

Case studies of managing US funding in Europe

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Zurich: Home of two leading Universities

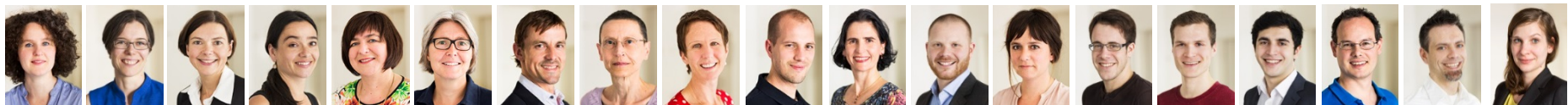


	University of Zurich	ETH Zurich
Founded	1833	1855
Ranking (THE QS Shanghai)	104 85 54	9 9 20
Nobel Prize Laureates	12	21
Enrollments	25'634	18'616
Staff	6098 (4014)	8143 (5065)

EU GrantsAccess



- Joint office of the University of Zurich and ETH Zurich
- The office for International Research Programmes
- At both institutions under VP Research
- Euresearch Regional Office
- Networks EURAXESS, EARMA, IARU, LERU, NCURA, swissnex
- 19 Collaborators



Federal Funds in Zurich

grants
access

	Universität Zürich	ETH Zürich
NIH	4 main, 8 subs (1 Mio \$/y)	1 main, 4 subs (0.7 Mio \$/y)
Other federal funds (grants)	500'000 \$/y	1 Mio \$/y
Federally funded contracts	-	2 Mio. \$/y
FP7	234 / 145 Mio € 235(21 Mio €/y)	558 / 359 Mio € (51 Mio €/y)
H2020	56 / 24 Mio €	122 / 69 Mio €

European funding vs. US funding

	EU Projects (FP6, FP7, H2020)	US Projects (NIH, NSF..)
Long tradition	✓	✗
Critical Mass of Project Participation	✓	✗
National Support Network	✓	✗
Contacts with the Funding Agency	✓	✗
Contacts with other GrantsOffices dealing this type of funding	✓	✓
Cultural «Proximity»	✓	✗

Registration in US Systems

Registration of ETH Zürich and University of Zurich in US different systems

DUNS	Proposal Central
NCAGE	Federal Helpdesk
CCR / SAM	Department of Defense
eRA commons	ebrap
NSF	NASA
Federal Wide Assurance (FWA)	Office of Research Integrity (ORI)
Institutional Review Board (IRB)	Animal Welfare
Grants.gov	Federal Demonstration Partnership
PMS	

