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**BRE-JBZ**

[redacted]

**From:** Kaai, Geran
**Sent:** vrijdag 3 april 2015 16:06
**To:** Verweij, Ellen
**Subject:** FW: Proposed EU Data Protection Regulations - COM(2012) final
**Attachments:** Quintiles - Detailed Analysis of Issues Re the Proposed EU DP Regs- Oct2012.docx; Quintiles - Amendments on the Proposal for a Regulation-Oct2012.docx; Core ICF template.docx; ATT00001.txt

**Follow Up Flag:** Follow up
**Flag Status:** Completed

[redacted]

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**From:** [redacted] [mailto[redacted]
**Sent:** maandag 22 oktober 2012 18:38
**To:** Kaai, Geran
**Subject:** Proposed EU Data Protection Regulations - COM(2012) final

Dear Mr. Kaai,

We are a leading contract research organisation (CRO) operating within the Life Sciences industry, and consequently, handle enormous volumes of personal data for medical research, treatments, therapies and drug development. We very much appreciate the encouragement from the European Commission, the Representatives from the Permanent Representations and the Members of the European Parliament to contribute to the development of this proposed Regulation.

During our review of the proposed text we have identified areas of concern where the current iteration of the proposed Regulations could give rise to unintended consequences for the Life Sciences Industry, potentially to the ultimate detriment of medical research advancement and public health.

In the attached documents which we provide for your review and consideration, we have provided a Summary of those Issues of primary concern to Quintiles, and table our suggested Amendments to the proposed draft Regulation to address these concerns.

Also attached is a copy of a generic template version of an Informed Consent Form (ICF). We thought it would be useful to attach this as a reference document to our comments on Consent and Lawfulness of Processing, since the patient informed consent process is fundamental to the conduct of a clinical trial. The contents of these ICFs are generally prescribed by the Good Clinical Practice Guidelines. Whilst this ICF is generic, country specific ICFs (which meet local regulatory requirements) are generated from the generic templates. We have different template ICFs for Paediatric and for specific types of clinical trial studies, and would be happy to forward other sample templates to you, if you are interested.

We have had the opportunity to meet and discuss our concerns with certain of your colleagues but unfortunately not with yourself. Nevertheless, we remain at your disposal for any questions you may have, and look forward to having an opportunity to engage in discussions with you in the future on this important matter.

Yours sincerely,

[redacted]

[redacted] EU Data Protection

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**Proposed EU Data Protection Regulation**
**Summary of Issues**

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# Summary of Issues for Quintiles in Respect to the Proposed EU Data Protection Regulation

## 1. Consent and Lawfulness of Processing - *[Amendment 1, 2, 3, 4 and 5]*

In a clinical trial's setting, patient Informed Consent Forms are obtained in writing, pursuant to specified criteria in the Good Clinical Practice Guidelines. Patient and Investigator sign the Informed Consent Forms confirming that patient consent was freely given. The Investigator is responsible for providing full information and explanation to the subject about the trial, the drug, the side effects, and the right to withdraw, and must be satisfied and certify that the subject understands the risks and consequences of participation.

Under the proposed Regulation, consent will continue to be an important legal justification for processing personal data. Nevertheless, Article 7(4) of the proposed Regulation provides that *"consent shall not provide a legal basis for the processing where there is a significant imbalance between the position of the data subject and the data controller"*.

This requirement causes **great uncertainty with respect to clinical trials**. Arguably, there is an inherent imbalance between the position of the individual patient participating in a trial and ultimately the company conducting it. This implies that the validity of the consent may be questioned at any time thus potentially invalidating the patient's participation in the clinical trial and thereby potentially requiring that patient's data to be erased. (See also point 3 below)

If the validity of subject consent in a clinical trial is unreliable, then this may **risk non compliance with the Clinical Trials Directive[1] and the Good Clinical Practice Guidelines[2]** - which both require consent of data subjects[3] - and bring the proposed Regulations into conflict with those requirements.

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[1] Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121, 01.05.2001, p. 34.

[2] Guidance on Good Clinical Practice, CPMP/ICH/135/95. The full text of the GCP Guidance document can be found here.

[3] Article 3(2)(d) of the Clinical Trials Directive requires: *"the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation"*. Similarly, paragraph 2.9 of the Good Clinical Practice Guidelines states that: *"Freely given informed consent should be obtained from every subject prior to clinical trial participation"*.

## 2. Compliance with legal obligations – *[Amendment 6]*

International companies, including life sciences companies, are increasingly subject to laws and legal obligations and voluntary codes of practice in countries outside the EU, many of which are to protect the rights and freedoms of individuals. For example, life sciences companies in performing clinical trials are required to comply with the Good Clinical Practice Guidelines, which is an international quality standard that is provided by the International Conference on Harmonisation (ICH).

Failure to comply with such requirements can lead to regulatory action and fines. The current EU Data Protection Directive also contains in Article 7(c) a legal ground for processing personal data where "the processing is necessary for compliance with a legal obligation to which the controller is subject". In an era of increased globalization, it is important that controllers and processors can comply with international legal requirements.

