GUIDELINE, TOOLKIT and CASE STUDY
for
HEALTHCARE PROFESSIONALS and INSTITUTIONS COLLABORATING IN ERNs
on the use of the
ERN STANDARDISED CONSENT FORM

December 2017

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Introduction to the Guideline Toolkit and Case Study on using the ERN Standardised Consent Form

Objective

The primary purpose of this Guideline, Toolkit and Case Study is to provide a step-by-step guide for healthcare professionals engaged in ERNs who are responsible for requesting consent from patients for sharing data in ERNs. It is designed to support the use of the ERN Standardised Consent Form.

This Guideline is provided as a simple one page document which summarises the key issues addressed by the Standardised Consent Form. This one page document could be provided as an information sheet to healthcare professionals charged with requesting consent from patients for sharing data in ERNs.

Following the one page Guideline, the Toolkit provides more detail on each of the key elements highlighted in the Guideline. It should be noted however that the Toolkit is not exhaustive and may need to be further enhanced by local clarification to address practice by any given care provider institution.

As a further educational tool a short Case Study has been developed which can be used as an *aide-memoire* to ensure that the key points set out in the Toolkit have been well understood.

Scope

The Standardised Consent Form is based on the principles of data protection as set out in the European Data Protection Directive and General Data Protection Regulation (GDPR), which will enter into force in May 2018. Although this is an EU level regulation, and will have a widely harmonised interpretation at national level, it is important to note that some variation will exist between Member States in their interpretation of particular requirements. Where such variation can be foreseen, the Toolkit notes that users should obtain local information, but national variations are not addressed.

Health data are classified as 'sensitive data' within the GDPR. Accordingly, the collection and processing of health is, *prima facie*, prohibited. However, a number of exceptions to that prohibition exist. The most important of these for ERNs is that health data processing is allowed when the data subject (patient) has freely given his or her explicit and informed consent to the processing of those personal data for one or more specified purposes.

These are the concepts which are addressed in the Toolkit. However, in addition to the exception of consent, health data may also be collected in certain other circumstances, including if to do so is necessary to protect the vital interests of a data subject who is physically or legally incapable of giving consent. It is unlikely that an ERN will process data using the emergency derogation; as such emergencies will usually be treated at national level. However, it is of course possible that a patient might lack the physical or intellectual capacity to give consent, but the expertise of a clinician in the ERN is needed to treat the patient. In such cases the ERN might indeed make use of the emergency processing derogation.

It is important to note that the ERN Standardised Consent Form is only for data collection; it is not a consent form for treatment. To the extent that treatment is provided by an ERN member, the healthcare provider organisation will need to ensure that legally acceptable separate consent to treatment has been provided by the patient.

It should also be noted that use of the Standardised Consent Form does not create any financial or legal liability for the care provided to the patient. The form addresses only the consent to share health data within an ERN in order for healthcare professionals to share experiences and knowledge in order to assist the treating physician(s) develop diagnoses and care plans for the patients under their care. Once again, if a treatment is provided through by an ERN member, on the basis of the patient shared health data, a legally acceptable different consent to treatment will have to be provided by the patient.

Where care is provided by an ERN member who is not located in the Member State where the patient is resident, reimbursement will be regulated under the rules of Directive 2011/24 EU on patients' right to cross-border care or Regulation 883/2004 on the coordination of social security systems. These issues are not addressed in the Guideline and Toolkit. In terms of legal liability for the quality care, under both the Directive and the Regulation this remains the responsibility of the legal entity providing the care. The advice provided within an ERN between healthcare professionals does not attract either a legal or financial responsibility outside the one already existing between the treating physician and the patient.

Purpose

The Standardised Consent Form has been constructed to be concise, easily readable and to give all the information required in order to make the consent given legally acceptable under the GDPR. However, a number of points on the Standardised Consent Form indicate that the patient may request further information. Accordingly, the healthcare professional charged with presenting the Standardised Consent Form must be suitably informed about ERNs and the data collection and sharing processes of the care institution in which he or she is working. It should be noted that at EU level there is no strict specification of who should request consent, but individual care providers may specify that it should be the treating physician or another specific member of the treating team.

