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Armin Kohlrausch, Daniël Lakens, Alejandro Osses. Ethical requirements for behavioural experiments and some considerations about storing and sharing experimental data. Doctoral. Netherlands. 2016. hal-03873552

HAL Id: hal-03873552

<https://hal.science/hal-03873552>

Submitted on 26 Nov 2022

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Ethical requirements for behavioural experiments & some considerations about storing and sharing experimental data

Armin Kohlrausch, Daniël Lakens and Alejandro Osses

Human-Technology Interaction,
IE&IS, TU/e

BATWOMAN Workshop,
27 January 2016

TU/e Technische Universiteit
Eindhoven
University of Technology

Where innovation starts

Outline

- Ethical issues when planning an experiment:
 - Within the BATWOMAN project
 - Within the HTI Group
- Conducting an experiment at the HTI group
 - Experimental proposal: submission, revision and approval
 - Recruitment of participants
 - Informed consent: examples
 - After the experiment: data storage

Ethical issues within the consortium (1 of 3)

- Existing guidelines for ethics within Marie Curie actions (“Ethics Issues Table”):
 - No research on Human embryonic stem cell
 - Dual use: use of technologies for peaceful aims (and not military)
 - Ethics regulatory body
 - Informed consent
 - Privacy and data protection
- All these points are addressed in “Research proposal – Part B” (pages 37-39) and in “Annex I of the Grant Agreement” (Part B,6 in pages 31-32)

Research proposal: [ITN_BATWOMAN_PART-B_MASTER_20121122.pdf](#) (in Archiv/Dropbox/BATWOMAN (1).zip/0_EPSS_BATWOMAN_Submission_2013/)

Annex I: [ITN 2013 - BATWOMAN \(605867\)_ Annex I-final.pdf](#) (about the same location, but in negotiations folder)

Ethical issues within the consortium (2 of 3)

- Ethics regulatory body:
 - All experiments subject to inspection and approval of the Ethics committees of the host institutions
 - Procedures have to be fully compliant with ethical guidelines by Human Right Acts (2000) and the Declaration of Helsinki (1964).
- Informed consent:
 - Testing with one or more participants at a time
 - Obtain their informed written consent (before testing)
 - Subjects free to withdraw their data at any time
 - Clear explanation of the experiment

Ethical issues within the consortium (3 of 3)

- Data maintenance and protection:
 - No sensitive data will be collected from participants
 - Privacy assured using numerical codes to dissociate their names
 - Data will be kept securely (password protected), with access only to authorised staff

Ethical issues within HTI (1 of 3)

- Ethics regulatory body:
 - HTI Daily board (DB) inspects and approves every experiment
 - Compliant Human Right Acts and Declaration of Helsinki, current versions:

Ethisch reglement TU/e-HTI – februari 2013 – Pagina 3

Het onderzoek wordt opgezet en uitgevoerd in lijn met de Nederlandse wetgeving, de beroepscode van de Nederlands Instituut voor Psychologen (NIP, 2007), de Ethics Code van de American Psychological Association (APA, 2010), de Declaration of Helsinki of the WMA (2008), en de richtlijnen van de Centrale Commissie Mensgebonden Onderzoek (Handleiding voor de toetsing van medisch-wetenschappelijk onderzoek met mensen, 2002).

Ethical issues within HTI (2 of 3)

- **Informed consent:**
 - Testing with **one** or more participants at a time
 - Obtain their informed written consent (before testing)
 - Subjects free to withdraw their data at any time
 - Clear explanation of the experiment

Informed consent form

This document gives you information about the study “Modeling the sensation of fluctuation strength”. Before the experiment begins, it is important that you learn about the procedure followed in this experiment and that you give your informed consent for voluntary participation. Please read this document carefully.

- [...] After the completion of each experiment you can take a small break to rest and then continue with the remaining ones.

Ethical issues within HTI (3 of 3)

[...] Risks

The experiment does not involve any risks or detrimental side effects.

Voluntary

Your participation is completely voluntary. You can refuse to participate without giving any reasons and you can stop your participation at any time during the experiment. You can also withdraw your permission to use your experimental data up to 24 hours after the experiment is finished. All this will have no negative consequences whatsoever.

