**Part 1** Application: the research question

**Process**

1. Applicants are requested to fill out the form below completely and truthfully and submit it to extractieverzoek@stichting-nice.nl
2. Once a month, the science committee assesses all submitted applications on content (is the research question valid, are there no ethical- and privacy issues, and can the research question be answered with NICE data). The science committee will decide whether or not the application will be approved on the basis of the content. The NICE R&S will prioritize the applications based on their ongoing work.
3. In case the research question is approved, the applicants should fill in the methodological and statistical form (Part 2 at the back of this form). This form includes a clear statistical plan describing which tables and figures are desired, which inclusions and exclusions are used, and which statistical methods will be used.
4. The NICE R&S team will assesses the statistical analyses plan and will discuss the statistical methods in more detail with the applicants and (if possible) make suggestions to further improve the proposed methods.
5. Depending on the requested support from the NICE R&S team, NICE R&S will start with the analyzes or prepare an anonymous dataset and set up the infrastructure for the applicants so that they can carry out the analyzes themselves.

Please answer the following questions and submit the form to extractieverzoek@stichting-nice.nl.

1.1 What is the project title? We suggest to use the provisional title of the proposed scientific publication.

1.2 What is the research question?

1.3 Give a short introduction with background information on the research topic supported by existing literature.

1.4 Please describe your research in approximately 100 words in Dutch. This summary will be published on the NICE website after approval of the application.

1.5 Give at least five keywords which describe the project.

1.6 What are the intended journals?

1.7 Please fill in the details of the project members and their role in the application team

 table below:

|  |  |  |  |
| --- | --- | --- | --- |
| * **Name, title**
* **Position and organization**
* **Email address**
 | Contact person for this application (Yes/no) | Main contact person for NICE in his/her ICU (Yes/no) | Expertise (analytics/epidemiology, field of medical specialty,..) |
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2.1 Is the project part of a larger project? If the answer is ‘yes’, please give details on how this project fits into the larger project. If this project is part of a PhD project, explicitly state that you are aware of the art 8 of ‘Voorwaarden voor NICE extractieverzoeken’.

2.2 Given the duration and complexity of the projects and the limited capacity at NICE R&S, projects that are carried out by internship students or which are part of internships should be carried out under supervision of an intensivist, epidemiologist or statistician of the applicants with limited or elaborated support from NICE R&S. Indicate whether this is part of an internship yes or no, and if yes who provides supervision.

2.3 If data/results might trace back to individual hospitals and/or patients, the participating hospitals must give a written permission before starting the research. Are additional permissions from ICUs required for this project?

If yes, please use the form on our website https://www.stichting-nice.nl/extractieverzoek\_procedure.jsp to obtain the permissions. We can only start the analyses after receiving a written permission from each of the participating hospitals.

3.1 Which data registration modules from NICE are required (MDS, SOFA, KIIC etc). Look at the [data dictionary](https://www.stichting-nice.nl/dd/#modules) to make a proper selection?

3.2 Are any additional (non-NICE) data required to carry out this project?

4.1 What are the outcome measures used in the project?

4.2 Give a brief summary of the statistical methods that will be used in the project. In case of approval, the statistical methods need to be described extensively in the methodological and statistical part of this form.

4.3 For all applications, NICE R&S will be involved in the study design by evaluating and discussing the methodological approach that has been filled in and submitted during the second part of the application process. The NICE R&S and a NICE board member (intensivist) will also review the results and determine whether the correct interpretations/conclusions have been made. Therefore NICE R&S and a NICE board member will always be a co-author of the manuscript. The applicants are always responsible for writing the first draft and for submitting the manuscript to the intended journal.

For support during the analyses and the writing process, the applicants can choose from one of the following packages.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Limited support | Elaborated support  | Execution by NICE R&S |
|  | *
 |  |  |
| *Analyses* | Excluded | Support in consultation | Included |
| *Supervision of the writing*  | Excluded | Support in consultation | Support in consultation |
| *Study design* | Included | Included | Included |
| *Writing of the first draft* | Excluded | Excluded | Excluded  |
| *Interpretation of results* | Included | Included | Included |
| *Submission to the intended journal* | Excluded | Excluded | Excluded  |

In case limited support is requested, the applicants will get access to anonymized data to perform the analyses by themselves. Limited support from NICE R&S only includes technically arranging data access in the secured data environment and answering questions on the meaning of the data items. Performing the analyses by yourself can only be chosen when the applicant or his/her supervisor have sufficient experience is performing scientific research as described in 1.7*.*

In case elaborated support is requested, the NICE R&S researcher(s) who is involved becomes part of the project team. An appointment with the entire project team will first be scheduled to further discuss at forehand the details concerning each step of the process, data access, analyses (supervision), and authorship (positions following international ICMJE rules for author responsibilities) and corresponding responsibilities.