## 3. Right to be Forgotten - *[Amendment 7 and 8]*

While the proposed Regulation provides an exemption from the obligation to erase personal data for historical, statistical and scientific research purposes (Art 17(3) (c)), in practice it may not always be clear when this exemption applies. Would a clinical trial be considered "scientific research" for the purposes of Article 17(3)(c)?

Any ability for individuals to erase their personal data including their medical health records and invoking the right to be forgotten could have a significant impact on their safety, the validity of scientific findings in clinical trials and epidemiological studies.

Clinical trial subjects' motivation for withdrawal would normally be that they are non-responders to the trial drug, they are not happy with their progress or they have suffered a drug adverse event. However, all such data is necessary to properly and adequately analyze the risk benefit balance of the drug as well as its safety and efficacy.

Non-availability or limited availability of clinical trial data can potentially have significant safety repercussions including:

- Reporting of serious adverse events incidents may be based on missing or inaccurate data;
- The admission of necessary treatments, drugs or other medications to the market might be prevented or delayed;

- Submissions for regulatory approvals may be de-qualified, or regulatory approvals might be withdrawn; and

- Drugs already approved on available data might be withdrawn or recalled from the market.

Moreover, non-availability of data including patient medical records will result in an inability to locate patients and to **inform them on safety issues** discovered during the monitoring and verification process.

There is also an inconsistency as the Regulation provides that withdrawal of consent shall not affect the lawfulness of the processing based on consent before its withdrawal – Art 7(3) – but this seems to be overridden by the right to erase data under the Right to be Forgotten.

**4. Administrative Burden – Data Processors and Data Controllers - *[Amendments 9, 10, 11, 12, 13 and 14]***

Quintiles operates numerous clinical trials across the globe. Since 2011, **1.197.000 patients** were involved in clinical trials conducted by Quintiles in more than **88.000 sites** (*i.e.* hospitals, clinics etc). **Clinical trials can cost up to $100 million.** For example: - Phase I clinical trials - $250 K-$1.5 million - Phase II clinical trials - $2 million-$20 million - Phase III clinical trials - $20 million-$100 million.

The proposed text in Article 28 introduces a host of new requirements for data processors. Some of these additions increase administrative burdens and compliance costs, without improving privacy protection. For example:

- Both the data controller and the data processor are required to maintain documentation of all processing operations under its responsibility – Art 28(1)

- Both the data controller and the data processor are require to undertake an evaluation of risks – Art 28(2)

- The data controller and the data processor, acting on the controller's behalf, shall carry out a privacy impact assessment where the processing present specific risks – Art 33(1)

- The data controller and the data processor, acting on the controller's behalf, shall consult with the supervisory authority in relation to a data protection assessment – Art 34(1)

Specific risks include information on health, provisions of health care, epidemiological research or surveys where the data are processed "for taking measures or decisions regarding specific individuals on a **large scale**". Art 33(2) (b).

Duplicating these requirements on both data controllers and data processors is inefficient and **does not improve privacy protection** for the individual.

It should be possible to have a data protection impact assessment that covers all clinical trials unless a new clinical trial introduces a new specific risk.

Increased compliance costs and administrative burdens will most likely:

- Significantly extend the timetable of clinical trial studies which already can take circa 10+ years per compound; and
- **Prevent or delay the admission of necessary treatments**, drugs or other medications to European patients.

The requirement to consult with supervisory authorities on data protection impact assessments for Quintiles, which organises thousands of clinical trials for pharmaceutical companies, could also add very significant costs and administrative burdens. In addition, the requirement to consult with supervisory authorities appears contrary to the principle of accountability which is an important part of the proposed Regulation. Quintiles therefore proposes the deletion of the current requirements to obtain authorisation, consult and notify supervisory authorities.

The requirement to obtain the views of data subjects as part of a data protection impact assessment should be optional. It should not be mandatory because seeking and obtaining the views of data subjects may involve the controller in expending disproportionate effort, with the potential to increase administrative burdens for controllers without providing additional privacy protection for data subjects. Additionally, in the clinical trials context requiring the sponsor to seek the views of the data subjects / patients may be logistically difficult as they may not be able to locate them. Also in order to do so, the sponsor may be required to collect more data than necessary, thereby breaching the principle of data minimization.

**5. International Data Transfers - *[Amendments 15, 16, 17, 18, 19 and 20]***

Quintiles' operates globally with **14,000 drug development staff in 90 offices in about 60 countries.**

**Proposed EU Data Protection Regulation**
**Summary of Issues**

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Data transfers are currently effected internationally using a number of different legal mechanisms, including a US Safe Harbor certification, local country registrations and EU Standard contractual clauses. Quintiles has their data management centres in India, Kansas and South Africa. Clinical research associates and Biostatisticians necessary for the statistical review and analysis of the clinical data are located in multiple jurisdictions across the globe.

