

How to write your project license application

General

- **Treat your project application like you would a grant application: take it seriously.**

However, realize that the purpose is completely different. In a grant proposal you try to sell your ideas. In CCD project plan you explain what you want to study, why that is useful, and (in the appendices, DAPs) you describe what this means for the animals involved. Take your time to write a project license application and do it thoroughly. Make full use of this document, the CCD guideline to project license application and the CCD guideline acceptable projects ('handreiking invulling definitie project'). Make sure to answer all items in case of combined questions. Make sure your descriptions are consistent throughout the project and its appendices.

The time between submitting the project to the AWB and getting a project license is approximately 4-6 months. This may be shorter if the project is fully up to standards, but significantly longer if it is not. In addition to the longer duration, a project that is rejected by the CCD will still cost you quite a sum of leges money. The DEC and CCD both can (only) use one round of addressing questions and concerns.

- **Make full use of the expertise of your senior scientists.**

Due to the higher aggregation level and the thorough scientific background that the CCD expects, the input of the senior scientist responsible for the project (PI, project leader) is invaluable in the writing process. He or she has the overview of the research field and will be able to formulate well-justified and achievable aims for the project. He or she should therefore always be intimately involved in the writing process and primarily responsible for the submitted final version of the proposal.

- **Make good use of your peers and persons that have previously gained experience with their license application.**

You could for instance plan with colleagues to review each other's projects, and/or have your department coordinator review it before submission. Look at published project licenses (<https://www.radboudumc.nl/en/research/radboud-technology-centers/animal-research-facility/ccd-licenses>) to check the level of detail needed.

- **Pay ample attention to the project aggregation level.**

One criterion of the CCD is the project definition. The project application should form one concise unit, with a single research question. Combining a number of objectives or research lines within one project is generally not acceptable. The project aims should be achievable within the time frame of the project and objective criteria for achieving the aims should be provided. The strategy and structure should be clearly described and there should be a clear coherence between the different animal procedures. All animal procedures should be sufficiently described, enabling the DEC to understand the level of discomfort for each animal you will use. Make sure all information for making an ethical evaluation is present and well structured. More information about acceptable project contents can be found in the CCD guideline 'acceptable projects' (only in Dutch:

<https://www.centralecommissiedierproeven.nl/documenten/formulieren/16/6/6/invulling-definitie-project>).

For detailed information about how fill out the forms (in Dutch only) see, on the CCD website, 'Toelichting invullen formulieren projectvergunning dierproef':

<https://www.centralecommissiedierproeven.nl/onderwerpen/aanvraag-vergunning/documenten/formulieren/2020/12/18/info>

- **Use the expertise of the AWB to improve your project license application.**

Have you gone through the information provided, but do you still have some specific questions regarding your project license application? Please contact the AWB. During the review phase, make sure you adequately address the questions and comments by the AWB. They are meant to help you improve your project and increase your chance at a rapid license approval.

Project Proposal (PP)

- **Provide a sound scientific background, using references to back your statements.**

The scientific background is an important section to show how your research project is embedded in the research field concerned. Take your time to provide a sound, adequately structured background. Describe the current state of the research field, backing up your statements with references from your own (if applicable) and others' work. It is helpful to end the section with a description of the 'gap' in current knowledge that you intend to address in this project.

- **Provide an aim that is specific, objective and achievable.**

Make sure the aims of your study are specific and objective, and follow logically from your scientific background and the 'gap' in current knowledge described there. Also explain why the aim(s) should be achievable within the time span of the project. To do so, you can mention for instance previous work you have done on the subject, experience you have gained, relevant collaborations you have, materials and methods that have already been

developed and grants or funding received to perform this research.