Confidentiality

All research conducted at the Human-Technology Interaction Group adheres to the Code of Ethics of the NIP (Nederlands Instituut voor Psychologen – Dutch Institute for

Certificate of Consent

[...]

I, (NAME)..... have read and understood this consent form

[...]

- **Data maintenance and protection:**
 - Will be shown later, during the Archie system demonstration

Conducting an experiment at HTI: procedure

1

- Submit Proposal to Ethical Board

2

- Get OK, Perform Study

3

- Upload Data & Materials
- HTI system for submission of proposals and data storage: **Archie**

Conducting an experiment at HTI (Submit proposal)

- Submit proposal:
 - Experiment proposal and informed consent



Submission form for HTI studies

General study information		
1	Supervisor(s)	Prof. Armin Kohlrausch, Alejandro Osses V.
2	Study name	Modeling the sensation of fluctuation strength
3	Study type	Normal

Conducting an experiment at HTI (Get OK)

- Second feedback on proposal (from DB):

Below the response of the experiment evaluation committee.

If you need help, you can visit Ingrid Vogels today.

348: Rejected. The idea that 6 SD fall within the IQ range is incorrect. 6 SD is for the entire range in the bloxplot (excluding outliers). Equation 1 is a formula for confidence intervals but does not take random variation in data into account. As such, it does not provide a probability of e.g., 90% that you will obtain a confidence interval in the range you want to observe. Sample size planning based on accuracy is possible (see Maxwell, Kelley, & Rausch, 2008: Sample Size Planning for Statistical Power and Accuracy in Parameter Estimation) but the approach is slightly more complex than you propose here. As last time, the sample size estimation is not valid. You say ‘The objective of the

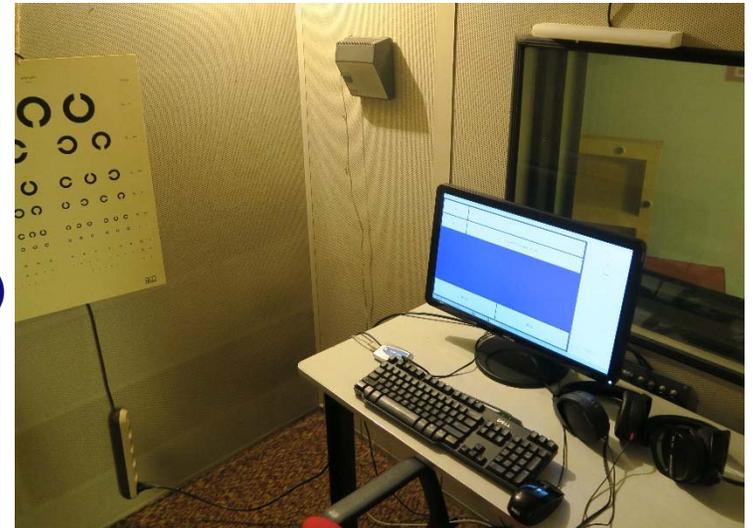
In the end, we determined sample size by an hypothesis test (t-test)

Informed consent: rewrite in non-technical language that can be understood by participants. The sentence “The aim of this study is to assess your perception of the fluctuation strength attribute to stimuli under varying parametrical conditions.” does not explain the goal of the study in a clear language. Translate ‘fluctuation strength’ into a description people understand. Try to give a practical example.

- Go to Archie: summary of the experiment milestones

Conducting an experiment at HTI (Perform study)

- Conducting the experiment:
AuditoryLab (IPO 0.52)
 - IAC double walled sound booth
 - PC + Audio interface M-Audio Transit (2-O)
 - Sennheiser HD265 Linear



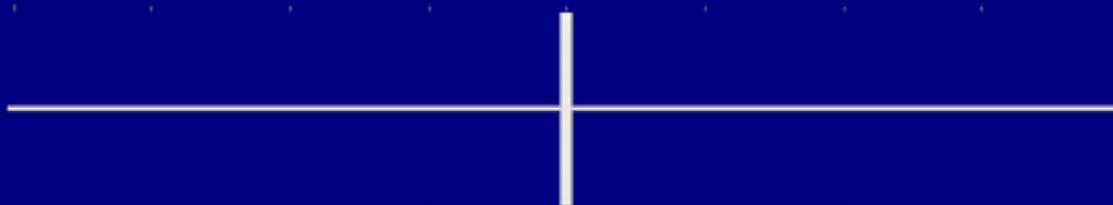
How much does the second sound fluctuate with respect to the first one?