The Standardised Consent Form has been constructed to obtain consent to three different issues:

I. Consent to sharing de-identified data for **care** purposes.
II. Consent for the inclusion of de-identified data in **ERN registries.**
III. Consent to be contacted in the context of **research** initiatives (in order to provide specific consent to data sharing for a named research project).

The Guideline and Toolkit are provided to help the healthcare professional charged with presenting the Standardised Consent Form to understand the terms of the form and respond to questions. The Guideline and Toolkit are not exhaustive and may be complemented by further information or training provided by individual ERN Members.

Guideline on the use of the ERN Standardised Consent Form (ERN-SCF)

Note: Further detail on the terms described are available in the ERN-SCF Toolkit

What is the ERN Standardised Consent Form for?

- The ERN-SCF asks the patient (or his or her legal guardian) to provide consent to three types of data sharing:
  I. Consent to sharing de-identified data for **care** purposes.
  II. Consent for the inclusion of de-identified data in ERN **registries**.
  III. Consent to be contacted in the context of research initiatives.

What is the patient consenting to?

- This is a request to consent to sharing information in an ERN; this is NOT a request for consent to treatment.
- Consent to treatment remains the responsibility of the institution where the patient is receiving care.
- The patient may consent to one or more of the three types of data sharing. Each type has its own consent box. A patient may consent to one type of sharing and withhold consent to others.

What is required to make consent legally acceptable?

- **Freely given** - the patient must understand that they can withhold consent and that their care provider will still provide care to the best of their ability.
- **Informed** - the patient must understand what an ERN is and why sharing data in an ERN could be beneficial. Any risks that might exist to such data sharing should also be made clear.
- **Explicit and Unambiguous** - for this reason each type of data sharing foreseen within ERNs has its own consent box on the form.
- **Specific** - the consent must be related to a specific type of data sharing; this is why the ERN-SCF must list all ERNs which may be consulted. The healthcare professional charged with presenting the ERN-SCF must fill in the names of the ERNs and must also sign the ERN-SCF.

What is de-identified data?

- The form states that data shared in the ERNs will be de-identified.
- Patients must understand that this means that immediately identifying markers such as name, full date of birth, address and national ID number will be removed before records are shared.
- Because the medical data shared will make it possible to re-identify the data, the patient's consent is needed to share the de-identified data.

What are ERN Registries or Databases?

- The ERN–SCF requests consent to add data to a Registry or Database.
- The patient should understand that such databases are secure, as well as their value in building knowledge about each condition.
- The patient must understand that they can withhold consent to including data in a Registry or Database.

What is consent to be contacted for ERN Research?

- The ERN–SCF asks if the patient consents to being contacted about research initiatives.
- The patient must understand that consent must be given to a specific research initiative, rather than general research in their condition. Accordingly they are consenting to being contacted to provide specific consent if an ERN Member believes they could be suitable for a given research initiative.

What Rights does the patient have?

- The ERN-SCF states that ERNs have a legal responsibility to ensure that data are secure. This means that a patient has right to remedy if a data breach occurs, which the patient can address to the hospital or clinic where care is provided.
- Patients have a right to access data held about them and to know which data are shared in an ERN.
- Patients have a right to copies of their data in a portable, readable and shareable format. The healthcare professional charged with presenting the ERN-SCF must be aware of where to refer a patient if they ask for such access or data portability. This will vary in each healthcare provision institution.
- Patients have a right to withdraw consent given previously at any time and to obtain the erasure of their personal and health data. However, data erasure might not occur in ERNs when such erasure would render impossible or seriously impair scientific research.

Toolkit on using the ERN Standardised Consent Form

Introduction

The healthcare professional charged with presenting the Standardised Consent Form should fully understand the nature of informed consent as required by the GDPR and should be able to answer any questions the patient may ask on the three issues for which the patient is being asked to provide consent, as well as the rights accorded to the patient.