Under the proposed Regulation there will continue to be restrictions on transfers of personal data to countries outside the EEA which are not considered to provide an adequate level of protection. While the ability to make international transfers has been assisted with some provisions in the Regulation such as not having to get authorisation from supervisory authorities for such data transfers and the ability to adopt Binding Corporate Rules for processors there are still some issues:

(i) none of the solutions BCRs, Safe Harbor, EU Contractual Clauses provide a comprehensive solution for global companies such as Quintiles.

(ii) as a derogation transfers may be made for the purposes of legitimate interests pursued by a data controller or a data processor where an adequacy assessment has been made provided the transfer is **not "frequent or massive"** - Art 44(1)(h). It is not clear why this derogation cannot be used for large data transfers particularly for a company such as Quintiles that has strict requirements in place to protect the data such as those recommended under the Good Clinical Practice Guidelines.

(iii) one of the factors that should be taken into account with adequacy assessment under Article 44(1)(h) is the fact that the data being transferred is invariably key coded and used for limited purposes such as medical research and clinical trials.

FAQ 14-7 of the Safe Harbor Scheme recognises that key coded data should be treated differently providing that key coded data sent by a researcher in the EU to a pharmaceutical company in the US would not constitute a transfer where the US pharmaceutical company only receives key coded data and is not aware of the identity of the patients which will only be known to the researcher in the EU.

In addition, the proposed Regulation fails to take into account that many international data transfers conducted by life sciences companies are required for public health reasons, including for example providing information to health authorities outside the EU or in order to establish global safety databases. This should therefore be reflected in the derogations provided for in Article 44(1), particularly since the data transferred is invariably key coded and used for limited purposes such as medical research and clinical trials.

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# DRAFT AMENDMENTS TO PROPOSED EU DATA PROTECTION REGULATION

**Amendment 1 - [It needs to be acknowledged that some Union and Member States laws already require consent]**

**Proposal for a regulation**
**Recital 31**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 31. In order for processing to be lawful, personal data should be processed on the basis of the consent of the person concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or Member State law as referred to in this Regulation. | 31. In order for processing to be lawful, personal data should be processed on the basis of the consent of the person concerned, ***including where consent is explicitly required by Union or Member State law, or on*** some other legitimate basis, laid down by law, either in this Regulation or in other Union or Member State law as referred to in this Regulation. |

Or. en

*Justification*

*The Clinical Trials Directive specifically requires the informed consent of clinical trial subjects. Therefore it is important that the proposed Regulation recognises that controllers can rely on consent as a legal basis to process personal data in a clinical trial.*

**Amendment 2 - [It should be made clear that consent does provide a valid legal ground for clinical trials]**

**Proposal for a regulation**
**Recital 33**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 33. In order to ensure free consent, it should be clarified that consent does not provide a valid legal ground where the individual has no genuine and free choice and is subsequently not able to refuse to withdraw consent without detriment. | *Deleted* |

*Justification*

*The proposed requirement causes great uncertainty with respect to clinical trials. Arguably, there is an inherent imbalance between the position of the individual patient participating in a trial and ultimately the company conducting it. This implies that the validity of the consent may be questioned at any time thus potentially invalidating the patient's participation in the clinical trial. If the validity of subject consent in a clinical trial (where consent is required) is unreliable, then this may risk non compliance with the Good Clinical Practice Guidelines and bring these Regulations into conflict with those requirements. It is therefore important to specify that the significant imbalance requirement is limited to specific scenarios, such as in the employment context or where the controller is a public authority (see amendments 4 and 5).*

**Amendment 3 - [It should be made clear that invalidity of consent for significant imbalance does not apply to clinical trials]**

**Proposal for a regulation**
**Recital 34**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 34. Consent should not provide a valid legal ground for the processing of personal data, where there is a clear imbalance between the data subject and the controller. ***This is especially the case where the data subject is in a situation of dependence from the controller, among others, where personal data are processed by the employer of employees' personal data in the employment context. Where the controller is a public authority, there would be an imbalance only in the specific data processing operations where the public authority can impose an obligation by virtue of its relevant public powers and the consent cannot be deemed as freely given, taking into account the interest of the data subject.*** | 34. ***In the employment context,*** consent should not provide a valid legal ground for the processing of personal data, where there is a clear imbalance between the data subject and the controller. |

*Justification*

*The proposed requirement causes great uncertainty with respect to clinical trials. Arguably, there is an inherent imbalance between the position of the individual patient participating in a trial and ultimately the company conducting it. This implies that the validity of the consent may be questioned at any time thus potentially invalidating the patient's participation in the clinical trial. If the validity of subject consent in a clinical trial (where consent is required) is unreliable, then this may risk non compliance with the Good Clinical Practice Guidelines and bring these Regulations into conflict with those requirements. It is therefore important to specify that the significant imbalance requirement is limited to specific scenarios, such as in the employment context or where the controller is a public authority (see amendments 4 and 5).*

**Amendment 4 - [It should be made clear that invalidity of consent for significant imbalance does not apply to clinical trials]**