None
▼

Half
▼

Equal
▼

Double
▼



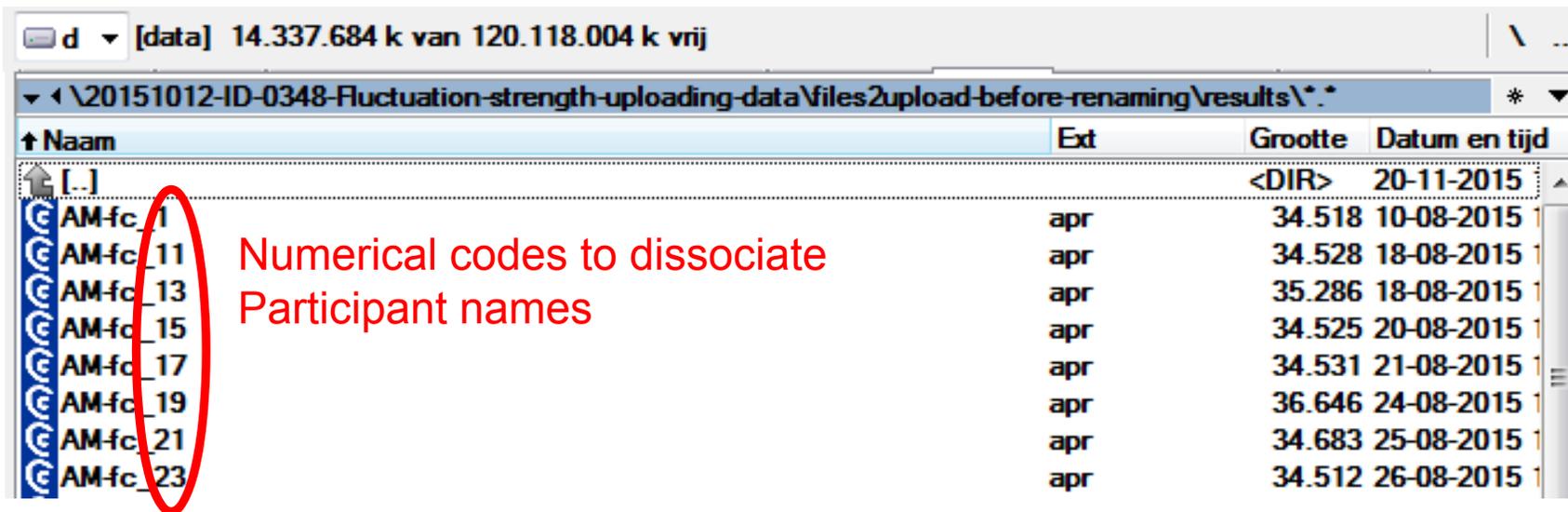
Start

Conducting an experiment at HTI (Perform study)

- **Participants recruitment:** JF Schouten database (<http://ppdb.ieis.tue.nl/main.php>)
- Filter by multiple criteria (age, normal hearing, etc.)
- Rule of thumb:
request of participation sent to 4 x sample size.

Conducting an experiment at HTI (Data, materials)

- Before looking at a result experiment file... let's check the data protection and storage using Archie.
 - Archie (data retrieval) needs connection to TU/e ethernet connection



↑ Naam	Ext	Grootte	Datum en tijd
[.]		<DIR>	20-11-2015
AM-fc_1	apr	34.518	10-08-2015
AM-fc_11	apr	34.528	18-08-2015
AM-fc_13	apr	35.286	18-08-2015
AM-fc_15	apr	34.525	20-08-2015
AM-fc_17	apr	34.531	21-08-2015
AM-fc_19	apr	36.646	24-08-2015
AM-fc_21	apr	34.683	25-08-2015
AM-fc_23	apr	34.512	26-08-2015

Conducting an experiment at HTI (Data, materials)

