

## **PSY-2021-S-0482 Entrepreneurs financial strain: Panel study**

Principal investigator: AKK Kleine

General instructions on how to use EC Request can be found by clicking 'Help' in the top right corner of your screen. Specific instructions for individual questions are to the right of these questions (in colour). Please read these instructions carefully.

Questions marked with an asterisk \* are mandatory: you can only proceed to the next page if you provide an answer.

If you would like to see a complete overview of the questions in this form, this can be downloaded here:

[BSS EC Request Form Overview \(PDF\)](#)

[BSS EC Request Form Overview \(Word\)](#)

Additional information and templates for the Informed Consent, the research plan and a research data management plan can be found on the [website of the EC-BSS under preparations](#).

\* Is this an amendment, namely, a previously approved request that has now been reopened for modifications? If so, please explain what you have changed and why when submitting the form. The form can be submitted on the last page, where a comment field for extra explanation is available.

- ☐ Yes  
☒ No
- 

### **Module 1: Start**

The questions below concern basic information on who holds responsibility for the research.

\* What is the p-number of the principal investigator (PI)?

P288202

As per the GDPR, this information will also be in the UG Research Register. Principal investigators (PIs) are researchers who carry final responsibility for the research. They need to have obtained a PhD degree. In other words, (PhD and other) students may in principle not be PIs. There are a few exceptions. Contact [your EC-chamber](#) to learn which and how to communicate them in EC Request. Also note that the affiliation of the PI should be the same as the BSS department of the EC the proposal is submitted to.

\* What are the initials of the PI?

AKK

\* What is the last name of the PI?

Kleine

\* What is the e-mail address of the PI?

Ⓐ a.k.kleine@rug.nl

In case the request for ethics review is submitted by someone who is not a PI, the system needs to know the e-mail address of the PI, who will then be asked to confirm the request. In case you are the PI, please select your own e-mail address.

You can only select from the e-mail addresses of those with whom the study has been shared in the Research Portal. If the PI is not among the e-mail addresses, please share the study with the PI in the Research Portal first, then reload this page.

\* Who are the other research team members, who are also affiliated with the UG? Please enter names, e-mail addresses, p-numbers or s-numbers, faculties, and departments. If there are no other UG-affiliated research team members, please say so.

Dr Antje Schmitt, a.schmitt@rug.nl, P282810, Department of Psychology  
Prof Dr Barbara Wisse, b.m.wisse@rug.nl, P166882, Department of Psychology

Please list all internal members of the research team who are not PIs, including Bachelor students, Master students, PhD students, and all other people involved. Make sure you share your project in the Research Portal with all of them. If you intend to involve students but their names are not yet known, please make sure to mention this here and add their names later on.

Note: Do not include external team members, i.e. those not affiliated with the UG. These you can list in the next question.

\* Who are the other research team members, who are NOT affiliated with the UG? Please enter names, e-mail addresses, and affiliation (institute or company, location). If there are no other research team members, please say so.

n/a

Please list all external members of the research team who are not PIs, including Bachelor students, Master students, PhD students, and all other people involved.

\* What is the research start date?

17-5-2021

(dd-mm-yyyy)

This date should reflect the start of data processing (which includes data collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure, dissemination, combination, restriction, archiving, and erasure). Additional information will be asked in Module 3 (Data Management and Privacy).

\* What is the research end date?

6-11-2021

(dd-mm-yyyy)

This date should reflect the end of data processing (which includes data collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure, dissemination, combination, restriction, archiving, and erasure). Additional information will be asked in Module 3 (Data Management and Privacy).

\* Does the research plan exclusively involve the re-use of existing data for new research purposes?

- ☒ No
- ☐ Yes

When new data are going to be collected, the EC asks researchers for different information than when existing data are to be re-used for new research purposes.

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## Module 2A: Research plan for new data collection

The questions below concern your specific plan for collecting data during the research. Please see the research plan (RP) guideline on the faculty intranet:

[BSS Research Plan Guideline \(Word\)](#)

Is this a research plan that has been granted exemption for review by a Medical Ethics Review Board ('Medische Ethische Toetsingscommissie', METc)? If yes, please upload the exemption letter.

*No file has been uploaded*

According to the local METc, the PI decides whether or not to first submit the research plan for review according to the Medical Research Involving Human Subjects Act ('Wet Medisch-wetenschappelijk Onderzoek met mensen', WMO). If the METc decides that the research plan is exempt for such a review, it will issue an exemption letter. For examples of 'non-WMO' research and information on how to apply for an exemption letter, see:

<https://metcgroningen.nl/indienen/non-wmo-research>. In case of doubt on whether the research plan requires review according to the WMO, please contact the local METc via [metc@umcg.nl](mailto:metc@umcg.nl). Please note the EC(P) may also decide the research plan should first be submitted to the METc.

