Reuse of care data for the purpose of research

Standard operating procedure

SOP-ID	002
Version	3.0

*Only the on-line electronic version is considered to be up to date. Off-line versions and paper-based versions are not determinative

Objective

Electronic Health Records *(EPDs)* contain a wide range of patient-related care data that can also be relevant for the purpose of scientific research. However, care data cannot be reused without considering the patient's privacy and autonomy. National legislation and self-regulation provide the conditions under which care data can be reused as research data.
This Standard Operating Procedure (SOP) provides a practical implementation of these conditions and describes the steps to follow when reusing care data as research data in the Amsterdam UMC.

Legal framework and self-regulation

The legal framework for research with care data (i.e. non-WMO research) consists of the General Data Protection Regulation (*AVG*), and the Medical Treatment Contract Act. The latter is included in the Dutch Civil Code, book 7 *(Burgerlijk Wetboek, boek 7, afdeling 5 inzake de geneeskundige behandelingsovereenkomst, WGBO; see* in particular articles 7:457 and 7:458 Civil Code.

In addition to working within the legislative framework, self-regulation is of importance too. In 2022, the *Stichting COREON* established a revised version of the Code Good Conduct *(Code Goed Gedrag).* Purpose of the code is to translate the general (abstract) legal norms into explicit rules of conduct. This SOP also follows the Amsterdam UMC Research Code.

Scope

This SOP is applicable to the reuse of care data from Electronic Health Records within Amsterdam UMC for scientific research, such as Epic, imaging, gene banks and others. It covers the reuse of data for screening and selecting patients for inclusion in studies, for data extraction and for access to Epic for operational tasks within clinical studies.
The reuse of care data solely for monitoring, controlling and improving the quality of care is beyond the scope of this SOP.