The three issues for which the patient is being asked to provide consent are:

i. Consent to sharing de-identified data for **care** purposes.
   - The healthcare professional should be able to provide a simple background on how ERNs will work to share knowledge in order to help with diagnosis and care planning.

ii. Consent for the inclusion of de-identified data in **ERN registries.**
   - The healthcare professional should be able to explain in broad terms what a Registry is, and why such databases about rare diseases are an important tool in developing new knowledge about rare diseases.

iii. Consent to be contacted in the context of **research** initiatives (in order to provide specific consent to data sharing for a named research project).
   - On the matter of research in ERNs it is important that patients understand that they are not being asked to provide consent to research now, but simply to inform them that in future, research projects may arise in which patients whose cases have been discussed in ERNs could be asked to be included.

Understanding the core elements of consent

Below the core elements of valid consent are explained. Consent must be **freely given, informed, explicit and unambiguous, and specific.** The section below explains each of the four key components of legally valid consent.

Consent must be freely given

- Patients must have a real choice of giving or withholding consent. This means patients must not be given the impression that their care will be better if they give consent to their data being shared in an ERN, or indeed that withholding consent could negatively impact their care.
- In an ERN context this issue must be addressed carefully. The reason consent is being sought is to allow the treating doctor to consult other doctors in order that he or she may enhance knowledge and (hopefully) provide better care to the patient. The key issue is therefore to ensure that the patient understands that even if his or her data cannot be shared in the ERN, the treating doctor will treat the patient to the best of his or her ability regardless of the patient's willingness for data to be shared in the ERN.
- Accordingly, it is important that final bullet point in box entitled WHAT ARE THE EUROPEAN REFERENCE NETWORKS AND HOW CAN THEY HELP ME? of the Standardised Consent Form is drawn to the patient's attention and is understood by the patient:

Data about you will not be shared without your consent, and even if you choose not to give your consent your doctors will continue to take care of you to the best of their ability.

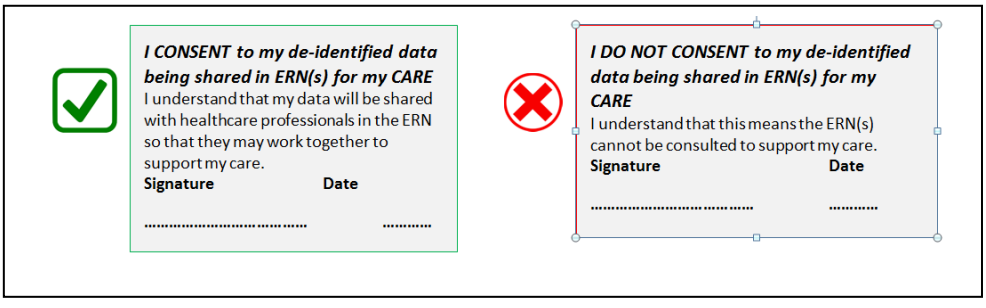
Consent must be informed

- In order for consent to be valid the patient must not only give consent freely, but must understand to what he or she is consenting. Patients must understand what data is being gathered, who will have access to it, and how it will be used. This means that the healthcare professional charged with presenting the Standardised Consent Form to the patient must be able to explain why data are collected.
- Generally, a patient should derive value from the disclosure of the data he or she shares in some way. Therefore efforts should be made to help patients understand why allowing their data to be shared in an ERN is positive, but such information must not be so persuasive that it could be seen as coercive.
- These issues are outlined in simple language in the first box of the Standardised Consent Form entitled WHAT ARE THE EUROPEAN REFERENCE NETWORKS AND HOW CAN THEY HELP ME? However, the Standardised Consent Form states that patients (or legal guardians) may ask for further information, accordingly healthcare professionals must be equipped to answer questions or refer a patient to someone who can answer.