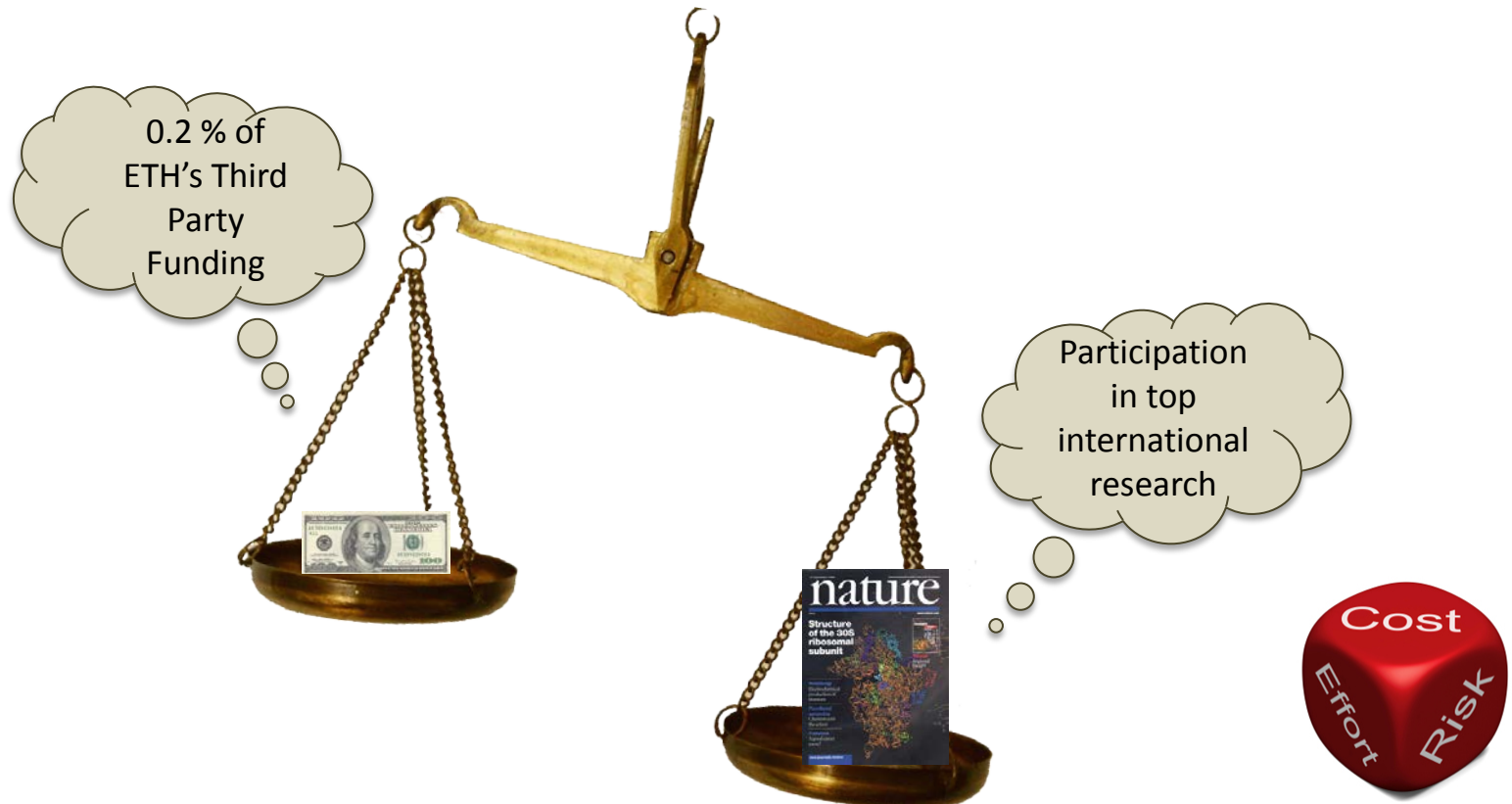
Trying to understand the complex US funding schemes and rules

- Read the documentation (GPS, Uniform Guidance, NoA...)
- Visit workshops and conferences
 - NCURA PRA / FRA (<http://www.ncura.edu/Education/MeetingsConferences.aspx>)
 - NCURA International Region Meeting
 - EARMA Conference (<http://www.earma.org>)
 - INORMS (<http://www.inorms2016.org>)
- Webinars (<http://www.ncura.edu/Education/OnlineEducation/Webinars.aspx>)
- Tutorials (<http://www.ncura.edu/Education/OnlineEducation/Tutorials.aspx>)
- Talk to grants specialist / manager
- Build network!!
- Best Practice Exchanges
- Apply for a NCURA Fellowship and be a NCURA Host



Weighting the pros and cons of US Federal Funding

Convince the board of your institution of the importance of US Grants and Compliance with US Regulations



Finding funding made easy.



Why applying for US funds?