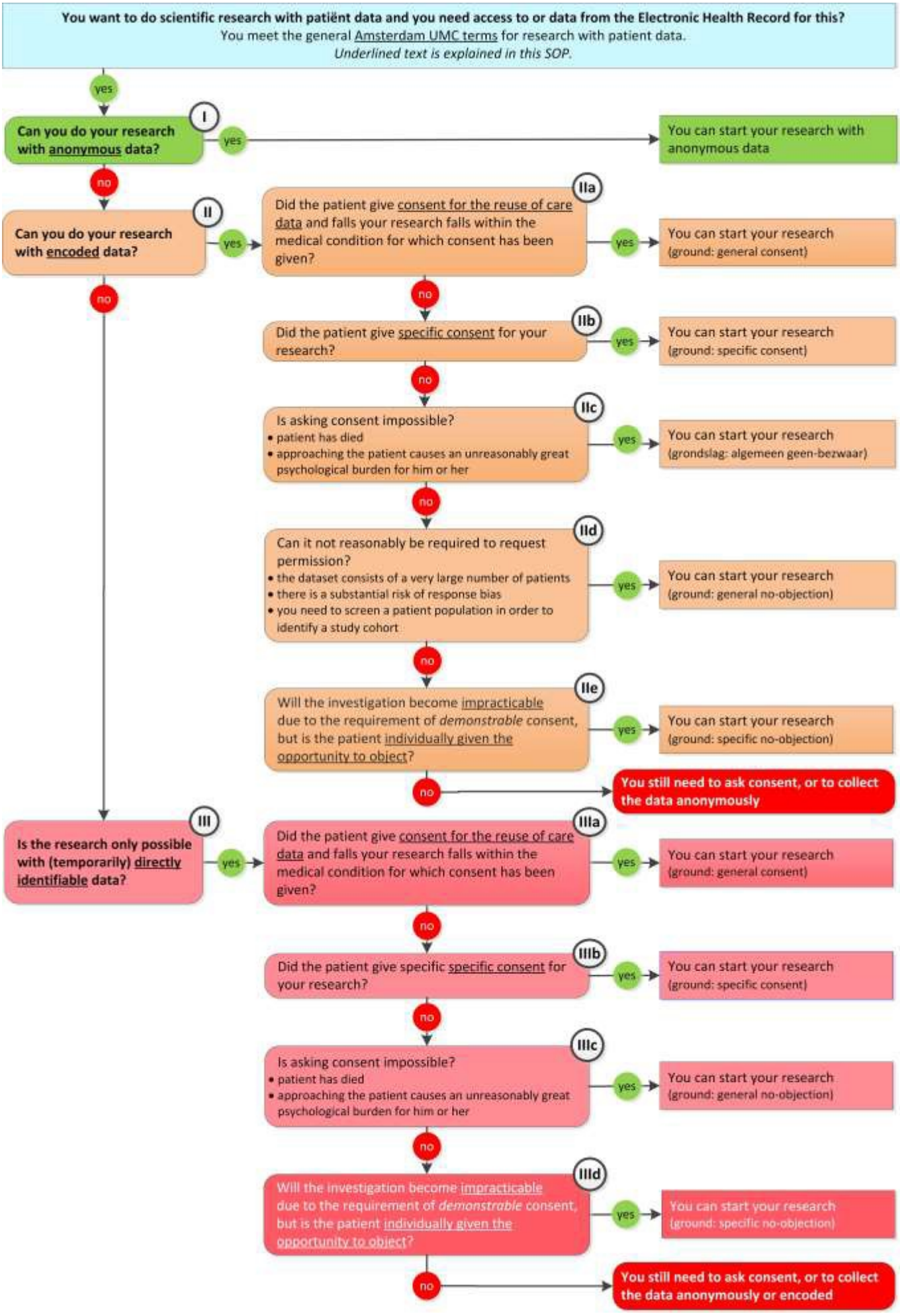
Responsibilities

This SOP has been developed by Research Data Management and is authorised by the board of directors. The heads of all Amsterdam UMC departments are responsible for adherence to this SOP and must ensure that their employees, involved in research with human subjects, are informed of this procedure.

Structure of this SOP

The SOP guides the reader through a flow chart that can be used to choose the appropriate procedure in a given situation. For submitting a request for the reuse of care data, the following form is required:

- RDM2 F01 Aanvraag extractie zorggegevens


You want to do scientific research with patiënt data and you need access to or data from the Electronic Health Record for this?
You meet the general Amsterdam UMC terms for research with patient data.
Underlined text is explained in this SOP.
yes
I
Can you do your research with anonymous data?
yes
You can start your research with anonymous data
no
II
Can you do your research with encoded data?
yes
IIa
Did the patient give consent for the reuse of care data and falls your research falls within the medical condition for which consent has been given?
yes
You can start your research (ground: general consent)
no
IIb
Did the patient give specific consent for your research?
yes
You can start your research (ground: specific consent)
no
IIc
Is asking consent impossible?
• patient has died
• approaching the patient causes an unreasonably great psychological burden for him or her
yes
You can start your research (grondslag: algemeen geen-bezwaar)
no
IId
Can it not reasonably be required to request permission?
• the dataset consists of a very large number of patients
• there is a substantial risk of response bias
• you need to screen a patient population in order to identify a study cohort
yes
You can start your research (ground: general no-objection)
no
IIe
Will the investigation become impracticable due to the requirement of demonstrable consent, but is the patient individually given the opportunity to object?
yes
You can start your research (ground: specific no-objection)
no
You still need to ask consent, or to collect the data anonymously
no
III
Is the research only possible with (temporarily) directly identifiable data?
yes
IIIa
Did the patient give consent for the reuse of care data and falls your research falls within the medical condition for which consent has been given?
yes
You can start your research (ground: general consent)
no
IIIb
Did the patient give specific specific consent for your research?
yes
You can start your research (ground: specific consent)
no
IIIc
Is asking consent impossible?
• patient has died
• approaching the patient causes an unreasonably great psychological burden for him or her
yes
You can start your research (ground: general no-objection)
no
IIId
Will the investigation become impracticable due to the requirement of demonstrable consent, but is the patient individually given the opportunity to object?
yes
You can start your research (ground: specific no-objection)
no
You still need to ask consent, or to collect the data anonymously or encoded

Terms and conditions for reuse of care data for the purpose of research

1. Before you can start doing your research with care data, the following general prerequisites have to be fulfilled:
   a. the research serves a public interest:
   b. it provides new (scientific) knowledge;
   c. it is investigator initiated;
   d. it has no commercial purposes.