- No sensitive data is stored. An example output file (in APEX):

```
AM-fc_1.xml
1 <apex:results experiment_file="file:/C:/APEX_shared/experiment/AM-fc.apx"
2 xmlns:apex="http://med.kuleuven.be/exporl/apex/result">
3 <general>
4   <description>Magnitude estimation experiment to determine the dependence
5 of center frequency on fluctuation strength for AM tones</description>
6   <startdate>2015-08-10T15:25:22</startdate>
7   <enddate>2015-08-10T15:34:11</enddate>
8   <duration unit="seconds">528</duration>
9   <xsltscript>slider.xsl</xsltscript>
10 </general>
11 <trial id="trial16">
12 <procedure id="procedure1">
13 <trial_start_time>2015-08-10T15:25:55</trial_start_time>
14 <correct_answer>2</correct_answer>
15 <stimulus>stim6</stimulus>
16 <standard>stimref1</standard>
17 </procedure>
18 <screenresult>
19   <element id="slider_1">50</element>
20 </screenresult>
21 <responsetime unit='ms'>2884</responsetime>
22 <randomgenerators>
23
24 </randomgenerators>
25 </trial>
26
27 <trial id="trial14">
```

Annotations:

- Start, end date/time
- Total experiment duration [s]
- Trial ID
- Trial start time
- Stimuli in this trial
- "50%" (stim6 is half as fluctuating as stimref1)
- Response time [ms]
- Next trial ID...

Conducting an experiment at HTI (Data, materials)

- Data storage. It is mandatory:

Archive information for "Modeling"

- * Scanned signed consent forms, or -for online
- * Participant information
- * Description of methods and procedures
- * Description of environmental conditions
- Audio files
- Authorware files
- Description of stimuli
- E-Prime files
- Eye tracker files
- Input files
- Processing scripts and their output
- Publication or manuscript
- Raw output files
- Source code files
- Statistical analysis files

– We have backed-up:

Experiment-informed-consent-forms.pdf

Experiment-files-for-APEX.zip

Experiment-stimuli.zip (audio in *.wav)

Experiment-results-raw-data.zip

README-experiment-details.txt

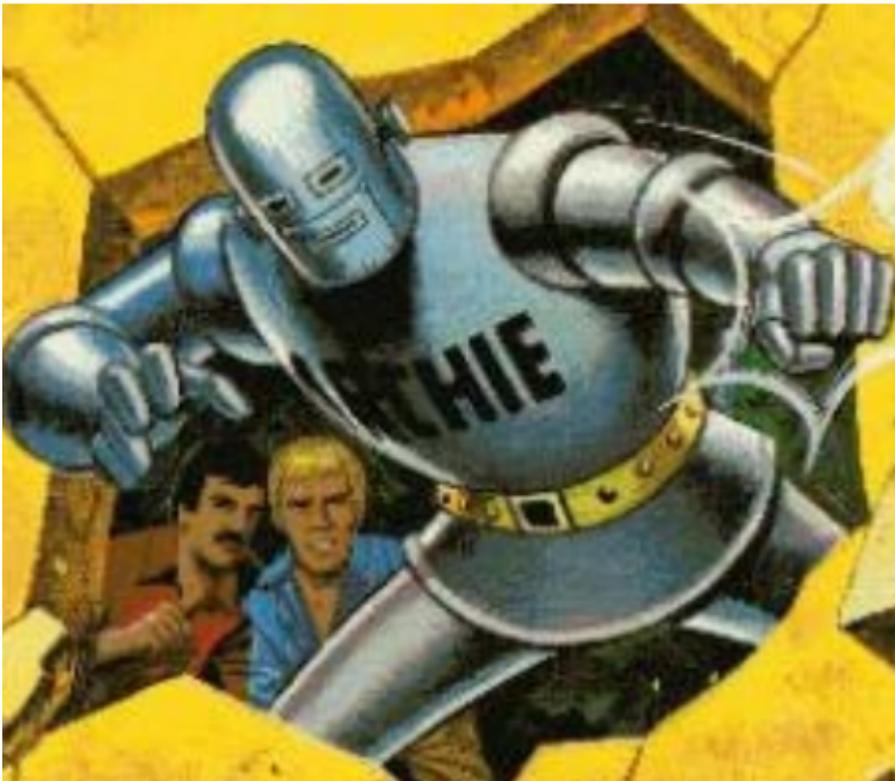
(description of methods and participants)