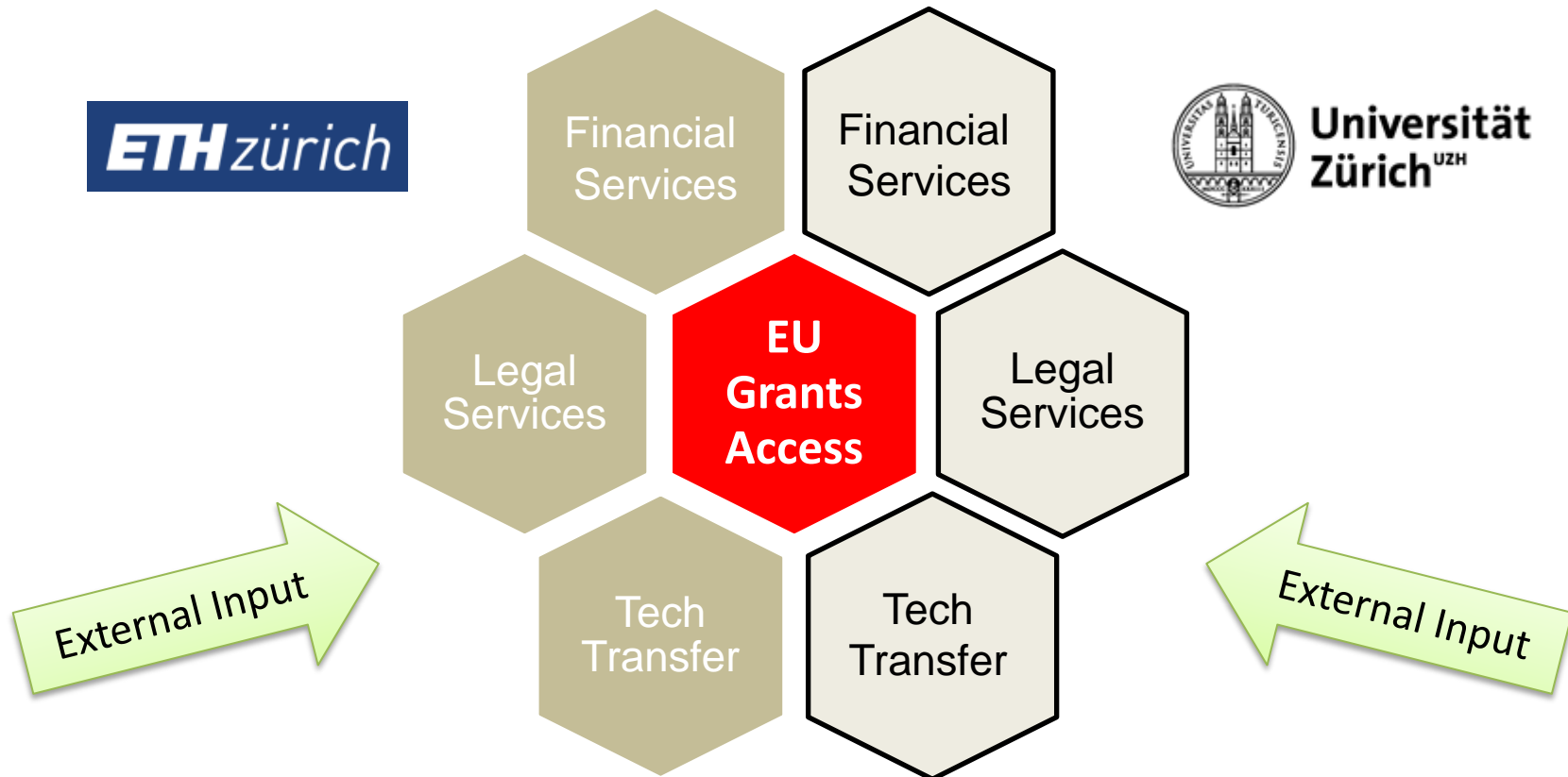


«Participation in NIH funded projects provides me the unique opportunity to participate in cutting-edge and research with my peers in the US.»



«My NIH Grant is an excellent arrangement that it allows us to participate at the highest international level with other research teams working in this area.»