   If these conditions are not met, only procedure I, IIa, IIb, IIIa and IIIb apply.
2. A protocol or action plan is available describing the objective, background, design, study population, methods, analysis and literature references.
3. The reuse of the care data is necessary for conducting the research; no more than the data required for this will be used.
4. In principle, consent is required for the reuse of encoded and directly identifiable data. Any appeal to one of the exceptions on this demand must be motivated.
5. Prior to obtaining the data, a Data Protection Impact Assessment (DPIA) is performed and the data collection is registered.
6. The care data required for the research will be made available or viewed in an anonymous way or, if this is not possible, as ‘encoded data’. If the research cannot be performed with anonymous or encoded data, the required data can be made available or viewed in an identifiable form.
7. As soon as the performance of the research project permits it, directly or indirectly identifiable data are de-identified, for example by:
   a. replacing identifiable data with a code and keeping the key file separate from the research data;
   b. replacing individual data with a group indication (age in years or age cohort instead of date of birth, socio-economic status of zip code area instead of entire zip code);
   c. removing the least significant parts from a date field (replace admission and discharge date with duration of admission, remove day and month from a date).
8. The Amsterdam UMC procedures with regard to research data management are elaborated in a Data Management Plan.
9. If the applicant is not an employee of Amsterdam UMC, a confidentiality statement must be signed. Please contact the Privacybescherming en informatiebeveiliging (PB&IB): privacy@amsterdamumc.nl.
10. Approval of your research, either WMO or non-WMO compliant, by the METC of Amsterdam UMC is required.

Procedures for reuse of care data for the purpose of research

I Can you do your research with anonymous data?

Research data are anonymous if tracing back to individual patients would require a disproportionate effort on the part of anyone who gets hold of the data. Anonymous data do not contain identifiable or encoded data (for example, name, telephone number, (e-mail) address, social security number, patient number, date of birth or (partial) zip code). The risk of spontaneous recognition must also be very low and individual variables (such as a rare diagnosis) or combinations of variables (such as gender, date of admission and diagnosis) must not be identifiable to individual patients.
Anonymous data can only be obtained from the Electronic Health Record via an electronic extract. If a researcher or applicant extracts data from the Electronic Health Record itself, the data set is by definition directly identifiable, even if it is stored anonymously.

Note: be careful with classifying a data set as anonymous in the context of the AVG and the WGBO. Only datasets that consist of many patients and few variables can, in principle, be classified as anonymous. Aggregated data, such as a count of a minimum of five patients with identical data records, are classified as anonymous.

If you can work with an anonymous data extract, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
Only if it is not possible not work with an anonymous data extract and you need access to identifiable or encoded data, or if you have to look up your data in Epic before you anonymize them, answer **'no'** and go to **question II.**

II Can you do your research with encoded data?

Encoded data can only be traced back to individual patients via a code. Each data record of a data set contains a meaningless code with no identifiable characteristics, for example name, telephone number, (e-mail) address, social security number, patient number, date of birth or (partial) zip code. The link between the code and the individual patient is in the key file (code list or subject identification log) and is separated from the research data file.

Encoded data can only be obtained from the Electronic Health Record via an electronic extract. If the research can only be carried out because the applicant himself extracts the data from the Electronic Health Record, the data is always directly identifiable, even if the data obtained is stored encoded immediately afterwards.

If you can work with encoded data, answer **'yes'** and continue with **question IIa: Did patients give consent for the reuse of care data?**
If you need to work with identifiable data, answer **'no'** and go to **question III.**

IIa Did the patient give consent for the reuse of care data?

A general consent procedure has been implemented in several departments of Amsterdam UMC. In such procedures, patients are informed about the potential reuse of their care for future research in the field of the medical condition for which they visit Amsterdam UMC. The patient's agreement or disagreement must be documented in Epic or at departmental level.