**Proposal for a regulation**
**Recital 35 a new**

| *Text proposed by the Commission* | *Amendment* |
| --- | --- |
| | ***35 a (new). Where the controller is a public authority, there would be an imbalance only in the specific data processing operations where the public authority can impose an obligation by virtue of its relevant public powers and the consent cannot be deemed as freely given, taking into account the interest of the data subject.*** |

Or. en

*Justification*

*The wording in the current Recital on the application of significant imbalance to public authorities should be included in a new Recital to distinguish it from the significant imbalance in the employment context.*

**Amendment 5 - [It should be made clear that invalidity of consent for significant imbalance does not apply to clinical trials]**

**Proposal for a regulation**
**Article 7 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. Consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller. | 4. ***In the employment context,*** consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller. |

Or. en

*Justification*

*The proposed requirement causes great uncertainty with respect to clinical trials. Arguably, there is an inherent imbalance between the position of the individual patient participating in a trial and ultimately the company conducting it. This implies that the validity of the consent may be questioned at any time thus potentially invalidating the patient's participation in the clinical trial. If the validity of subject consent in a clinical trial (where consent is required) is unreliable, then this may risk non compliance with the Good Clinical Practice Guidelines and bring these Regulations into conflict with those requirements. It is therefore important to specify that the significant imbalance requirement is limited to specific scenarios, such as in the employment context or where the controller is a public authority (see amendment 4).*

**Amendment 6 - [Compliance with legal obligations]**

**Proposal for a regulation**
**Article 6 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The basis of the processing referred to in points (c) and (e) of paragraph 1 must be provided for in:<br>(a) Union law, or<br>(b) the law of the Member State to which the controller is subject.<br><br>The law of the Member State must meet an objective of public interest or must be necessary to protect the rights and freedoms of others, respect the essence of the right to protection of personal data and be proportionate to the legitimate aim pursued. | 3. The basis of the processing referred to in points (c) and (e) of paragraph 1 must be provided for in:<br>(a) Union law, or<br>(b) the law of the Member State to which the controller is subject, ***or***<br>***(c) law or a legal obligation of a third country that the controller or processor may be subject to.***<br><br>The law of the Member State, ***and the law or a legal obligation in a third country that the controller or processor may be subject to,*** must meet an objective of public interest or must be necessary to protect the rights and freedoms of others, respect the essence of the right to protection of personal data and be proportionate to the legitimate aim pursued. |

Or. en

*Justification*

*Many international companies are subject to laws, legal obligations and voluntary codes of practice in countries outside the EU, including life sciences companies that are required to comply with the Good Clinical Practice Guidelines when performing clinical trials. The Good Clinical Practice Guidelines is an international quality standard that is provided by the International Conference on Harmonisation (ICH). Failure to comply with such laws, legal obligations and codes can lead to regulatory action and fines. The current EU Data Protection Directive also contains in Article 7(c) a legal ground for processing personal data where "the processing is necessary for compliance with a legal obligation to which the controller is subject". In an era of increased globalization it is important that controllers and processors can comply with international legal requirements.*

**Amendment 7 - [The Right to be Forgotten in Article 17 should not apply to pharmacovigilance and clinical trials]**

**Proposal for a regulation**
**Recital 53**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 53. Any person should have the right to have personal data concerning them rectified and a 'right to be forgotten' where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for reasons of public interest in the area of public health, for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. | 53. Any person should have the right to have personal data concerning them rectified and a 'right to be forgotten' where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, ***including clinical trials, epidemiological studies and medical research***, for reasons of public interest in the area of public health, ***including to ensure high standards and quality and safety, inter alia, for medical treatment, medical products and medical devices,*** for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. |

Or. en

*Justification*

*It is important to clarify that clinical trials are considered as "scientific research" for the purposes of Article 17(3)(c).*

**Amendment 8 - [The Right to be Forgotten in Article 17 should not apply to pharmacovigilance and clinical trials]**

**Proposal for a regulation**
**Article 17 – paragraph 3 – point c**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The controller shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary:<br>(a) for exercising the right of freedom of expression in accordance with Article 80;<br>(b) for reasons of public interest in the area of public health in accordance with Article 81;<br>(c) for historical, statistical and scientific research purposes in accordance with Article 83;<br>(d) for compliance with a legal obligation to retain the personal data by Union or Member State law to which the controller is subject; Member State laws shall meet an objective of public interest, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued;<br>(e) in the cases referred to in paragraph 4. | 3. The controller shall carry out the erasure without delay, except **where** the retention of the personal data is necessary:<br>(a) for exercising the right of freedom of expression in accordance with Article 80;<br>(b) for reasons of public interest in the area of public health, ***including to ensure high standards and quality and safety, for medical treatment, medical products and medical devices,*** in accordance with Article 81;<br>(c) for historical, statistical and scientific research purposes, ***including clinical trials, epidemiological studies and medical research***, in accordance with Article 83;<br>(d) for compliance with a legal obligation to retain the personal data by Union, Member State law **or the law of a third country,** to which the controller is subject; Member State **and third country** laws shall meet an objective of public interest, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued;<br>(e) in the cases referred to in paragraph 4. |