- **Clarify strategy, structure and coherence.**

The research strategy and the coherence and structure of the animal procedures will largely determine whether or not the CCD finds a project acceptable. A good way to answer the questions on strategy and coherence could be to first give a bird's eye view of the entire project. To clarify the structure and coherence of the experiments, you may use a flowchart or timeline. Make sure to depict the decision points within the project. Next, you can summarize the content of each DAP. Avoid leaving too much of the research strategy open: the DEC and CCD will then be unable to make an ethical evaluation. Finally, you may further describe the coherence between experiments and DAPs and specify the decision points and criteria. All animal procedures should be necessary for achieving your aim, and provide a structure for the execution of the animal procedures (DAP's) is needed (see CCD guideline on acceptable projects).

- **Divide the project into well-defined DAPs.**

One DAP is meant to include one type of experiment performed in a certain group of animals. This experiment may contain multiple different procedures that the animals undergo sequentially. However, the total experiment that the animals undergo should be the same or very similar for all of the animals within one DAP.

Description Animal Procedure (DAP)

- **Provide sufficient detail for DEC and CCD to weigh discomfort against benefits.**

In order to make a sound ethical evaluation, the DEC and CCD need to have full insight into the number of animals used, their species and discomfort. These choices cannot be left open. Therefore it is important to describe clearly which animals will undergo which procedures, when, how, how often and for how long. All these factors need to be justified. Explain the consequences of your procedures for the health, wellbeing and integrity of the animals. Define the level of discomfort per group of animals based on these procedures. Include an estimation (in numbers or percentages) of how many animals fall into which discomfort class and how many animals are expected to reach a humane endpoint. Provide clear and objective humane endpoints. Include any steps you take to reduce the negative consequences. Discuss thoroughly why there are no alternatives not requiring animals, or less animals.

- **Make a justified estimate of the number of animals needed.**

A justification of the number of animals is needed for the CCD to evaluate the 'reduction' aspect of your project proposal. Providing a number without explanation, or solely based on the numbers of animals you used in previous years is not acceptable. One way to provide a good justification of the number of animals you need, is to use the number of experiments

you will perform, the number of groups per experiment and the number of animals per group. Be sure to include some extra animals in case losses (drop-outs) may occur, as well as animals used for pilots, optimization of the experiment and training of the technique(s). You do not need to include power calculations in the project (as opposed to what is required in work protocols) . Make sure the numbers in the text, the table Animals and the NTS match.

- **Keep some space for making future decisions.**

In a 5-year project, it may be hard to give all the details on your animal procedures. To prevent having to frequently amend to the project, you can keep some latitude for future decision making. You do not need to provide details of for instance drug dosages, power analyses, etc. If you have to leave some decisions open (for instance depending on the results of a pilot or of a previous animal procedure), you should clearly describe which criteria you will use to make the decision.

- **Use both sexes *or* provide a sound justification for the use of only one sex.**

To decrease the number of experimental animals killed without being used in an experiment, the CCD propagates the use of both males and females. If no differences between the sexes are expected, it is best to include both. If you have a strong (scientific) reason for only using one sex, make sure to provide a justification for this.

Non-Technical Summary (NTS)

- **Have a Dutch friend or family member (native speaker, *not* a scientist) read your NTS.**

The NTS should be written in Dutch lay language. Scientific and technical terminology are not allowed. If no lay language term is available, you should provide an understandable explanation of the term when it is first used. As a researcher, it may sometimes be difficult to estimate whether your text is comprehensible to a layman, especially if Dutch is not your mother tongue. Therefore, asking a Dutch friend or family member (*not* a scientist) to comment on your NTS for you, is crucial. Ask them whether they can understand the bigger picture of the project and whether there are words or sentences that they are unable to follow. Adapt the NTS accordingly.

Detailed information on the procedures, the scientific background and the justification of methods, numbers, etc, does not belong in the NTS.

- **Stay within the word limit for the NTS.**

The word limit for the NTS is provided in the excel template file per question. Exceeding these limits by a larger extend will lead to a request to rewrite the NTS. No elaborate detailing of procedures and no justifications are needed, therefore it should always be possible to stay within the word limits.