If you can work with encoded data, consent for the reuse of care data has been obtained, and your research falls within the medical condition for which consent has been given, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
Only if it is demonstrably impossible to obtain specific consent, answer **'no'** and go to **question IIc.**
If no consent for the reuse of care data has been obtained, go to **question IIb.**

IIb Did the patient give specific consent for your research?

In a specific consent procedure, information is given to potential study participants in a understandable manner. For non-WMO studies use the template consent letter on the METc website (Open the folder Documenten nieuwe niet-WMO indiening: METC-Model-toestemmingsformulier-niet-WMO). For WMO studies use the template consent letter on the CCMO website.

The patients´ treating physician must inform the patient, ask his consent and inform him of the possibility to object against the participation in the study.
The treating physician can also ask the patient consent for another person to approach him for participation in the study. If the patient agrees this must be documented. Next, the other person can receive the patients contact information and approach the patient to ask for study participation.

If you can work with encoded data and you have obtained specific consent for your research, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
Only if it is demonstrably impossible to obtain specific consent, answer **'no'** and go to **question IIc.**

IIc Is asking consent impossible?

If it is demonstrably impossible to ask consent, this can be due to patient related reasons that allow you to work with encoded data without consent. These reasons are:

1. Patient has died, therefore he or she cannot be approached to ask for their consent.
2. Approaching the patient causes an unreasonably great psychological burden for him or her. This burden must be demonstrable and the argumentation must be documented. *Examples:*
   - an unpleasant feeling among the potential participants is not an adequate argument;
   - it is well documented that parents of neonates have PTSS and asking permission is too burdensome for many parents.

Argumentation why permission cannot be obtained must be independently verified by the METc of Amsterdam UMC or the *niet-WMO* committee of Amsterdam UMC.

If you can work with encoded data and you must appeal to one of these exceptions, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk. If
you do not appeal to one of these exceptions, answer **'no'** and go to **question IId.**

IId Can it not reasonably be required to request permission?

If it is demonstrably impossible to ask consent, this can be due to logistical or methodological arguments that allow you to work with encoded data without consent. These arguments are:

1. Due to its size, approaching the group of participants requires an unreasonable effort ('large numbers'). This can be invoked on the basis of a substantiated consideration between the required efforts for all parties involved (researchers, care providers, etc.), the availability of low-threshold options for making contact with potential participants, and the risk that within a reasonable term and financing insufficient response is obtained from the survey. With 10,000 or more participants required, no consideration is necessary, this is not reasonably possible. The fact that recruiting is not successful within an internship period is not a sufficient argument since you can expect this and recruitment can therefore take place before the internship period.
   The number of patients needed must be demonstrated by e.g. a power calculation or literature.
2. There is a substantial risk of response bias. The expected bias must be well substantiated, statistically, with literature and/or figures from previous consent questions among this target group that by asking the consent question, such a selection bias can be expected that the results are no longer relevant or representative.

3. You need to screen a patient population in order to identify a study cohort. The selected patients will then be asked for consent by their treating physician.

The fact that recruiting is not successful within an internship period is not a sufficient argument since you can expect this and recruitment can therefore take place before the internship period.
Argumentation why permission cannot be obtained must be independently verified by the METc of Amsterdam UMC or the *niet-WMO* committee of Amsterdam UMC.

If you can work with encoded data and you must appeal to one of these exceptions, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk. If you do not appeal to one of these exceptions, answer **'no'** and go to **question IIe.**

IIe Will the investigation become impracticable due to the requirement of demonstrable consent, but is the patient individually given the opportunity to object?

If it is demonstrably impossible to obtain consent, a research study can become impracticable if a sufficient response is not achieved within the (predetermined) duration and funding of the investigation. This may be an argument not to ask for consent, but only if this can be properly substantiated and if patients are offered the opportunity to object against the reuse of their care data.

The patient's treating physician must inform the patient and point out the possibility to object against the study participation. In this specific no-objection procedure, brief information is given to potential study participants in a short and understandable manner. If no objection has been made within 4 weeks, either in writing, by e-mail or by telephone, you may use the data in your database in encoded form.