Or. en

*Justification*

*It is important to clarify that clinical trials are considered as "scientific research" for the purposes of Article 17(3) (c). Also it is important to take into account that a controller subject to a third country's law might be required to retain personal data in order to comply with local legal requirements, i.e. with respect to the reporting of adverse events.*

**Amendment 9 - [The obligation to keep detailed documentation should only apply to the data controller and not also the data processor]**

**Proposal for a regulation**
**Recital 65**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 65. In order to demonstrate compliance with this Regulation, the controller ***or processor*** should document each processing operation. Each controller ***and processor*** should be obliged to co-operate with the supervisory authority and make this documentation, on request, available to it, so that it might serve for monitoring those processing operations. | 65. In order to demonstrate compliance with this Regulation, the controller should document each processing operation. Each controller should be obliged to co-operate with the supervisory authority and make this documentation, on request, available to it, so that it might serve for monitoring those processing operations. |

Or. en

*Justification*

*The proposed Regulation introduces a host of new requirements for data processors. Some of these additions increase administrative burdens and compliance costs, without improving privacy protection. Duplicating these requirements on both data controllers and data processors is inefficient and does not improve privacy protection for the individual.*

**Amendment 10 - [The obligation to keep detailed documentation should only apply to the data controller and not also the data processor and deletion of delegated act]**

**Proposal for a regulation**
**Article 28**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Each controller ***and processor*** and, if any, the controller's representative, shall maintain documentation of all processing operations under its responsibility. | 1. Each controller and, if any, the controller's representative, shall maintain documentation of all processing operations under its responsibility. |
| 2. The documentation shall contain at least the following information: | 2. The documentation shall contain at least the following information: |
| (a) the name and contact details of the controller, or any joint controller or processor, and of the representative, if any; | (a) the name and contact details of the controller, or any joint controller or processor, and of the representative, if any; |
| (b) the name and contact details of the data protection officer, if any; | (b) the name and contact details of the data protection officer, if any; |
| (c) the purposes of the processing, including the legitimate interests pursued by the controller where the processing is based on point (f) of Article 6(1); | (c) the purposes of the processing, including the legitimate interests pursued by the controller where the processing is based on point (f) of Article 6(1); |
| (d) a description of categories of data subjects and of the categories of personal data relating to them; | (d) a description of categories of data subjects and of the categories of personal data relating to them; |
| (e) the recipients or categories of recipients of the personal data, including the controllers to whom personal data are disclosed for the legitimate interest pursued by them; | (e) the recipients or categories of recipients of the personal data, including the controllers ***and processors*** to whom personal data are disclosed for the legitimate interest pursued by them; |
| (f) where applicable, transfers of data to a third country or an international organisation, including the identification of that third country or international organisation and, in case of transfers referred to in point (h) of Article 44(1), the documentation of appropriate safeguards; | (f) where applicable, transfers of data to a third country or an international organisation, including the identification of that third country or international organisation and, in case of transfers referred to in point (h) of Article 44(1), the documentation of appropriate safeguards; |
| (g) a general indication of the time limits for erasure of the different categories of data; | (g) a general indication of the time limits for erasure of the different categories of data; |
| (h) the description of the mechanisms referred to in Article 22(3). | (h) the description of the mechanisms referred to in Article 22(3). |
| 3. The controller ***and the processor*** and, if any, the controller's representative, shall make the documentation available, on request, to the supervisory authority. | 3. The controller and, if any, the controller's representative, shall make the documentation available, on request, to the supervisory authority. |
| 4. The obligations referred to in paragraphs 1 | 4. The obligations referred to in paragraphs 1 |

| | |
|---|---|
| and 2 shall not apply to the following controllers ***and processors***:<br>(a) a natural person processing personal data without a commercial interest; or<br>(b) an enterprise or an organisation employing fewer than 250 persons that is processing personal data only as an activity ancillary to its main activities. | and 2 shall not apply to the following controllers:<br>(a) a natural person processing personal data without a commercial interest; or<br>(b) an enterprise or an organisation employing fewer than 250 persons that is processing personal data only as an activity ancillary to its main activities. |
| ***5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the documentation referred to in paragraph 1, to take account of in particular the responsibilities of the controller and the processor and, if any, the controller's representative.*** | ***5 (new).*** The Commission may lay down standard forms for the documentation referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2). |
| 6. The Commission may lay down standard forms for the documentation referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2). | |

Or. en

*Justification*

*The proposed Regulation introduces a host of new requirements for data processors. Some of these additions are already required by existing Union or Member State laws (e.g. the Clinical Trials Directive and related guidance documents) thereby increasing administrative burdens and compliance costs, without improving privacy protection. Duplicating these requirements on both data controllers and data processors is inefficient and does not improve privacy protection for the individual. It is also not necessary for the Commission to adopt a delegated act on what documentation must be retained.*

**Amendment 11 - [A data protection impact assessment should cover all clinical trials and not be required for each new clinical trial]**

