Version 20.05.2015

APPLICATION FORM FOR RESEARCH WITH HUMAN PARTICIPANTS

IMPORTANT:
Please fill out this form with care, making sure you are not skipping fields that should be filled in. Incomplete forms will not be accepted by the committee and will be sent back for correction.

1. Date of submission of this application form:
   Click here to enter a date

2. What is the title of the project?
   Click here to enter text

3. Enter estimated start and end date of the study
   Start: Click here to enter a date
   End: Click here to enter a date

4. What is the main context of the study? Please choose one of the following options:
   - ☐ Student Project (Bachelor)
   - ☐ Student Project (Master)
   - ☐ Staff Research

5. Where will the research be conducted? Choose any of the following options:
   - ☐ Via the internet in the Netherlands
   - ☐ Via the internet in another country *
   - ☐ In a room in one of the buildings of the University, please specify:
     Click here to enter text
   - ☐ Somewhere else, please specify:
     Click here to enter text

Different rules and regulations may apply outside of the Netherlands. Please read the note at the bottom of the form

6. Enter the personal data of the *Principal Investigator (PI)* who carries ultimate responsibility for the research; he/she must have a personnel number of the University of Groningen.

Name:	Click here to enter text
Division ('Afdeling'):	Click here to enter text
Personnel number:	Click here to enter text
Email address (@rug.nl):	Click here to enter text
Telephone number:	Click here to enter text
Room number:	Click here to enter text
Faculty:	Click here to enter text

A staff member of the RUG must carry ultimate responsibility in all cases

7. Enter the personal data of the *Substitute Investigator* who takes over when the PI is absent due to illness or unforeseen circumstances; he/she must have a personnel number of the University of Groningen.

For all studies involving human participants a substitute researcher is *obligatory*

Name: Click here to enter text
Division ('Afdeling'): Click here to enter text
Personnel number: Click here to enter text
Email address (@rug.nl): Click here to enter text
Telephone number: Click here to enter text
Room number: Click here to enter text

8. Are the participants selected individually or via an institution?
   - ☐ Individually
   - ☐ Via institution

9. If participants are selected individually, what method is used?
   - ☐ More or less random selection, on the basis of a leaflet/folder etc.
   - ☐ Non-random selection, on the basis of the fact that participants are *patients*. Please specify selection criteria:
     Click here to enter text
   - ☐ Non-random selection, on the basis of participation in earlier study or studies. Please specify selection criteria:
     Click here to enter text

If participants are selected because they are patients, a *Statement of Exemption* from the METc is required

10. To what age group do some or all participants belong? Please choose every category that is applicable.
    - ☐ Minor child: 0 up to and including 11 years old. Will permission be obtained from the parents/primary caretakers/legal guardian?
      - ☐ Yes
      - ☐ No
    - ☐ Underage adolescent: 12 up to and including 15 years old. Will permission be obtained from *both* the adolescent *and* the parents/primary caretakers/legal guardian?
      - ☐ Yes
      - ☐ No
    - ☐ Adult: 16 years and older. If the participant is 16 years or older, parental consent is *not* required.

11. If the participants are adult, are they mentally competent?
    - ☐ Yes
    - ☐ No

      If No, will you obtain permission from the parents/primary caretakers/legal guardian?
      - ☐ Yes
      - ☐ No

12. What is the research question of the study?

    Click here to enter text

    Please provide a brief description of the main research question

13. Are participants presented with one or more stimuli?
    - ☐ Yes
    - ☐ No

      If Yes, please specify the nature of the stimuli (and attach an example of the stimuli with the application):

      Click here to enter text

    With stimuli, texts, words, pictures etc. are meant that are presented to the participants

    Please specify what the stimuli look like and whether the stimuli can possibly have an aversive effect on the participants

14. Is there any other manipulation (e.g., of the social situation in which the participant is studied)?
    - ☐ Yes
    - ☐ No

      If Yes, please specify the nature of the manipulation:

      Click here to enter text

    Please specify what the situation(s) look like and whether the situation can possibly have an aversive effect on the participants

15. What type of measurement is used in the study? Please choose every method that is used.
    - ☐ Questionnaire
    - ☐ Observation
    - ☐ Audio/Video recording
    - ☐ Recording of behavioural data (Reaction times, errors, etc.)
    - ☐ Recording of physiological data (Heart rate, ERPs, fMRI, etc.)
    - ☐ Other, namely:

      Click here to enter text

16. How many sessions are needed to complete participation in the study?

    Click here to enter text

17. What exactly does the participant have to do in each of these sessions?
    Click here to enter text

Please list the tasks per session and their estimated duration (in minutes)

18. What is the estimated total duration of time participants have to spend in the activities of the study as a whole?
    Click here to enter text

Please specify the estimated (maximal) duration of the experiment (in minutes)

19. Is it possible that the study has negative consequences for participants or that it causes them discomfort?
    ☐ Yes
    ☐ No
    If Yes, please explain why that is the case, and indicate the steps that will be taken to minimize any discomfort or negative consequences:
    Click here to enter text

20. What is the (estimated) number of participants?
    Minimum: Click here to enter text
    Maximum: Click here to enter text

21. Are the participants, outside the context of the study, in a dependent/subordinate position to the PI?
    ☐ Yes
    ☐ No
    If Yes, please specify:
    Click here to enter text

22. Will it be made clear (e.g., in the information brochure or informed consent form) to the participants that they can withdraw their cooperation at any time, and that they can do so without any consequences to them?
    ☐ Yes
    ☐ No

23. What kind of reward do the participants receive?
    ☐ No reward
    ☐ Money
    Please specify how much (if used currency is not the euro, please also specify conversion to euros):
    Click here to enter text
    ☐ Course credit
    Please specify how much:
    Click here to enter text

☐ Other

Please specify:

Click here to enter text

24. What information about the study do participants (and/or their parents/primary caretakers/legal guardian in case of children or participants who are not mentally competent) receive *before* they take part in the study?

This concerns information about the *purpose, nature, duration, risks* and any *drawbacks* of the study

☐ Full information

☐ None or partial information

Please specify what information is left out and why:

Click here to enter text

☐ Misleading information

Please specify what information is given, what information is left out, and why giving misleading information is necessary:

Click here to enter text

Note that information given before the start of the study must *never* mislead the participants about the possible risks or drawbacks of participation

25. In all cases where full information is *not* provided beforehand, will this information be provided *immediately after the study*, along with the reasons for not giving this information before the study (*debriefing*)?

☐ Yes

☐ No

If No, please specify why this is not the case:

Click here to enter text

26. Will the participants (and/or their parents/primary caretakers/legal guardian in case of children or participants who are not mentally competent) give *active informed consent* before they take part in the study?

In *active informed consent*, participants (or their representatives) give their *explicit* consent to take part in the study, either by signing a form, or, in online research, by clicking an authorization checkbox, or by other actions which have been explicitly indicated as signifying consent

☐ Yes

☐ No

If No, please explain why participant may not give their explicit consent to take part in the study:

Click here to enter text

27. Are the research data made anonymous?

☐ Yes

☐ No

If No, please explain why that is not the case:

Click here to enter text

28. Will the participants have access to the data (e.g., in case of audio/video recordings)?
    - ☐ Yes
      Please specify how:
      Click here to enter text
    - ☐ No
      Please explain why not:
      Click here to enter text

29. Will personal data (such as, e.g., name, address, phone number, etc.) be collected?
    - ☐ Yes
    - ☐ No
      If Yes, please give a brief explanation why that is necessary:
      Click here to enter text
      If Yes, do participants give their explicit permission to use and/or retain this personal information?
      - ☐ Yes
      - ☐ No
        If No, please explain why not:
        Click here to enter text
        If Yes, will this personal information be stored separately from the research data (in another file, and in another location), so the anonymity of the participants is guaranteed?
        - ☐ Yes
        - ☐ No
          If No, please explain why not:
          Click here to enter text
          If Yes, please list the people who will have access to this personal information:
          Click here to enter text

Attachment checklist

After completing the form, make sure you attach the following documents:

- ☐ Information brochure
- ☐ Informed consent form
- ☐ Debriefing (if applicable)
- ☐ Stimuli (if applicable)

(*) DISCLAIMER

When a research applicant asks the CETO for an ethical review of an *online* study *in another country* than The Netherlands, the research applicant automatically declares

that he/she accepts the conditions set out in the following disclaimer and he/she agrees with it: “Applications for online research that will be conducted among inhabitants of another country will be evaluated according to criteria based on Dutch laws and regulations. It is possible that these criteria are different from the laws, regulations and procedures in the home country of online participants. It is the responsibility of the *Principal Investigator* to ensure that the study concerned complies with local regulations”.