You are entitled to receive further information about the purposes for which your data will be processed and who will have access to it. Your doctor can tell who can help you if you would like more information

Consent must be explicit and unambiguous

- With respect to consent generally, the GDPR requires that consent must be unambiguous.
- The law generally requires that consent must be shown through clear affirmative action, such as ticking a box, signing a form or giving a clear oral affirmation.
- With respect to health related data the GDPR requires that consent must also be explicit. While there is no direct guidance on the difference between explicit and unambiguous consent, in the context of ERNs it is important that the act of consent is recorded.
- Since the Consent Form requests consent for three different forms of data sharing, the option to provide a positive or negative response for each type of sharing has been included.
- It should be made clear to the patient that they can choose Yes for one category and No for another without this having any impact on the way in which their care is provided.



Consent must be specific

- The consent provided must relate specifically to the situation at hand. It may not be general consent to 'use my data to treat me' but must clarify which data will be shared, for what purpose and by whom.
- The box entitled PATIENT DATA SHARED FOR CARE WILL BE DE-IDENTIFIED sets out the broad range of data types that might be shared. The healthcare professional should be able to give clarity on this range to the patient with respect to his or her particular case and should be able to explain its use in understandable terms to the patient.
- The healthcare professional should also be able to clarify the term DE-IDENTIFED. A separate note on this issue is provided below.
- Specific consent requires also that the patient knows who will have access to the data. It is not required that all healthcare professionals who may have access are listed, but the healthcare professionals charged with requesting consent must ensure he or she is able to list the ERNs which may be consulted, as provided for in the top box of the reverse side of the Form - where more than three ERNs might be consulted, additional pages may be added to the Form.

Patient Rights with respect to Consent to Data Processing

Patients have a right to withdraw consent given previously

- The GDPR specifically requires that it must be possible for a data subject (a patient in the ERN situation) to withdraw consent for data processing.
- The healthcare professional charged with requesting consent must therefore be able to explain how consent may be withdrawn in future, and also able to respond to a request to withdraw consent which has already been given.
- The option to withdraw the consent must exist for some or all data processing activities. Subsequently after withdrawing, consent processing should stop as soon as possible.
- The GDPR requires that data subjects are informed of the option of consent withdrawal; accordingly withdrawal is included on the Standardised Consent Form. Hospitals and clinics will need to ensure that staff is equipped to answer questions about withdrawal of consent with sufficient detail on process and impact.

Patients have a right to access data concerning them

- According to the GDPR, as well as the Data Protection Directive, patients have a right to access data held about them and to request correction to any errors they might find.
- The organisation holding patient data must therefore be able to provide access to the patient records and also to respond to requests for correction.
- The law also describes a right to deletion, and in the GDPR introduced a 'Right to be forgotten' which will in certain cases allow a patient to demand that their record is entirely deleted.
- However the extent to which this right applies in healthcare or a health research setting is complex and is not addressed in detail here.

Patients have a right to data portability

- The right to data portability is a new patient right introduced in Article 20 of the GDPR. It is a right which is closely related to, but differs from, the right of access in many ways. It allows patients to receive the data which they have provided to a healthcare professional, in a structured, commonly used and machine-readable format, and to transmit them to another healthcare professional if they choose to do so.
- The purpose of this new right is to empower the patient and give him/her more control over the personal and medical data concerning him or her. In other words, it allows patients to obtain and reuse their personal and medical data for their own purposes.
- Organisations must be able to provide, free of charge, to each patient (or directly to another organisation treating the patient, if requested by the patient), his/her personal and medical data in a structured, commonly used and machine readable form (which means that the information is structured so that another organisation can use the data).
- Organisations must be ready to respond to patients' requests without undue delay. The GDPR does not define undue delay, but guidance from some Member States indicates that the organization must provide the patient with a timeframe within which an answer shall be provided and if this period is lengthy to explain the reasons for the time taken.
  Organisations must be able to accommodate a redaction of data, so that where medical data related to one patient concerns other individual (eg medical history or genetic data), the rights of other individuals will not be compromised.