**Proposal for a regulation**
**Recital 71**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 71. This should in particular apply to newly established large scale filing systems, which aim at processing a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects. | 71. This should in particular apply, ***on a one-off basis***, to newly established large scale filing systems, which aim at processing a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects. ***Where the data processor's professional activity is to conduct similar or identical processing operations, which present specific risks to the rights and freedoms of data subjects, a single data protection impact assessment shall be carried out, unless new specific risks to the rights and freedoms of data subjects are introduced.*** |

Or. en

*Justification*

*The requirement to conduct individual data protection impact assessments for Quintiles, which organises thousands of clinical trials for pharmaceutical companies, could add very significant cost and administrative burdens without additional privacy protection. It should be possible to have a single data protection impact assessment that covers all clinical trials unless a new clinical trial introduces a new specific risk.*

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**Amendment 12 - [A data protection impact assessment should cover all clinical trials and not be required for each new clinical trial]**

**Proposal for a regulation**
**Article 33 – paragraph 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | 3 a (new). ***Where the data processor's professional activity is to conduct similar or identical processing operations, which present specific risks to the rights and freedoms of data subjects pursuant to paragraph 2, a single data protection impact assessment shall be carried out, unless new specific risks to the rights and freedoms of data subjects are introduced.*** |

Or. en

*Justification*

*The requirement to conduct individual data protection impact assessments for Quintiles, which organises thousands of clinical trials for pharmaceutical companies, could add very significant cost and administrative burdens without additional privacy protection. It should be possible to have a single data protection impact assessment that covers all clinical trials unless a new clinical trial introduces a new specific risk.*

**Amendment 13 - [It should be optional whether to obtain the views of data subjects as part of a data protection impact assessment]**

**Proposal for a regulation**
**Article 33 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. The controller ***shall*** seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of the processing operations. | 4. The controller ***may*** seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of the processing operations. |

Or. en

*Justification*

*Obtaining the views of data subjects as part of a data protection impact assessment should be optional. It should not be mandatory because seeking and obtaining the views of data subjects may involve the controller in expending disproportionate effort, with the potential to increase administrative burdens for controllers without providing additional privacy protection for data subjects. Additionally, in the clinical trials' context requiring the sponsor to seek the views of the data subjects / patients may be logistically difficult as they may not be able to locate them. Also in order to do so, the sponsor may be required to collect more data than necessary, thereby breaching the principle of data minimization.*

**Amendment 14 – [The obligation to consult and obtain authorization from each supervisory authority is contrary to the accountability concept]**

**Proposal for a regulation**
**Article 34 – paragraph 1-9**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The controller or the processor as the case may be shall obtain an authorisation from the supervisory authority prior to the processing of personal data, in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for the data subjects where a controller or processor adopts contractual clauses as provided for in point (d) of Article 42(2) or does not provide for the appropriate safeguards in a legally binding instrument as referred to in Article 42(5) for the transfer of personal data to a third country or an international organisation. | ***deleted*** |
| 2. The controller or processor acting on the controller's behalf shall consult the supervisory authority prior to the processing of personal data in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for the data subjects where: | |
| (a) a data protection impact assessment as provided for in Article 33 indicates that processing operations are by virtue of their nature, their scope or their purposes, likely to present a high degree of specific risks; or | |
| (b) the supervisory authority deems it necessary to carry out a prior consultation on processing operations that are likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope and/or their purposes, and specified according to paragraph 4. | |

3. Where the supervisory authority is of the opinion that the intended processing does not comply with this Regulation, in particular where risks are insufficiently identified or mitigated, it shall prohibit the intended processing and make appropriate proposals to remedy such incompliance.

4. The supervisory authority shall establish and make public a list of the processing operations which are subject to prior consultation pursuant to point (b) of paragraph 2. The supervisory authority shall communicate those lists to the European Data Protection Board.

5. Where the list provided for in paragraph 4 involves processing activities which are related to the offering of goods or services to data subjects in several Member States, or to the monitoring of their behaviour, or may substantially affect the free movement of personal data within the Union, the supervisory authority shall apply the consistency mechanism referred to in Article 57 prior to the adoption of the list.

6. The controller or processor shall provide the supervisory authority with the data protection impact assessment provided for in Article 33 and, on request, with any other information to allow the supervisory authority to make an assessment of the compliance of the processing and in particular of the risks for the protection of personal data of the data subject and of the related safeguards.

7. Member States shall consult the supervisory authority in the preparation of a legislative measure to be adopted by the national parliament or of a measure based on such a legislative measure, which defines the nature of the processing, in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for

the data subjects.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for determining the high degree of specific risk referred to in point (a) of paragraph 2.