\* Please upload your research plan. Preferably this plan has been drawn up according to the EC guideline linked to at the top of this page.

[Research Plan\\_OS\\_updated.docx](#)

See the EC guideline linked to at the top of this page for expected content. In terms of format, you may either follow the EC guideline or use another format (e.g. you may upload your research plan as described in your grant application, provided it is accurate and complete).

\* How will participant recruitment take place?

- ☐ Letter to potential participants aged 16 or higher
- ☐ Letter to potential participants below 16 years of age
- ☐ Letter to parents / legal representatives
- ☐ Letter to managers/heads of relevant institutions
- ☐ Flyer or brochure
- ☐ Newspaper advertisement
- ☐ Public advertisement on website (for example: Facebook)
- ☒ Targeted advertisement via research panel website (for example: SONA, MTurk, Prolific Academic, Qualtrics Panel, Flycatcher, Panelclicks, I&O Research)
- ☐ Other, as specified in the research plan

This question is concerned with the various written means by which potential research participants will be solicited for participation in the research, that is letters, flyers, brochures, advertisements, et cetera. This information may be directed to the potential participants themselves, to parents or (legal) representatives, or to the institution (e.g., the school) to which the participants belong.

For each type of recruitment material, please upload the actual text you intend to use on the next page. The material should not (a) unduly influence individuals to participate, (b) state or imply certainty of a favourable outcome or other benefits beyond what is outlined in the information form to be used during the informed consent procedure, (c) unduly promote compensation or benefits, (d) use terms such as 'new intervention' without clarifying the research component, and (e) emphasise compensation, particularly when recruiting minors.

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\* Please upload the 'Targeted advertisement via research panel website (for example: SONA, MTurk, Prolific Academic, Qualtrics Panel, Flycatcher, Panelclicks, I&O Research)'

[Recruitment letter\\_OS.docx](#)

\* Will any personal data be processed? Most likely, the answer to this GDPR-related question is Yes. See the instructions for more information.

- ☒ Yes
- ☐ No, research participants are completely anonymous during all phases of the data life cycle

According to the GDPR, (1) personal data means any information relating to an identified or identifiable natural person, and (2) processing means any set of operations which is performed on personal data. Data may include records, samples, specimens, databases, surveys, etc.

More specifically, (1) personal data means any information relating to an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person, and (2) processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

For definitions in Dutch, see: <http://www.privacy-regulation.eu/nl/artikel-4-definitities-EU-AVG.htm>.

If, and only if, no personal data are being processed, then your research participants are completely anonymous. In this case, the data are neither obtained nor stored with identifiers that can be directly or indirectly linked back to the participants. In other words, research participants are only completely anonymous if anonymisation of their data happens right at the time point at which the data are being collected.

Please note that if data anonymisation takes place at a later stage than at the time of data collection then the raw data hold personal data. Examples include the removal of personally identifiable information when feeding survey responses into a database or when transcribing audio recordings. This means that in such cases, for as long as the raw data exists, the entire dataset can never be considered anonymous. This is true even after applying data protection measures such as pseudonymisation! See more on [the FAQ personal data and the GDPR](#).

\* Does the research exclusively involve observation of individuals, groups, or organisations?

- ☐ Yes, observation of individuals in public spaces
- ☐ Yes, observation of groups or organisations (not necessarily in public spaces)
- ☒ No

Public spaces are publicly accessible areas such as parks and streets, and include vehicles present in these areas. For classroom studies, choose the second or third option depending on the level of analysis (groups versus individuals). For research involving observation of individuals, but not in public spaces, choose the third option.

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## Module 3: Data management and privacy

The questions below concern the data you will be processing (collecting, storing, analyzing, et cetera) during the research. Please see the data management plan (DMP) guideline on the faculty intranet:

[BSS Data Management Plan Guideline \(Word\)](#)

Has there been contact about data management and privacy with the Research Support department or with the Research Data Office? If not, leave this question blank. If yes, please include the correspondence as an additional upload at the end of the application or - if applicable - specify the details of what has been discussed in your DMP and upload that at the end of module 3.

- ☐ Yes, concerning data management
- ☐ Yes, about technical support
- ☐ Yes, for a data protection impact assessment (DPIA)

Research Support ([intranet page](#)) may be contacted to provide technical support on the software and hardware used to conduct the study, to help with exploring options for secure data collection and storage, and to conduct a DPIA in case of complex studies with respect to personal data processing.

