regulations for compliance is obscure and the regulations are often very difficult to find and interpret.

*Themes were identified from the responses; they were not indicated in the question.