9. The Commission may set out standard forms and procedures for prior authorisations and consultations referred to in paragraphs 1 and 2, and standard forms and procedures for informing the supervisory authorities pursuant to paragraph 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

*Or. en*

*Justification*

*The requirement to obtain an authorisation from supervisory authorities for all data protection impact assessments for Quintiles, which organises thousands of clinical trials for pharmaceutical companies, could add very significant cost and administrative burdens and adds no additional privacy protection. The requirements to consult with each supervisory authority is also contrary to the concept of accountability which is introduced by the Regulation and which removes the need to make data protection notifications to existing DPAs.*

**Amendment 15 - [The Regulation should permit data transfers from the EU where required in the area of public health *e.g.* global safety databases]**

**Proposal for a regulation**
**Recital 86**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 86. Provisions should be made for the possibility for transfers in certain circumstances where the data subject has given his consent, where the transfer is necessary in relation to a contract or a legal claim, where important grounds of public interest laid down by Union or Member State law so require or where the transfer is made from a register established by law and intended for consultation by the public or persons having a legitimate interest. In this latter case such a transfer should not involve the entirety of the data or entire categories of the data contained in the register and, when the register is intended for consultation by persons having a legitimate interest, the transfer should be made only at the request of those persons or if they are to be the recipients. | 86. Provisions should be made for the possibility for transfers in certain circumstances where the data subject has given his consent, where the transfer is necessary in relation to a contract or a legal claim, where important grounds of public interest, ***including in the area of public health***, laid down by Union or Member State law so require or where the transfer is made from a register established by law and intended for consultation by the public or persons having a legitimate interest. In this latter case such a transfer should not involve the entirety of the data or entire categories of the data contained in the register and, when the register is intended for consultation by persons having a legitimate interest, the transfer should be made only at the request of those persons or if they are to be the recipients |

Or. en

*Justification*

*It is important to clarify that the "important grounds of public interest" also cover public health, including pharmacovigilance.*

**Amendment 16 - [The Regulation should permit data transfers from the EU where required in the area of public health *e.g.* global safety databases]**

**Proposal for a regulation**
**Recital 87**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 87. These derogations should in particular apply to data transfers required and necessary for the protection of important grounds of public interest, for example in cases of international data transfers between competition authorities, tax or customs administrations, financial supervisory authorities, between services competent for social security matters, ***or*** to competent authorities for the prevention, investigation, detection and prosecution of criminal offences. | 87. These derogations should in particular apply to data transfers required and necessary for the protection of important grounds of public interest, for example in cases of international data transfers between competition authorities, tax or customs administrations, financial supervisory authorities, between services competent for social security matters, to competent authorities for the prevention, investigation, detection and prosecution of criminal offences, ***for public health reasons, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia, for medical treatment, medical products and medical devices***. |

Or. en

*Justification*

*It is important to clarify that the "important grounds of public interest" also cover public health, including pharmacovigilance.*

**STRICTLY PRIVATE & CONFIDENTIAL**

**Amendment 17 - [The Regulation should permit data transfers from the EU where required in the area of public health *e.g.* global safety databases]**

**Proposal for a regulation**
**Article 44 – paragraph 1 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) the transfer is necessary for important grounds of public interest; or | (d) the transfer is necessary for important grounds of public interest, including ***public health reasons, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia, for medical treatment, medical products and medical devices***, or; |

Or. en

*Justification*

*It is important to clarify that the "important grounds of public interest" also cover public health, including pharmacovigilance.*

**Amendment 18 - [The Regulation should permit data transfers from the EU where required in the area of public health *e.g.* global safety databases]**

**Proposal for a regulation**
**Recital 88**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 88. ***Transfers which cannot be qualified as frequent or massive, could*** also be possible for the purposes of the legitimate interests pursued by the controller or the processor, when they have assessed all the circumstances surrounding the data transfer. For the purposes of processing for historical, statistical and scientific research purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration. | 88. ***Transfers should*** also be possible for the purposes of the legitimate interests, ***including the protection of public health, to ensure high standards and quality and safety, inter alia, for medical treatment, medical products and medical devices,*** pursued by the controller or the processor, when they have assessed all the circumstances surrounding the data transfer. For the purposes of processing for historical, statistical and scientific research purposes, ***including medical research, epidemiological studies and clinical trials***, the legitimate expectations of society for an increase of knowledge should be taken into consideration. |

Or. en

*Justification*

*It is important to clarify that the concept of "legitimate interests" and "legitimate expectations of society for an increase of knowledge" also covers public health, including the conduct of clinical trials.*

**Amendment 19 - [The Regulation should permit data transfers from the EU where required in order to comply with EU law or law in a Member State]**

**Proposal for a regulation**
**Article 44 – paragraph 1 – point gg (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***gg (new). the transfer is necessary for compliance with a legal obligation to which the controller or data processor is subject to, provided in Union or Member State or national law; or*** |

Or. en

*Justification*

*It is important to clarify that international data transfers are permitted where necessary to comply with legal obligations under Union or Member State or national law.*

**Amendment 20 - [The derogation for data transfers from the EU where an adequacy assessment has been made should not exclude transfers which are "frequent or massive".]**