Does the study involve the processing of PERSONAL data of one or more of the following groups? If not, leave this question blank.

- ☐ Minors under 12 years of age
- ☐ Minors over 11 and under 16 years of age
- ☐ Minors 16 or 17 years of age
- ☐ Vulnerable adults
- ☐ Adults who are not actively consenting to participate, for example because they are being observed in a public space
- ☐ Adults who do not fall into one of the two preceding categories

Vulnerable people are people in a position of dependence (whether psychological, societal, economic, political or otherwise), easily stigmatised, discriminated against, prosecuted, or met with violence. Note: Students who participate in research in exchange for course credit (e.g. in the context of the first-year SONA practicum) are also considered in a position of dependence.

Does the study involve the processing of one or more types of SPECIAL CATEGORIES of personal data ('sensitive data')? If not, leave this question blank.

- ☐ Data revealing racial or ethnic origin
- ☐ Data revealing political opinions
- ☐ Data revealing religious or philosophical beliefs
- ☐ Data revealing trade union membership
- ☐ Genetic data
- ☐ Biometric data for the purpose of uniquely identifying persons
- ☐ Data concerning health
- ☐ Data concerning a person's sex life or sexual orientation

This is a mandatory GDPR question for the UG research register. Under the GPDR, these special categories of data may be processed but active informed consent from research participants is mandatory.

Which types of identifiers will be processed during the study? If none, leave this question blank.

- ☐ Name and address details
- ☐ Telephone number
- ☐ E-mail address
- ☐ IP address
- ☐ Other, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register.

\* Does the study involve the processing of personal data on a large scale, in public spaces, or across multiple (combined) datasets?

- ☒ No
- ☐ Yes

Studies are considered large in scale by the UG when over 1000 participants are involved. Public spaces are publicly accessible areas (for example: streets, parks, cars, bicycles). The scale and complexity of processing are indicators of data processing operations that may entail higher ethics risks.

\* Does the study involve complex, sensitive, or intensive techniques for the processing of personal data?

- ☒ No
- ☐ Yes

Examples include the covert observation, surveillance, or (geo) tracking of individuals, using camera systems to monitor behaviour or record sensitive information, data mining (including data collected from social media networks), 'web crawling' or social network analysis, profiling individuals or groups (particularly behavioural or psychological profiling), using artificial intelligence to analyse personal data, and using automated decision-making that has a significant impact on the study participants.

\* Are personal data shared with collaborators/partners outside the European Economic Area (for processing, analysis, storage, etc.)?

- ☒ No
- ☐ Yes, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register. The sharing might involve personal data moving from the European Economic Area (EEA; European Union + Norway + Iceland + Liechtenstein) to elsewhere or from elsewhere to the EEA.

\* What is the purpose of the personal data processing?

Regarding anonymity of data, Prolific IDs are simply used by researchers to identify which Prolific user has submitted which response to a survey, in order to determine which submissions to approve (i.e. reward).

The researchers will have access to some basic demographic data about participants, but again this can only be linked to individuals using their Prolific ID. The full list of this demographic data can be found here:

<https://researcher-help.prolific.co/hc/en-gb/articles/360009391633-Exporting-Prolific-data>

Care has been taken to ensure that this list contains only anonymised demographics (e.g. age, sex, country of residence) and not more special category data which could theoretically be used

to identify individuals (e.g. specific locations).

In summary, Prolific IDs can only ever be used by researchers to match individual survey responses to Prolific submissions. The only other information linked to these IDs is the basic demographic data linked above, which can only be used for research/analysis purposes and not as personally identifiable information.

For more information about prolific's data protection and privacy see here:

<https://researcher-help.prolific.co/hc/en-gb/articles/360009094594-Data-Protection-and-Privacy>

Important points surrounding data protection and privacy can be found here:

<https://researcher-help.prolific.co/hc/en-gb/articles/360018895214-Prolific-Practices-and-Security-Systems>

This is a mandatory GDPR question for the UG research register. Describe, in a way that is understandable to a research participant, why their personal data are being processed in the context of the study.

\* In which (type of) systems are the personal data collected, processed, analysed, stored, and backed up?

- ☒ Systems hosted by the University of Groningen
- ☐ Systems hosted by a party other than the University of Groningen
- ☒ Own storage media
- ☐ Paper
- ☐ Other, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register. You will be asked to upload a data management plan below in which you can specify all systems used during the research.

\* Which data retention periods apply?

- ☒ 10 years
- ☐ 15 years
- ☐ Other, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register. Retention periods start after publication of the last publication that is based on the study. Notes: 1) All data on the Y drive are retained for at least ten years. The Y drive backup system makes sure that everything stored on that drive can be retrieved, even if someone edits or deletes data after it has been saved. 2) Retention periods for (original) audio/video recordings and suchlike are usually shorter. 3) In the data management plan you can specify which data will be retained for how long.