Working together to analyze critical issues



Definition of responsibilities and processes within the institution

ETH zürich

- Regulations on Projects from ETH Zürich Receiving Research Funds from US Funding Agencies
<http://grantsaccess.ethz.ch/en/servicesupport/legal/us-grants-regulations-eth-zuerich/>
- Attachment A: defines Responsibilities and Tasks
- Attachment B: defines Processes
- Attachment C: Checklist for Researchers
- Attachment D: FCOI Disclosure Form PHS
- Attachment E: FCOI Disclosure Form NSF
- Attachment F: FCOI Form for Subrecipients

Basis of Compliance: Institutional Policies



- Regulations on Financial Conflict of Interest in Projects Receiving Research Funds from the American National Institute of Health at the University of Zurich (Regulations NIH)

<http://grantsaccess.ethz.ch/en/servicesupport/legal/nih-regulations-uzh/>



- Regulations on Projects from ETH Zürich Receiving Research Funds from US Funding Agencies

<http://grantsaccess.ethz.ch/en/servicesupport/legal/us-grants-regulations-eth-zuerich/>

Financial Conflict of Interest

- Applicable to PI or any other person «responsible for the design, conduct, or reporting of research funded by the NIH»
- Web-based FCOI-Tutorial every 4 years
(<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>)
- When concluding or renewing a contract, Investigators must disclose their financial interests
- If a financial interests arises during the course of a project, investigators must update the disclosure form and inform officer in charge within 30 days.
- In the case of an actual conflict of interest, the disclosure form may be presented to the Chief Grants Management Officer at NIH (if main awardee) or to the University that is in charge of the project (if subawardee).



NIH Institutes and Centers (ICs)



Finding funding made easy.