Archie system

ARCHIE User Manual

Martin Boschman & Jan Roelof de Pijper

Version 1.1, September 2013



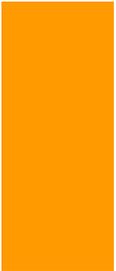
- **Internal solution HTI department TU/e**
- **Data stored 10 years**
- **Researchers can upload, but not modify, research data**
- **Some meta-data (sample size, age youngest participant, description of files)**



Some considerations about data storage and sharing experimental data

Regulations

- **Data storage is not organised through *laws*, but through *regulations*.**
- **The Netherlands Code of Conduct for Academic Practice, created by the VSNU (Association of Universities in the Netherlands), paragraph 3.**



3. Verifiability

Principle

Presented information is verifiable. Whenever research results are published, it is made clear what the data and conclusions are based on, from where they originate and how they can be verified.

Definition

Conduct is verifiable when it is possible for others to assess whether it complies with relevant standards (for instance of quality or reliability).

Elaboration

- 3.1. Research must be replicable in order to verify its accuracy. The choice of research question, the research set-up, the choice of method and the references to sources used are accurately documented in a form that allows for verification of all steps in the research process.
 - 3.2. The quality of data collection, data input, data storage and data processing is closely guarded. All steps taken must be properly reported and their execution must be properly monitored (lab journals, progress reports, documentation of arrangements and decisions, etc.).
 - 3.3. Raw research data are stored for at least ten years. These data are made available to other academic practitioners upon request, unless legal provisions dictate otherwise.
 - 3.4. Raw research data are archived in such a way that they can be consulted at all times and with a minimum expense of time and effort.
- 

Regulations

- **You, as a researcher, are personally responsible for storing all your raw data for at least 10 years.**
- **It is often efficient when departments or faculties develop practical recommendations how to do this.**

Regulations

- **If you are not aware of these rules, contact the information specialist at your university.**
- **We used to call information specialists ‘librarians’ but their work has changed a lot in the last 15 years, and they know a lot about storing and sharing data.**
- **Archie: internal solution HTI department TU/e**

NWO regulations

- **NWO has started a data management plan pilot, where researchers need to specify they have a data management plan in place**
- **Pilot started in 2015, will develop into requirements for all funded research.**

NWO regulations



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Data Management

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Start pilot Data Management

Responsible data management is part of good research. To make the data that emerges from NWO-funded research as accessible and reusable as possible, NWO started a pilot Data Management on 1 January 2015. NWO uses input from this pilot for the further development of policy and the implementation of data management in all its funding instruments.

Access to raw data is important for follow-up research and for replication and integrity studies. Full open access is the operating principle. Limited access applies where issues of privacy, public safety, intellectual property rights or commercial interests require this. Researchers must indicate how they will store their research data and how they will make it findable and suitable for re-use. They may list the costs of data management as part of the requested funding.

ERC regulations

- **Similar pilot is part of Horizon 2020**

A further new element in Horizon 2020 is the use of Data Management Plans (DMPs) detailing what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved.

The use of a Data Management Plan is required for projects participating in the Open Research Data Pilot. Other projects are invited to submit a Data Management Plan if relevant for their planned research.

Sharing data

- **We see a move towards data sharing requirements, although when and how data should be shared is still being discussed in many fields.**

Sharing data

- **Some journals already require data sharing**
- **PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, *with rare exception*.**



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Data Availability

The following policy applies to all of PLOS journals, unless otherwise noted.

PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception.

Sharing data

- **Other journals do not require data sharing, but stimulate it, for example by making it visible if you share your data and materials**



OPEN DATA



OPEN MATERIALS



PREREGISTERED

Sharing data

- For example Psychological Science:



Psychological
SCIENCE

Research, Theory, & Application in
Psychology and Related Sciences

A Journal of the Association for Psychological Science

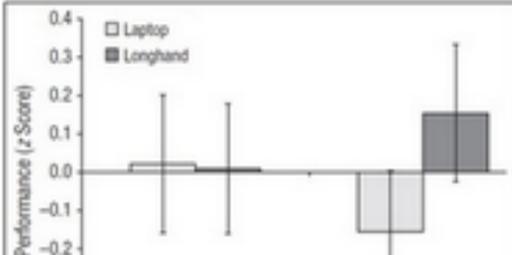
This Week in *Psychological Science* (TWiPS)

The links below take you to the journal via the APS website. If not already logged in, you will be redirected to log-in using your last name (Nosek) and Member ID (16341).

