TEMPLATE RESEARCH PROTOCOL

for non-WMO-applicable research

19-01-2023, versie 2

Full title of protocol	
Short title or Acronym	
Protocol ID / Panama number	
Version	
Date	
Coordinating investigator[1]/ Project leader	*Name and contact data*
Principal investigator[2] (in Dutch: hoofdonderzoeker/ uitvoerder) **<Multicenter research[3]: principal investigator per site>**	*Name and contact data*
Sponsor[4] (in Dutch: verrichter/opdrachtgever)	*Name and contact data*
Subsidizing party[5]	*Name and contact data*

Name	**Signature**	**Date**
Sponsor or legal representative: *<please include name and function>* *<For non-commercial research,>* **Head of Department:** *<include name and function>*		
Coordinating Investigator/Project leader/Principal Investigator: *<please include name and function>*		

1. *Coordinating investigator: Investigator who bears the responsibility for the coordination of investigators operating in the various centers participating in multicenter research. Not all multicenter research will have a coordinating investigator. There is no requirement to appoint one. A project leader has the responsibility to develop a research protocol and to complete the study within the predefined goals.*
2. *Principal investigator: Investigator who has the overall responsibility to comply and to complete the study within the predefined goals.*
3. *Multicenter research: as an alternative you can also state that these are specified in the list with participating centers including principal investigator. This separate document with version date must be uploaded under category I1.*
4. *Sponsor: The party that commissions the organization or performance of the research, for example a pharmaceutical company, academic hospital, scientific organization or the investigator's employee. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidizing party.*
5. *Subsidizing party: A party that provides funding for a study but does not commission it*

Table of Contents

Please note that it is not allowed to remove paragraphs from this template protocol. If a paragraph is not applicable, please mention this in the specific paragraph, preferably with a short motivation.

List of abbreviations and relevant definitions*

CTA	Clinical Trial Agreement
De novo biobank	A new data, human material or imaging collection
DMP	Data Management Plan
DPIA	Data Protection Impact Assessment
DTA	Data Transfer Agreement
Exception consent	Form Care for data Template, in Dutch: Formulier uitzondering toestemming
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation in Dutch: Algemene Verordening Gegevensbescherming
IC	Informed Consent
IFU	Instruction For Use
MTA	Material Transfer Agreement
NWTC	Non-WMO Review Committee; in Dutch: Niet WMO Toetsingscommissie
UAVG	Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet Algemene Verordening Gegevensbescherming
WMO	Medical Research Involving Human Subjects Act, in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

**Please add any new definitions that are used in the research protocol*

Summary

The summary should give a brief description of the central question that the research is intended to answer and its justification. It should specify the hypothesis (if applicable) and the research objectives. In addition, the synopsis should briefly describe the design, population, methods and procedures of the study. Finally, if applicable, the nature and extent of the burden and risks should be indicated.

Rationale
Please specify background and hypothesis (if applicable) of the study.

Objective(s)
Please specify the main and secondary objectives of the study.

Study type
Please describe the design of the study.

Study population
Please describe the study population, e.g., healthy volunteers, xx yearr old.

Methods
Please describe how you conduct research and which methods are used.

Burden and risks
Please describe the burden and risks associated with participation.

Recruitment and consent
Please describe the recruitment and informed consent procedures.

1. Introduction and rationale

Please specify background and hypothesis (if applicable) of the study.

2. Objective(s)

The objectives of the study are the questions that the study is intended to answer and are based on the scientific rationale and/or hypothesis formulated.
Please specify the main and <if applicable> secondary objective(s) of the study.