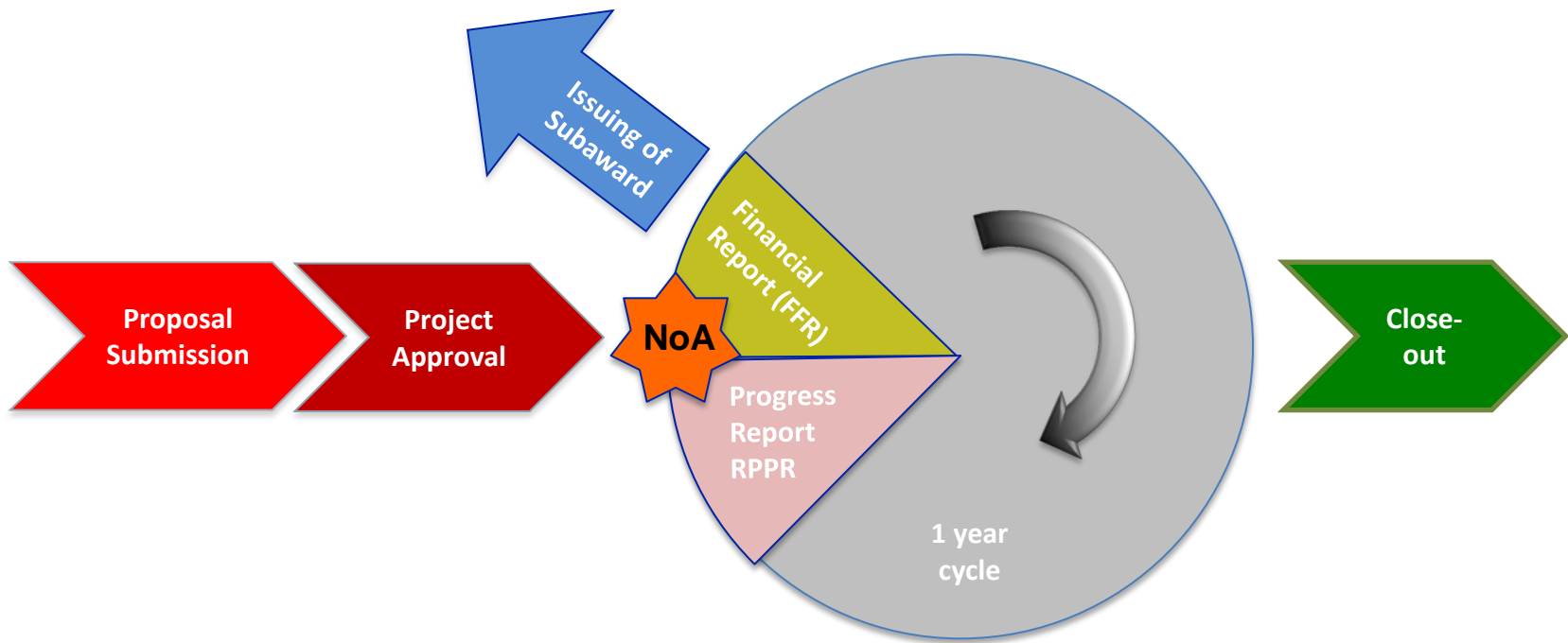
National Institutes of Health

- **US federal agency for (bio-)medical research**

«In general, foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants.»

- Founded 1887
- Budget of ~30 Billion USD year
- Grants cover ~83% (extramural) , 10% to own institutions
- 27 institutes and centers
- Online platforms: [Grants.gov](https://www.grants.gov) und [eRA commons](https://eRA Commons)
- NCBI (National Center for Biotechnology Information) online databases, e.g. dbGaP: <http://www.ncbi.nlm.nih.gov/>

Life Cycle of an NIH Award



NIH Grant Number

Application Type	Activity Code	Institute Code	Serial Number	Support Year	Extension
1	R01	CA	123456	01	A1 <small>(amended application)</small>

Application/Grant Types:

- 1 = New
- 2 = Renewal [Previous NIH term – Competing Continuation]
- 3 = Revision [Previous NIH term – Supplement]
- 4 = Extension
- 5 = Non-Competing Continuation
- 6 = Change of Organization Status (Successor-In-Interest) [e.g., name change, merger]
- 7 = Change of Grantee or Training Institution
- 8 = Change of Institute or Division (Type 5 transfer to another NIH IC)
- 9 = Change of Institute or Division (Type 2 transfer to another NIH IC)

Applicable Regulations: Do the existing ones comply?

Regulation	Comment	Recommendation / Risk	
Fly America Act	Open sky agreement between US and Switzerland	Compliance ensured	✓
Gun Control	Swiss Federal Law about Gun possession	Negligible	✓
Data and Safety Monitoring	Existing Laws on Swiss Federal Level: <ul style="list-style-type: none"> - Datenschutzgesetz (Data protection law) - Humanforschungsgesetz (Human research law) Existing Regulations on University Level <ul style="list-style-type: none"> - Richtlinien für Integrität in der Forschung und gute wissenschaftliche Praxis (Guidelines for Integrity in Research and proper scientific conduct) 	Assuming that compliance is ensured. To be sure, further investigation necessary	x
Animal Welfare	Existing Laws on Swiss Federal Level: <ul style="list-style-type: none"> - Federal Animal Welfare Act (TSchG) - Federal Animal Welfare Ordinance (TSchV) - Animal Experimentation Ordinance, TVV - Containment Ordinance (ESV) Existing Regulations on University Level <ul style="list-style-type: none"> - ETH Zurich's policy on laboratory animal research 	Compliance ensured	✓

Applicable Regulations

US-Grants: Checklist for Researchers ¶

DRAFT—Version 3—January 2016 ¶

Type of Grant ¶	¶
Researcher in Charge ¶	¶
Date and place ¶	¶
Confirmation ¶	I am aware of the rights and obligations as listed below referring to my grant and will implement them to the best of my knowledge. ¶
Signature PI ¶	¶
EU Grants Access Responsible ¶	¶
Financial Department Responsible ¶	¶