Call for Editor Nominations
Psychological Science in the Public Interest

[The Pen is Mightier Than the Keyboard: Advantages of Longhand Over Laptop Note Taking](#)
Pam A. Mueller and Daniel M. Oppenheimer





Category	Laptop (z-score)	Longhand (z-score)
Category 1	~0.02	~-0.02
Category 2	~-0.15	~0.15

It's becoming more and more common for students to type their notes on laptops rather than writing them out in longhand. In the first of several studies, the authors examined the effects of laptop note taking by having participants take notes on a TED talk using a laptop computer or a notepad. Thirty minutes later, the participants answered factual recall and

Where to share?

- **There are many solutions:**
 - 3TU Datacenter
 - Dans
 - Dryad
 - Figshare
 - Github
 - I prefer the Open Science Framework. Integrates well with the research cycle, store everything privately, make public when you want.

Open Science Framework

OSF | Home

Browser navigation bar showing the URL <https://osf.io> and navigation links: Apple, Disney, ESPN, Yahoo!, Virginia Sports, Google Scholar, Today baseball. The main navigation bar includes "Open Science Framework BETA", "Explore", "Help", a search box, and a "Create an Account or Sign-In" button.

Project management
with
proj
the public

<http://osf.io/>

The Open Science Framework (OSF) supports the entire research lifecycle: planning, execution, reporting, archiving, and discovery.

Password

Sign up

Sharing papers

- **NWO wants to move towards all Dutch tax funded research being open access.**
- **Right now, you can often already share your word document version (the *postprint*) of the final manuscript.**
- **Check on Sherpa/Romeo. Sharing postprints increases # citations.**

Publisher copyright policies & self-archiving

Search

Journal titles or ISSNs
 Publisher names

Journal of Experimental Social Psychology

Exact title
 starts with
 contains
 ISSN

[Advanced Search](#)

Search - Publisher copyright policies & self-archiving

One journal found when searched for: **journal of experimental social psychology**

Journal:	Journal of Experimental Social Psychology (ISSN: 0022-1031)
RoMEO:	This is a RoMEO green journal
Paid OA:	A paid open access option is available for this journal.
Author's Pre-print:	✓ author can archive pre-print (ie pre-refereeing)
Author's Post-print:	✓ author can archive post-print (ie final draft post-refereeing)
Publisher's Version/PDF:	✗ author cannot archive publisher's version/PDF
General Conditions:	<ul style="list-style-type: none"> • Pre-print allowed on any website or open access repository • Voluntary deposit by author of authors post-print allowed on authors' personal website, arXiv.org or institutions open scholarly website including Institutional Repository, without embargo, where there is not a policy or mandate • Deposit due to Funding Body, Institutional and Governmental policy or mandate only allowed where separate agreement between repository and the publisher exists. • Permitted deposit due to Funding Body, Institutional and Governmental policy or mandate, may be required to comply with embargo periods of 12 months to 48 months . • Set statement to accompany deposit • Published source must be acknowledged • Must link to journal home page or articles' DOI • Publisher's version/PDF cannot be used • Articles in some journals can be made Open Access on payment of additional charge • NIH Authors articles will be submitted to PubMed Central after 12 months
Mandated OA:	(Awaiting information)
Paid Open Access:	Open Access Articles
Notes:	<ul style="list-style-type: none"> • Publisher last contacted on 18/10/2013
Copyright:	Article Posting Policies - Rights & responsibilities - Funding Body Agreements - Green Open Access - Open Access License Policy Green Open Access - Elsevier Journal Specific Embargo Periods
Updated:	16-May-2014 - Suggest an update for this record

Thank you for your attention!

Do you have any questions or remarks?

Slides 8, 16-32 were provided by Daniël Lakens