3. Study type

3.1. **Study type**

☐ Retrospective
☐ Prospective
☐ Combination Retrospective/Prospective

3.2. **Single center / Multicenter**

☐ Single center
☐ Multicenter

3.3 **Check all the applicable boxes**

☐ Medical records (re-use of data from healthcare, including AI)
☐ Case report
☐ Re-use data from research
☐ Evaluations of quality of healthcare (retrospective
☐ Research with additional use of residual material from regular healthcare
☐ Research with re-use of human material from research or existing biobank
☐ De novo biobank
☐ Phase IV research
☐ Healthcare evaluation research (prospective)
☐ Research with medical devices
☐ Research with In Vitro Diagnostic Tests
☐ Other research, describe

4. Study population

4.1. Study population

☐ Adults (16 years and older)

☐ Minors (younger than 16 years)

☐ Incapacitated adults (16 years and older)

☐ Incapacitated minors (younger than 16 years)

4.2. Population (base)

Describe the population (patients and controls if applicable), e.g. healthy human volunteers, xx-xx year old, adults, minors and/or incapacitated adults or minors. Specify and justify the number of subjects required for the study.

4.3. Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

4.4. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

4.5. Sample size calculation

Specify and justify the number of subjects required for the study, estimated number of subjects, or number of subjects in the period of evaluation.

5. Methods

5.1. Research methods

Please describe how you conduct research and which methods are used, e.g., questionnaires, human material collection, extraction of data from medical records, analysis of images, the use of an app/medical device/diagnostic test, clinical tests to be performed, etc. Include information on frequency, duration, volumes. If a Data Management Plan is available, please upload DMP.

5.2. Standard clinical care versus extra for research

Indicate which of the methods are part of standard clinical care and which tests and/or visits are extra for research purposes i.e., not standard clinical care.

5.3. Burden and risks

Please describe the burden and risks associated with participation, e.g. the amount and number of blood samples, biopsies, liquor, hair, urine, nails, saliva etc., the number of site visits, physical examinations or other tests, questionnaires or diaries that have to be filled out, physical and psychological discomfort associated with participation.
If there is no burden and risk because there is no direct involvement from participants needed please describe this.
If a study is carried out with minors or incapacitated subjects, it should also be specified whether the risks are negligible and the burden minimal and why the study is group related (i.e., study can only be done using these patients groups).

5.4. **Medical device(s) / In vitro diagnostic tests**
Describe which medical device and/or in vitro diagnostic test is used, what the intended use of the medical device is and whether the medical device/diagnostic test is already available in the participating centers.

6. Incidental findings

6.1. **Chance of incidental findings**
Is there a chance of incidental findings?

☐ Yes

☐ No

6.2. **Procedures**
If yes, describe who will be notified and how the subjects and other parties will be notified in case of incidental findings from the study that may be in the interest for the participant's health.

7. Statistical analysis
Describe how data will be analyzed

7.1 **Main study parameters/endpoints**
Please describe the main study parameters/endpoints.

7.2 **Secondary study parameters/endpoints**
Please describe the secondary parameters/endpoints, how the analysis will be done for the outcome parameters.

7.3 **Other study parameters**
Please describe the other parameters/endpoints.

7.4 **Analysis**
Please describe how the analysis will be done for the outcome parameters.

8. Ethical considerations

8.1 **Regulation statement**
The study will be conducted according to the principles of the Declaration of Helsinki (version, date, see for the most recent version: www.wma.net), Gedragscode Gezondheidsonderzoek 2022 and in accordance with other guidelines, regulations and Acts (if applicable, please specify).

8.2 **Informed consent**

Will the subjects be asked for informed consent?

☐ Yes *(Upload Participant Information Letter and Informed Consent)*

☐ No, consent already given in previous study *(Upload Participant Information Letter and Informed Consent previous study)*

☐ No, this research will be performed under the exception consent *(Upload form Care for data Template, in Dutch: Formulier uitzondering toestemming)*

☐ Other (e.g. partly, indirectly) *Please describe the situation.*

8.3 **Recruitment and informed consent procedures**
If yes, please give a description of the recruitment and informed consent procedures. How and by whom (investigator, supervising doctor, other person) participants will be informed about the study and asked for their consent, how much time will they be given to consider the decision. The patient information letter with informed consent form should be attached as a separate document.

8.4 **Exception consent**
If no, exception consent: *describe how it is safeguarded that subjects are excluded who have objected against the re-use of their data, human material, images.*
The Form Care for data Template should be attached as a separate document.

9. Handling and storage of data / images / sound recordings / photos / film recordings

9.1 **Data / images / sound recordings / photos / film recordings**
Please describe which data / images / sound recordings / photos / film recordings is/are used, are they obtained for regular healthcare purposes or in the context a research project, or a combination.