\* Who are the suppliers of the personal data that are used in the study?

- ☒ The research participants



- ☐ The University of Groningen
- ☐ Public sources outside the University of Groningen, as specified in the data management plan (to be uploaded below)
- ☐ Non-public sources outside the University of Groningen, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register. Examples of public sources include data sets from publicly available repositories such as DANS ([www.dans.nl](http://www.dans.nl)). Examples of non-public sources include non-public data shared by researchers or research institutes. In your data management plan you can specify which public and non-public sources outside of the University of Groningen will be used to supply data.

Are there external parties that provide a tool or service on behalf of the study and that process personal data? Examples are (non-UG) companies involved in collecting the data or hired to transcribe audio or video data. This concerns parties that do not decide what to do or how to do things - they only provide a service or tool or data that you use. If yes, please upload the data processing agreement.

[Researcher\\_Terms.pdf](#)

This is a mandatory GDPR question for the UG research register. When you work with data provided by services like CBS or DANS, agreements or data usage protocols may be in place which need to be uploaded here as well. Note: For external parties that have an existing data processing agreement with the UG (for example, Qualtrics), researchers usually do not need to upload such an agreement. When in doubt, please contact Research Support.

\* Are there external research partners you collaborate with, that also process (collect, analyse, store) personal data? Collaborating partners think along with you on what to do and how to do it. Other partners need to be addressed in the previous question.

- ☐ No
- ☒ Yes, and there is a formal collaboration agreement
- ☐ Yes, but there is no formal collaboration agreement

For example, studies may involve external research partners who collect and store the data in collaboration with you and subsequently share these with UG researchers or vice versa. In this case, you and your partners must set out your respective responsibilities in a collaboration agreement.

\* Which technical and organisational security measures are being used to minimize the privacy risk to study participants?

- ☒ Pseudonymization or de-identification
- ☐ Anonymization (as legally defined)
- ☐ Cryptography
- ☐ Other, as specified in the data management plan (to be uploaded below)

This is a mandatory GDPR question for the UG research register. Pseudonymization = substituting personally identifiable information (such as a person's name) with a unique identifier that is not connected to their real-world identity. While pseudonymization can protect individual study

participants with a degree of protection and confidentiality, pseudonymized data still fall within the scope of personal data because it is possible to re-identify the participants (by reversing the pseudonymization process). The same is true for other de-identification techniques (more about them on [this FAQ personal data and the GDPR](#)). Anonymization = the use of techniques that can be used to convert personal data into anonymised data. Note that anonymization is permanent: anonymized data that can never, under no circumstances be used to re-identify individuals. True anonymization is therefore increasingly challenging. When in doubt, consider your dataset pseudonymized or de-identified. Cryptography = encryption or hashing applied during transport and storage of personal data.

Please upload your data management plan. While uploading a data management plan is currently not required, it is considered good practice to prepare one and will be helpful during ethics review.

[Data Management\\_OS.docx](#)

In the data management plan you explain how you will make sure that personal data are safely processed, stored, and published, i.e. conforming to current laws and regulations, in particular the GDPR. See the EC guideline linked to at the top of this page. Note: If the research exclusively involves the reuse of existing data, the data management plan primarily discusses the consequences of the research for the privacy of the original research participants.

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## **Module 4: Research information for participants**

The questions below concern the research information that is provided to participants as part of the consent procedure. Please see the information form (IF) guideline on the faculty intranet, in English and Dutch:

[BSS Information Form Guideline \(Word\)](#)

[GMW Richtlijn Informatieformulier \(Word\)](#)

Are (some) participants aged 16 years or older? If yes, please upload the research information for these participants.

[Information Form\\_updated.docx](#)

This concerns the research information that is offered during the informed consent procedure. The consent form itself can be uploaded in the next module. Please consult the information form (IF) guideline linked to at the top of this page. Note that information should be provided at a level that is appropriate for the participants' age and other personal characteristics.

Are (some) participants aged 12-15 years? If yes, please upload the research information for these participants.

*No file has been uploaded*

Participants aged 12-15 years are older than 11 and younger than 16 years. This concerns the research information that is offered during the informed consent procedure. The consent form itself

can be uploaded in the next module. Please consult the information form (IF) guideline linked to at the top of this page. Note that information should be provided at a level that is appropriate for the participants' age and other personal characteristics.

Are (some) participants younger than 12 years of age and did you develop a separate version of the research information for them? If yes, please upload this optional research information.

