Understanding alcohol and gambling addiction from a goal-directed perspective
DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

Understanding alcohol and gambling addiction from a goal-directed perspective
Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

New datasets will be generated.
Content of the data: numerical data from human participants (reaction times in computer tasks, response choices, ratings on validated questionnaires), ordinary personal data (age, gender), and special categories of personal data (clinical diagnostics, treatment schemes).
Format: new numerical databases will be created. Data will be digital. Data will be raw and processed afterward.
Mode of data collection: experimental research and surveys administered in the laboratory.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

1. Designation of responsible person (If already designated, please fill in his/her name.): Agnes Moors (for KU Leuven); Xavier Noël (for ULB).
2. Storage capacity/repository Storage capacity/repository:

- During and after the research, pseudonymized digital data will be stored on the KU Leuven-protected servers for at least 10 years. These data will be stripped of any identifiable information.
- After the research, these data will be made available via the Research Data Repository (RDR) of the KU Leuven. By adding metadata and an internal review process of the RDR, we will ascertain that all data are made available following FAIR principles (i.e., Findability, Accessibility, Interoperability, and Reuse of digital assets).
- A GDPR Data processing and data ownership agreement will be signed between research partners and KU Leuven.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

NA

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

We will collect health-related data from vulnerable participants. To guarantee privacy, data will be pseudonymized: Participants receive a random code. Links between participants' identifying information and these codes are stored in a separate password-protected document to which only the responsible person has access.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

NA

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Yes

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FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA
Experiments: a/c: AUD = alcohol use disorder b/d: GD = gambling disorder WP1a-b: Inflated estimations of stimulus-goal discrepancies (Social Judgment Task) WP2a-b: Biased estimations of outcome expectancies of addictive behavior after stimulus-goal discrepancies (personalized script) WP3a-b: Rigid response-outcome expectancies of addictive behavior under time pressure (Reversal Learning task) WP3c-d: Rigid response-outcome expectancies of stimulus-goal discrepancy (personalized script + Reversal Learning Task	Computer experiment: Social Judgment Task and/or Reversal Learning Task Categorical approach: clinical participants vs. healthy controls. This research will be conducted at ULB. Dimensional approach: in general population. This research will be conducted at KU Leuven.	Generate new data	Digital	Observational	.csv, .txt	< 1GB
Clinical and neuropsychological assessment	Clinical diagnosis Questionnaires to measure symptom severity and neuropsychological questionnaires	Generate new data	Digital	Observational	.csv, .txt	< 1GB
EEG data		Generate new data	Digital	Observational	.edf, png	< 100GB

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

For the AUD patient studies (categorical approach), data about clinical diagnoses are already present, obtained from the Brugman Hospital, Brussels.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

We will apply for GDPR and ethical approval through the PRET and SMEC portals. Once the approval numbers are available, they will be added.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

1. For the categorical studies with patients:
1.1. Ordinary personal data: names, email addresses, age, gender
1.2. Special categories of personal data:

- Data concerning (physical and/or mental) health
- Health: diagnoses and symptoms
- Health: medication use
- Health: data about mental health such as stress, depression, etc.
- Health: hospitalization data

2. For the dimensional studies with participants from the general population
2.1. Ordinary personal data: names, email addresses, age, gender
2.2. Special categories of personal data:

- Data concerning (physical and/or mental) health
- Health: diagnoses and symptoms
- Health: data about mental health such as stress, depression, etc.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

For each study, there will be a separate folder containing the following elements:
1. Readme.txt file: objectives, procedure, methodology, hypotheses, analysis plan. This information will also be preregistered at the Open Science Framework (OSF).
2. Codebook.xlsx file: anonymized information about participants, variable list and data types, variable descriptions and units, summary statistics.
3. Analyses.R/.py/.m file: thoroughly commented statistical analysis code.
4. Experiment.py file: thoroughly commented experiment code.
5. All the study documents: Ethical application and approval, informed consent form example, instructions we gave participants. The PDFs of all questionnaires will be included.
6. Data file with pseudonymized raw data.
7. Encrypted file with identifiers.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- Yes

For the EEG data: European Data Format (.edf) allows us to store metadata.

3. Data storage & back-up during the research project

Where will the data be stored?

Data collected at KU Leuven (studies with dimensional approach; samples from general population): OneDrive linked to a KU Leuven account
Data collected at ULB (studies with categorical approach; clinical samples): OneDrive linked to a ULB account

How will the data be backed up?

The data from KU Leuven will be continuously and automatically backed-up by the standard back-up system provided by KU Leuven ICTs for my storage solution.
The data from ULB will be continuously and automatically backed-up by the standard back-up system provided by ULB.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All data will be pseudonymized with unique identifiers. The latter will be stored separately in encrypted files, which can be accessed only by the main researcher (the KU Leuven research by the PI at KU Leuven; the ULB research by the PI at ULB).
The pseudonymized data will be shared with the involved researchers.
The (internal and external) hard drives of the researchers' laptops will be encrypted using specialized software.
Identifiers will be removed after 5 years.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Neglible costs

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

All data will be preserved for 10 years according to KU Leuven RDM policy.

Where will these data be archived (stored and curated for the long-term)?

KU Leuven Research Data Repository (RDR)

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

No expected costs.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in an Open Access repository
- Yes, in a restricted access repository (after approval, institutional access only, …)
- No (closed access)

The pseudonymized data from categorical studies (with clinical participants) will be stored in a restricted access repository. This will be the case for all data types (from experiments, questionnaires, and EEG).
The pseudonymized data from dimensional studies (with members from the general population) will be stored in an Open Access repository. This will be the case for all data types (from experiments, questionnaires, and EEG).
Encrypted files are closed access.

If access is restricted, please specify who will be able to access the data and under what conditions.

For the data in the restricted access repository (stemming from the ULB research), access will be enabled by the PI from ULB. Conditions: These will be specified later.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects

Privacy aspects: For both open access and restricted access data: Only pseudonymized data will be accessible.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

All pseudonymized data will be shared via:

- KU Leuven RDR
- Open Science Framework (OSF)

When will the data be made available?

Upon publication of research results (in scientific article).

Which data usage licenses are you going to provide? If none, please explain why.

CC-BY 4.0 (data)
GNU GPL-3.0 (code)

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

Yes, a PID/DOI/accession number will be added upon deposit in RDR.

What are the expected costs for data sharing? How will these costs be covered?

No expected costs.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

For KU Leuven: Agnes Moors (PI KU Leuven), PhD student: to be determined / For ULB: Xavier Noël (PI ULB), PhD student: to be determined.

Who will manage data storage and backup during the research project?

For KU Leuven: Agnes Moors (PI KU Leuven), PhD student: to be determined / For ULB: Xavier Noël (PI ULB), PhD student: to be

determined.

Who will manage data preservation and sharing?

For KU Leuven: Agnes Moors (PI KU Leuven), PhD student: to be determined / For ULB: Xavier Noël (PI ULB), PhD student: to be determined.

Who will update and implement this DMP?

For KU Leuven: Agnes Moors (PI KU Leuven), PhD student: to be determined / For ULB: Xavier Noël (PI ULB), PhD student: to be determined.