In case execution is requested, the applicants will not get access to raw data but will be provided with the results of the analyses. An appointment with the entire project team will first be scheduled to discuss the details concerning each step of the process, data access, analyses (supervision), and authorship (positions following international ICMJE rules for author responsibilities) and corresponding responsibilities. The NICE R&S researcher who performs the analyses is 2nd author of the paper. In case the main applicant is a junior researcher, the team guarantees supervision by a senior researcher with track record *(please provide more detail on level of experience, diplomas and/or certificates)*to guide the writing process.

5.1 All applicants should pay a standard fee of 500,- euros to arrange the data infrastructure and/or as a limited reimbursement of costs for the support of the analyses of the data. Please provide full details for invoicing the contribution. We can start the project application after receiving this amount. For applicants who do not have access to funding, a motivated exemption can be requested via the NICE science committee (extractieverzoek@stichting-nice.nl).

5.2 If funding is obtained for the project, NICE will ask a fee for the support given by the NICE R&S researcher. This will be 100 euros per working hours with a maximum of 50% of the total funding budget. Provide information on:

 How will this project be funded?

 How much funding is obtained and by which organization (ZonMW, SKMS,

 internal fund, ….)?

 As an approximation, how many hours do you want to obtain from NICE R&S?

5.3 In case you will be using Vektis data for long-term outcomes a contribution of 2000,- euros is requested. Please, provide full details for invoicing this contribution. For applicants who do not have access to funding, an motivated exemption can be requested via the NICE science committee (extractieverzoek@stichting-nice.nl).

By submitting this form, I agree to be bound by the “Voorwaarden verbonden aan een data-extractieverzoek bij NICE”.

Name:

Date:

Signature:

\*: The information in this form is stored for administrative and communication purposes and are subject to the Privacy Policy as described on the website of the NICE Foundation.

**Part 2** Application: Methods and Data-analyses

*Part 2 need to be filled in after approval of Part 1*

**Process**

1. Applicants are requested to fill out the methodological and statistical form below completely and truthfully after the application (Part 1) is approved by the science committee and submit it to extractieverzoek@stichting-nice.nl. This form includes a clear statistical plan describing which tables and figures are desired, which in- and exclusion criteria are used, and which statistical methods will be used.
2. The NICE R&S team will assess the statistical analyses plan and will discuss the statistical methods in more detail with the applicants and (if needed) make suggestions to further improve the proposed methods. Once the applicant and NICE R&S researchers agree on the methodological- and statistical forms, only limited new analyses will be allowed to perform in order to avoid data dragging.
3. Depending on the requested support from the NICE R&S team, NICE R&S will start with the analyzes or prepare the anonymous dataset and set up the infrastructure for the applicants so that they can carry out the analyzes themselves.

Please answer the following questions and submit it to extractieverzoek@stichting-nice.nl.

* 1. Describe **the design of the study** and the **in- and exclusion criteria** for the population of interest.
	2. **Which data are required?** Please provide a complete, but concise description including time period. Use the NICE data dictionary on <https://stichting-nice.nl/dd/#start> to describe the required data. A minimum amount of variables will be used to ensure data and privacy protection. Describe how variables will be categorized, if appropriate. Non-standard definitions should be supported by references to the literature. This section should, together with the sections on outcomes and statistical methods, be equivalent to the methods section in a scientific publication. Contact NICE R&S (extractieverzoek@stichting-nice.nl) for questions regarding available variables and definitions.

1.3 **What are the outcomes used in the project?** Please define the primary outcome and any secondary outcomes clearly and fully, including references to the literature where necessary.

1.4 **What statistical methods will be used in the project?** Please be as precise as possible. Contact NICE R&S (extractieverzoek@stichting-nice.nl) regarding advise on available statistical methods. For complex questions it is recommended to plan a meeting with NICE R&S to discuss methodology.

1.5 **Which tables or figures do you want to include in your scientific publication?** Please provide empty tables and ‘fake’ figures (or copies from other sources), with as much information on the data you require.

By submitting this form, I agree to be bound by the “Voorwaarden verbonden aan een data-extractieverzoek bij NICE” attached to this document.

Name:

Date:

Signature:

\*: These data are stored for administrative and communication purposes and are subject to the Privacy Policy as described on the website of the NICE Foundation.