¶
The following Rights and Obligations have to be followed when being engaged in a US Grant. This Checklist is based on the public policy requirements mentioned in the Grants Policy Statement of the National Institutes of Health (NIH). It is assumed that similar compliance requirements are demanded from other US funding agencies. This checklist reflects the actual state of knowledge and is not exhaustive. Each PI is responsible to follow the individual requirements of the sponsor. ¶

ETH Zurich's legal office provided existing Swiss National regulations and laws covering the required regulations. Columns marked in red indicated cases, where no detailed check was possible in order to define whether the existing Swiss regulations are sufficient. ¶

Regulations ¶	Applicable ¶	
ETH internal ¶	Yes ¶	No ¶
Regulations on Projects from ETH Zurich Receiving Research Funds from US-American Funding Agencies (dated July 1, 2014, version January 1, 2016) ¶	X ¶	¶
Experiments with Animals ¶	¶	¶
Experiments with Humans ¶	¶	¶
NIH Grants Policy Statement, March 31, 2015 ¶	Applicable ¶	
4.1.3 Clinical Trials.gov ¶	¶	¶
4.1.10 Financial Conflict of Interest ¶	¶	¶
4.1.13 Human Stem Cell Research ¶	¶	¶
4.1.14 Human Fetal Tissue Research (Including Transplantation Research) ¶	¶	¶
4.1.15 Human Subjects Protections ¶	¶	¶

ETH internal Regulations ¶

Regulations on Projects from ETH Zurich Receiving Research Funds from US-American Funding Agencies (dated July 1, 2014, version January 1, 2016) ¶
<http://grantsaccess.ethz.ch/en/servicesupport/legal/us-grants-regulations-eth-zurich/> ¶

Experiments with Animals ¶

Fulfil the local requirements (see <https://www.ethz.ch/de/forschung/ethik-und-tierschutz/tierschutz.html>) ¶

EU Grants Access renews the Animal Welfare Assurance of ETH Zurich. ¶

Experiments with Human Research Participants ¶

Fulfil the local requirements: <https://www.ethz.ch/services/de/organisation/gremien-gruppen/kommissionen/ethikkommission.html> ¶

Complete NIH online training (<https://phrp.nihtraining.com/users/login.php>) and send CE to EU Grants Access ¶

NIH Grants Policy Statement, 11/2015 (NIH-GPS) ¶

4.1.3 Clinical Trials.gov ¶

Swiss National legal basis: ¶

--> HMG, VKlin, HFG, KlinV, HFV ¶

¶

Legal basis ETH Zurich: ¶

--> Richtlinien für Integrität in der Forschung und gute wissenschaftliche Praxis an der ETH ¶

¶

NIH-GPS: Applicants and recipients should familiarize themselves with the requirements of 282(j), also known as Sec. 801 of Public Law 110-85 (the FDA Amendments Act of 2007 or with respect to registration and results reporting requirements that may apply to certain particular note is that, in general, results of applicable clinical trials are due not later than

Our Services at UZH and ETH Zurich for NIH-Projects

- Registration in US Systems (DUNS, SAM, eRA commons, FWA, OLAW etc.)
- First contact at proposal stage
- Check and Submission of NIH Proposals (Submission package) if UZH or ETH Zurich as main
- Obtain (physical) signatures of Signing Official (e.g. Subawardee Commitment Form, Subaward, Letter of Intent, etc.)
- Monitoring of FCOI-disclosure
- Submission of Research Performance Progress Report (RPPR)
- Participation in Kick-off Meetings at project start; information on NIH requirements (non financial)

Keeping track of ongoing grants



US Grants
 suchen
 alle zeigen

 14. von 25 (Total: 112)
 neues Projekt
 drucke Projektdaten
 ▶ Int'l
▶ FP6
▶ FP7
▶