Key Concepts in the ERN Standardised Consent Form

De-identified Data

- The Standardised Consent Form states that data shared in the ERNs will be de-identified. It is important that patients and legal guardians understand what this term means.
- The term de-identification as used in the Standardised Consent Form is similar to the concept of pseudonymisation as used in the GDPR. The GDPR defines pseudonymisation as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual" (Article 4(3)(b) GDPR).
- It is important to note that de-identification (or pseudonymisation) is not the same as making data anonymous. If data are truly anonymous, as defined by the GDPR, they fall outside the ambit of the GDPR and accordingly no consent is needed to sharing such data.
- However, the GDPR considers data to be anonymous only when it cannot be identified by any means "reasonably likely to be used (...) either by the controller or by any other person" (Recital 23 GDPR).
- The data held in an ERN will be de-identified, that is the immediately identifying markers which make it possible to directly identify a patient such as name, full date of birth, address and national ID number will be removed. However, the nature of the medical data shared will make it possible to re-identify the data without a very significant effort. This is all the

more so because in the case of rare diseases the extent of the detail of medical history recorded and the rarity of the condition will make it relatively easy to identify a patient from the de-identified data.

- Thus, even if a given healthcare professional or researcher does not have access to the tools to re-identify data, such data, unlike anonymous data, remains subject to the remit of the regulation. Accordingly even though data will be de-identified, it is still important for patient to give consent to the data to be shared for care or registry purposes.

Registries and Databases

- Rare diseases pose great challenges for research, primarily because each condition affects so few people. Patients are dispersed in different Member States within the territory of the European Union and abroad, and very often no critical mass of knowledge about a given disease exists in any one country. Registries and databases are crucial tools in overcoming this challenge. However, in order for de-identified data to be contained in a Registry, patients must consent to their data being added to the Registry.
- In order for such consent to be valid in the terms outlined above (freely given, informed, explicit and specific), patients need to understand what Registries are, how they function, and in which specific Registries their data may be included. The healthcare professional charged with presenting the Form should therefore explain to patients that an ERN Registry collects detailed information about each specific rare disease patient, their medical history and the treatments they received, etc.

A Case Study on Informed Consent and Data Sharing

Julia, a citizen of Country A, has a daughter named Sophie who is 20 months old. Sophie had developed well up to the age of 8 months, but as soon as Julia started to introduce solids into Sophie's diet she showed signs of distress and abdominal pain. Julia discussed the issue with her family doctor, who advised delaying starting solids.

However, the issue persists at 9 months of age, so the family doctor refers Sophie to Dr A, a paediatrician at Hospital A in the family's home town. Dr A runs a number of tests, but no diagnosis can be established.

As Sophie fails to thrive, the paediatric team at Hospital A decide to refer her to Dr B in Hospital B, which is a member of the European Reference Networks for rare gastro-intestinal diseases (ERNICA) in country A.

After examining Sophie and reviewing her case **Dr B decides to seek further advice from ERNICA**[1] in order to be able to tap into the wider knowledge pool that exists around Europe to address Sophie's complex case.

Once an ERNICA virtual panel has been scheduled, **Dr B describes Sophie's case and shares the results**[2] of the tests performed at Hospital B. Following the successful first discussions with ERNICA, Dr B performs a number of new tests, and then shares the results with the ERNICA panel, who offer a potential diagnosis. Based on this diagnosis a new care plan is developed

ERNICA members note that the case presented by Dr B is interesting and **request that Sophie's case should be added to the ERNICA Registry**[3]**.**

Sophie's new care plan is implemented, and she starts to improve while following a highly specialised treatement. By the age of three Sophie is starting to develop in line with average developments for a child of her age, but her diet remains very restricted.

Some 10 years later, a researcher at Hospital C in Country C finds a reference to Sophie's case in the ERNICA registry**. Dr C would like to enrol the patient in a new study**[4] being launched at Hospital C.