9.2 **Privacy protection**
Describe how subject's privacy is protected. Describe how, when and by whom data is coded (unique code without initials or date of birth) and how the key table is safeguarded, mention the General Data Protection Regulation.

Please note: The handling of personal data has to comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (in Dutch: Algemene Verordening Gegevensbescherming en Uitvoeringswet Algemene Verordening Gegevensbescherming).

9.3 **Handling and storage of data**
Describe how data is handled and stored (i.e., which data management system/data capture system), anonymous / pseudonymized / coded / identifiable, who has access to the coded source data, how long data will be kept, which steps are taken to ensure data security, what happens with the data after the research has been completed.

In line with Erasmus MC guidelines, data will be kept 10 years after it is collected.

9.4 **Handling and storage of images / sound recordings / photos / film recordings**
Describe how images / sound recordings / photos / film recordings are handled and stored, how the subject's privacy is protected, anonymous / pseudonymized / coded / identifiable, what happens with images after the research has been completed.

In line with Erasmus MC guidelines, images / sound recordings / photos/ film recordings will be kept 10 years after it is collected.

9.5 **Approval of access to data / images / sound recordings / photos / film recordings**
Describe how the access is approved. Is access granted by the Data Board, Department, Principal investigator of the collection or other?

10. Handling and storage of human material

10.1 **Human material**
Please describe which human material is used.

10.2 **Check all the boxes which are applicable to the human material origin:**

☐ Residual material from regular healthcare

☐ Research (material acquired from a previous study).
Add the reference of the study i.e., MEC-number Erasmus MC.

☐ Re-use of human material from existing biobank
Describe whether the human material originates from research into the same disease.

☐ Other, *please specify*

10.3 **Handling and storage of human material**

☐ Anonymous, i.e. the material can never be traced back to an individual subject

☐ Pseudonymized/Coded

☐ Identifiable

Describe how human material is handled and stored (i.e. which data management system / data capture system), anonymous / pseudonymized / coded / identifiable, who has access to the human material, how long the human material will be kept, what happens with the data after the research has been completed.

In line with Erasmus MC guidelines, human material will be kept 10 years after it is collected.

10.4 **Biobank**
In case of new human material collection (biobank), describe how the human material is coded and stored (which registration system, Central Biobank or other location), who has access to the registration system and human material, by whom the key to the code is safeguarded, how long and where human material will be kept, what happens to the human material when the storage period is expired.

10.5 **Approval of access to human material**
Describe how the access is approved. Is access granted by the Department, Principal investigator of the collection or other?.

11. Exchange, sharing or transfer of data and/or human material and/or images

Describe with which organization the data and/or human material and/or images are shared, are they profit or non-profit organizations, whether these organizations are in the EU or outside the EU, how the privacy of subjects is protected outside the Erasmus MC and describe the procedures regarding

the exchange(s), whether a Data Transfer Agreement/Material Transfer Agreement is available (if yes, please upload the DTA/MTA).

12. Amendments

Amendments are changes made to the research after a favorable opinion by the NWTC has been given.

All amendments must be submitted to the NWTC that gave the favorable opinion.

Substantial amendments must be approved by the Niet WMO Toetsingscommissie before they can be implemented.

13. End of study report

Within one year after the end of the study a final study report will be submitted with the results of the study, including any publications/abstracts of the study.

In case the final study report will not be available within one year, another term should be defined including the reasons.

14. Publication

Do you have the intention to submit the study results in a manuscript for publication in a journal:

☐ Yes

☐ No, *please motivate*

Describe when the final study report with the results of the study will be submitted.

15. References

Include a list of all key references published in peer review journals that are relevant for the study and are discussed in the protocol

16. Attachments

☐ Participant information letter and Informed consent document

☐ Care for data Template – Formulier uitzondering toestemming

☐ Questionnaires

☐ Data Management Plan

☐ Data Transfer Agreement

☐ Material Transfer Agreement

☐ Clinical Trial (Site) Agreement

☐ Other, *please describe*