ID **802** **Projektangaben** Finanzieren

Projekt **USgrant** MainAward **RFA-NS-14-008** Subaward
 Programm **43 NIH** Private US funds
 Projekt Titel **NIH Proposal 2014 / BRAIN Initiative: Optimization of Transformative Technologie**
 Betreuer
 Status **Bewilligt** eingereicht am Beginn **30. Sep 2014** Dauer
 Ranking Dossier erstellt bewilligt am **23. Sep 2014** Ende **31. Jul 2017** 34 Mt.
 Human Subjects Involved yes no Animal Subjects Involved yes no

US Programme

Main Award UZH / ETH
Country Main Award

Institution Main Award

PI Main Award

Projektossier

AntragstellerInnen

Antragsteller (AS) hole 1. AntragstellerIn hole 2. AntragstellerIn
 #1379
 Helmchen Fritjof, Prof. m
helmchen@hifo.uzh.ch @
 Hirnforschung
 Rücktrittsdatum: 31. Jul 2031 Rücktrittsdatum:

Institution **Universität Zürich** HS **UZH** Dpt/Fak **MeF** Departements- / Fakultätsname **Medizinische Fakultät**

Bemerkungen **ACHTUNG: Ausnahmsweise mit 8% F&A Costs, da in NOA mit F&A, wurde von Doris Meyer und Bettina Lennström so entschieden an Sitzung am 30.9.2014**

NIH Budget Period

Budgetperiode

	Dauer von ... bis		Betrag \$	davon M
1	30. Sep 2014	31. Jul 2015	365'093.00	16'822
2	01. Aug 2015	31. Jul 2016	216'293.00	16'022
3	01. Aug 2016	31. Jul 2017	216'693.00	16'022
4				
5				
6				
7				
8				
9				
10				

applies to NIH proje

Keeping track of ongoing grants



suchen alle zeigen 14. von 25 (Total: 112)

14-008 Subaward

Private US funds

Optimization of Transformative Technologie

eingereicht am Beginn 30. Sep 2014 Dauer

bewilligt am 23. Sep 2014 Ende 31. Jul 2017 34 Mt.

no Animal Subjects Involved yes no

US Programme

Main Award UZH / ETH
Country Main Award

Institution Main Award

PI Main Award

Projektdossier

Finanzierung

ETH Fonds Nr.

ETH Forschungsreserve

bewilligter Betrag

Overhead %: Prof: ETH: UZH:

Total Overhead

hole 1. AntragstellerIn

hole 2. AntragstellerIn

Rücktrittsdatum:

HS Dpt/Fak Departements- / Fakultätsname

UZH MeF Medizinische Fakultät

Costs... da in NOA mit F&A... wurde von Doris Meyer und Bettina...
n. 30.9.2014

NIH Budget Period **FCOI**

FCOI

	Datum	Name Projektbeteiligte/r	Tutorial	FCOI Disclosure	
				FCOI	no FCOI
1	25. Sep 2014	<input type="checkbox"/> Fritjof Helmchen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2	01. Sep 2015	<input type="checkbox"/> Fritjof Helmchen	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

erneuern nach: 11 Monaten am: 1. Aug 2016 Erinnerungsmail am

Challenges in US grants management

- Different Funding Agencies – Different Rules ?
- FCOI training, disclosure
- Endless variety of subaward forms
- Constant monitoring of new regulations and implement changes new policies– Uniform Guidance
- Effort reporting
- Cost transfer
- Allowable / non-allowable costs
- F&A costs
- Export Controls
- Grant or Contract ?
- Training of staff
- Information of Researchers
- Monitoring of Subcontractors
-





Mitigation

- Try to understand the complex US funding schemes – visit workshops
- Convince the boards of the importance of US Grants and Compliance with US Regulations
- Set up regulations (FCOI)
- Set up Working Groups (lawyers, finance department, grants office) analyzing the critical issues
- Build up US Network – NCURA / EARMA
- Define responsibilities and processes
- Analyze whether new regulations are necessary
- Inform Researchers
- Be alert for new developments

Thank you!



Finding funding made easy.