Sophie, who is now 13 years old[5], is faring quite well, (albeit with a continued restricted diet), and she is enrolled in the study. During the course of the study Julia dies following sudden cardiac arrest, a fact which Sophie shares with the researchers.

The researchers believe her death might have relevance for the study they are conducting and would like to **access Julia's medical history**[6]**.**

What Key issues does this case raise in terms of Data Protection?

1. Dr B decides to seek further advice from ERNICA ….Before doing this Dr B must ensure that Julia is informed about ERNICA and how it could help find a diagnosis for Sophie. She must ensure that Julia knows that de-identified data about Sophie's case will be shared with doctors in other countries. She must inform Julia that if she prefers not to allow her to share the data with ERNICA, she will continue to care for Sophie for to the best of her ability.

Julia is hesitant and asks for more information, she wants to know:

- **Who are the ERNICA members?** Dr B must be able to provide information to Julia on the institutions involved with ERNICA.

- **Who will be responsible for Sophie's care**? Dr B should explain that she and the team at Hospital B will be responsible for her care, which will remain responsible for Sophie's care. Dr B should explain that ERNICA is advising her team in Hospital B, not involved in Sophie's direct care.
- **What does de-identified data mean?** Dr B must be able to explain that Sophie's name, address and full data of birth will not be shared, but relevant medical information will be shared. As this could potentially identify Sophie, Julia needs to consent to the data being shared.
- **How will the ERN work?** Dr B must explain that ERNICA will collaborate using a special collaboration platform which is under the joint responsibility of the European Commission and the technology company providing the platform. Hospital B will remain responsible for the care it provides, for quality of the data shared and for any nominative data about Sophie that the hospital holds.

  Once Julia is happy about the information she has received, she agrees to allow Sophie's data to be shared. Dr B, as an employee of a hospital which is a Member of ERNICA, must then ask Julia to sign the ERN Data Sharing Consent Form.

2. **Dr B describes Sophie's case** …… As only de-identified data may be shared on the Clinical Patient Management Systems of the ERNs, Dr B must work with the data management staff at Hospital B to ensure that immediately identifying features are stripped from the data or at least redacted.

3. **ERNICA members….request Sophie's case should be added to the ERNICA Registry.** As well as explaining about sharing Sophie's de-identified data for her care, Dr B should also explain about the potential of ERN registries and how they in turn might help in research initiatives. It is important that Dr B ensures that Sophie's mother understands she may withhold such consent. Furthermore, Dr B must make clear that at this time she is not asking for consent for Sophie to take part in a research study, only to allow researchers to contact Julia (or Sophie when she is older) if they think Sophie would be a good candidate for a study.

4. **Dr C would like to enrol the patient in a new study …..** Because Julia signed the part of the consent form agreeing that Sophie's data could be included in a registry and that a researcher could contact her if Sophie could be suitable for a study, it is acceptable for Dr C to now work with ERNICA to establish the identity of the patient behind the de-identified case in the registry and for Dr C to present the study (assuming that the study has been duly certified by the relevant Ethics). If such consent had not been given at the time when the data was entered in the registry, it would now not be possible to re-identify the data and make contact.

5. **Sophie, who is now 13 years old** ….. When the data about Sophie were first gathered she was a baby, accordingly her mother signed the consent form. Sophie is now 13 and it is possible that she is able to provide legal consent for herself. The GDPR allows for Member States to define individually what age (between the ages of 13 and 16) they will designate as the age of capacity to consent. Dr C must establish what rules apply in Country A, because the applicable law is the law of the country where the patient lives, not where the data is ultimately processed.

6. **Access Julia's medical history ….** Julia is deceased and cannot provide consent. Country A's law is silent on the matter of medical data protection after death. ERNICA researchers will therefore need to apply to the ethical committee of the hospital in country A which holds Julia's records, or other relevant institution, to establish if Julia's medical records can be released.