*No file has been uploaded*

This concerns the research information that is offered to the children during the informed consent procedure with their parents / representatives. It is possible that parents / representatives provide informed consent but that, on the basis of the information given to them, participants choose not to participate. Please consult the information form (IF) guideline linked to at the top of this page. Note that information should be provided at a level that is appropriate for the participants' age and other personal characteristics.

Does the research involve participants who are younger than 16 years, or who are 16 years or older but not legally competent? If yes, please upload the information form for parents or legal representatives.

*No file has been uploaded*

This question pertains to the research information provided in advance of an informed consent procedure. You will be asked to upload the consent document in the next module. Note: All adults are considered legally competent ("wilsbekwaam") unless a medical doctor has decided that someone is not legally competent to take certain decisions, e.g. due to an intellectual disability or dementia. Please consult the information form (IF) guideline linked to at the top of this page. Note that information should be provided at a level that is appropriate for the participants' age and other personal characteristics.

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## Module 5: Informed consent

\* During the consent procedure, will you withhold information or employ deception?

- ☒ No
- ☐ Yes

Withholding information = the nature, purpose and anticipated consequences of research participation are not made public. Deception = research participants are purposely misled about the nature, purpose and anticipated consequences of research participation.

\* Will you use an ACTIVE informed consent procedure?

- ☒ Yes, for all research participants and, if applicable, their parents or legal representatives
- ☐ No, even though research participants will be older than 11 years
- ☐ No, not for parents or legal representatives

Active consent means consent is provided by means of a deliberate act of the participants or their

representatives. In other words, they actively “opt-in” to the research (and provide personal data). Only special circumstances may call for an “opt-out” procedure.

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The questions below concern the consent text that is given to participants as part of the consent procedure. Please see the consent form (CF) guideline on the faculty intranet, in English and Dutch:

[BSS Consent Form Guideline \(Word\)](#)

[GMW Richtlijn Consentformulier \(Word\)](#)

\* How will participants or their representatives transfer their informed consent?

- ☐ Verbally
- ☐ By writing
- ☒ Digitally/electronically
- ☐ By other means, as specified in the research plan

This is most commonly done by writing but, depending on the type of research, any deliberate and plausibly demonstrable act of consent can be valid.

Will you ask informed consent from participants who are older than 16 years? If yes, please upload the consent form.

[Consent Form\\_OS\\_updated.docx](#)

Please see the consent form (CF) guideline linked to at the top of this page. Note: If informed consent is transferred verbally, instead upload a document outlining how you will ask for consent.

Will you ask informed consent from participants who are older than 11 and younger than 16 years? If yes, please upload the consent form.

*No file has been uploaded*

Please see the consent form (CF) guideline linked to at the top of this page. Note: If informed consent is transferred verbally, instead upload a document outlining how you will ask for consent.

Will you ask informed consent from participants who are younger than 16 years, or who are 16 years or older but not legally competent? If yes, please upload the consent form.

*No file has been uploaded*

In some cases it may be acceptable to ask someone other than the participants or their legal representatives for informed consent, e.g. a teacher or manager. Please see the consent form (CF) guideline linked to at the top of this page. Note: If informed consent is transferred verbally, instead upload a document outlining how you will ask for consent.

\* How will you register when and how and of whom informed consent has been obtained?

Consent (including time stamps) is recorded in the datafile created as part of the online survey completion.

For research that is not fully anonymous, registration is required of when and how and of whom informed consent has been obtained. Fully anonymous research also requires registration of when and how informed consent has been obtained, but not of whom. In other words, you are always required to register when and how a consent procedure has taken place. This is also true for assent and opt-out procedures (e.g., for children under 12 years of age).

The description of your registration procedure should include the storage location of the consent documents (or electronic equivalents) and specify whether access control is in place (i.e., who has access to the list of people who consented to participate).

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## **Additional uploads**

Examples of additional uploads include questionnaires to be used in the research, ethics approval documents from other institutions, collaboration agreements with external partners, and data privacy impact assessment (DPIA) outcomes.

If you would like to upload an additional file to go with this request, you can do so [here](#).

*No file has been uploaded*

If you would like to upload an additional file to go with this request, you can do so [here](#).

*No file has been uploaded*

If you would like to upload an additional file to go with this request, you can do so [here](#).

*No file has been uploaded*

If you would like to provide an explanation with any files uploaded above, you can do so [here](#).

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## **Agreement by principal investigator**

The principal investigator (AKK Kleine) has not yet agreed with the performance of this research. If the request is submitted by someone who is not the principal investigator, the request will be presented to the principal investigator.

## **Approval by reviewers**

The reviewers have not yet approved the request.