If you can work with encoded data and you appeal to this exception, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
If you do not appeal to this exception, you must answer **'no',** still request consent or process the data anonymously.

III Is the research only possible with (temporarily) directly identifiable data?

Use of directly identifying information is only required in the following situations:

1. The individual records of the study participants cannot be encoded as described under II, for example because they still have to be linked to other data files or analyses of human material. As a result, identifiable data is still part of the research file;
2. The data collection can only be carried out by the applicant himself and this requires access to the Electronic Health Record of the participants involved.

IIIa Did the patient give consent for the reuse of care data?

A general consent procedure has been implemented in several departments of Amsterdam UMC. In such procedures, patients are informed about the potential reuse of their care for future research in the field of the medical condition for which they visit Amsterdam UMC. The patient's agreement or disagreement must be documented in Epic or at departmental level.

If you must work with (temporarily) directly identifiable data, consent for the reuse of care data has been obtained, and your research falls within the medical condition for which consent has been given, answer **'yes',** record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
Only if it is demonstrably impossible to obtain specific consent, answer **'no'** and go to **question IIIc.**
If no consent has been obtained, go to **question IIIb.**

IIIb Did the patient give specific consent for your research?

In a specific consent procedure, information is given to potential study participants in a understandable manner. For non-WMO studies use the template consent letter on the METc website (Open the folder Documenten nieuwe niet-WMO indiening: METC-Model-toestemmingsformulier-niet-WMO). For WMO studies use the template consent letter on the CCMO website.

The patients´ treating physician must inform the patient, ask his consent and inform him of the possibility to object against the participation in the study.
The treating physician can also ask the patient consent for another person to approach him for participation in the study. If the patient agrees this must be documented. Next, the other person can receive the patients contact information and approach the patient to ask for study participation.

If you must work with (temporarily) directly identifiable data and you have obtained specific consent for your research, answer **'yes'.**

- If you need items stored as structured (discrete) data in the Electronic Health Record, such as diagnosis, medication, admission date or lab results, you can obtain a data extract in the format of a structured file. If it is possible to work with an automated data extract from the Electronic Health Record. Record your request for in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
- If you need to collect your data from notes, letters, reports etc., a data extract is sometimes an option. Another way is to get access to Epic to look up the unstructured information manually and convert it into discrete fields in your own database. In either way the METC Amsterdam UMC must have approved for you to receive personalised data. So far we are not able to pseudonimise free text. Epic access has to be requested by your superior via an *Epicmelding* with the specification that you have a research related request for the access. Specific training is required when requesting an Epic role.

IIIc Is asking consent impossible?

If it is demonstrably impossible to ask consent, this can be due to patient related reasons that allow you to work with identifiable data without consent. These reasons are:

1. Patient has died, therefore he or she cannot be approached to ask for their consent.
2. Approaching the patient causes unacceptably great psychological burden for him or her.

If you must work with (temporarily) directly identifiable data and you appeal to one of these exceptions, answer **'yes'.**

- If you need items stored as structured (discrete) data in the Electronic Health Record, such as diagnosis, medication, admission date or lab results, you can obtain a data extract in the format of a structured file. If it is possible to work with an automated data extract from the Electronic Health Record. Record your request in *RDM2 F01 Aanvraag extractie zorggegevens* and send this to the RDM helpdesk.
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IIId Will the investigation become impracticable due to the requirement of demonstrable consent, but is the patient individually given the opportunity to object?

If it is demonstrably impossible to obtain consent, a research study can become impracticable if a sufficient response is not achieved within the (predetermined) duration and funding of the investigation. This may be an argument not to ask for consent, but only if this can be properly substantiated and if patients are offered the opportunity to object against the reuse of their care data.

The patient's treating physician must inform the patient and point out the possibility to object against the study participation. In this specific no-objection procedure, brief information is given to potential study participants in a short and understandable manner. If no objection has been made within 4 weeks, either in writing, by e-mail or by telephone, you may use the data in your database in encoded form.

If you must work with (temporarily) directly identifiable data and you appeal to this exception, answer **'yes'.**

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