**Proposal for a regulation**
**Article 44 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. In the absence of an adequacy decision pursuant to Article 41 or of appropriate safeguards pursuant to Article 42, a transfer or a set of transfers of personal data to a third country or an international organisation may take place only on condition that:<br>(a) the data subject has consented to the proposed transfer, after having been informed of the risks of such transfers due to the absence of an adequacy decision and appropriate safeguards; or<br>(b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request; or<br>(c) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person; or<br>(d) the transfer is necessary for important grounds of public interest; or<br>(e) the transfer is necessary for the establishment, exercise or defence of legal claims; or<br>(f) the transfer is necessary in order to protect the vital interests of the data subject or of another person, where the data subject is physically or legally incapable of giving consent; or<br>(g) the transfer is made from a register which according to Union or Member State law is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, to the extent that the conditions laid down in Union or Member State law for consultation are fulfilled in the particular case; or | 1. In the absence of an adequacy decision pursuant to Article 41 or of appropriate safeguards pursuant to Article 42, a transfer or a set of transfers of personal data to a third country or an international organisation may take place only on condition that:<br>(a) the data subject has consented to the proposed transfer, after having been informed of the risks of such transfers due to the absence of an adequacy decision and appropriate safeguards; or<br>(b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request; or<br>(c) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person; or<br>(d) the transfer is necessary for important grounds of public interest; or<br>(e) the transfer is necessary for the establishment, exercise or defence of legal claims; or<br>(f) the transfer is necessary in order to protect the vital interests of the data subject or of another person, where the data subject is physically or legally incapable of giving consent; or<br>(g) the transfer is made from a register which according to Union or Member State law is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, to the extent that the conditions laid down in Union or Member State law for consultation are fulfilled in the particular case; or |

| | |
|---|---|
| (h) the transfer is necessary for the purposes of the legitimate interests pursued by the controller or the processor, ***which cannot be qualified as frequent or massive, and*** where the controller or processor has assessed all the circumstances surrounding the data transfer operation or the set of data transfer operations and based on this assessment adduced appropriate safeguards with respect to the protection of personal data, where necessary. | (h) the transfer is necessary for the purposes of the legitimate interests pursued by the controller or the processor, where the controller or processor has assessed all the circumstances surrounding the data transfer operation or the set of data transfer operations and based on this assessment adduced appropriate safeguards with respect to the protection of personal data, where necessary. |

Or. en

*Justification*

*By prohibiting transfers that are "frequent or massive", the derogation is unlikely to benefit providers that operate globally and transfer data almost on a daily basis. In a clinical trial setting, strict requirements are already in place to protect data subjects, such as those required under the Clinical Trials Directive and the Good Clinical Practice Guidelines including the pseudonymisation of the data. It is also unclear what is meant by "frequent or massive". In addition, excluding such transfers is contrary to the concept of accountability in the Regulation where data controllers take responsibility for compliance i.e. ensuring the adequacy assessment is legitimate.*

# Information sheet and consent form

**Study title:** <Study Title [verbatim as per protocol, with any acronyms spelled out]>

**Study protocol:** <Protocol Name and/or Number [verbatim as per protocol]>

**Study drug:** <drug name> referred throughout the document as the study drug

**Sponsor of the study:** <Sponsor Name>

**Investigator:** <Investigator's Name>

**Introduction**

You are invited to take part in a clinical research study. To help you decide, you should understand the study and what it will involve for you. To make an informed decision to take part – you should know the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

It cannot be promised the study will help you but in the future the information we get from this study may help improve the future treatment of people with the same condition.

Once you have decided if you want to take part, you will be asked to sign the informed consent form. You will have a copy of the signed form to keep, and the original will stay at the study centre.

<Around X subjects in X study centres in X countries will take part in this study.>

**What is the purpose of the study?**

< A summary of the purpose of study><Give the phase of the study and explain what that means.> <If possible, state evidence from other studies regarding the effectiveness of the study drug/treatment or procedure being investigated.> <If different subjects in the study are to receive different treatment schedules, a brief overview of what each subject group will receive should be provided.>

Optional generic text around the general purpose of Clinical Trials, only if required by regulatory body or Sponsor: *"A clinical trial is an investigation in humans of a medical treatment that is designed to discover or verify whether the treatment is effective and safe"*

**What medication is being tested?**

<Include a short description of the study drug/treatment>< Add the drug is an investigational product, and if already commercialized, who and where is it approved for use ><Add a sentence in lay terms on why/how the drug/treatment is efficacious if applicable in the study population.> <You should, when appropriate, state the dosage of the drug/treatment and method of administration.> <Details are needed of any contraindicated drugs, including over-the-counter drugs.>

**Why have you been invited?**

<Explain briefly why and how the participant was chosen, i.e. their suitability and eligibility for the study.>

**What will happen to you during the study?**

<Describe all study specific procedures, identifying any procedures which are experimental.> <Ensure that there is detailed reference to the planned number of visits, how long these visits will be and all planned examinations and tests.> <Enter reference to study design (i.e. placebo [definition - i.e. "A placebo is a 'dummy treatment', which looks like the genuine medicine but contains no active ingredient"] double blind [definition - i.e.: neither you nor your study doctor will know in which treatment group you are (although, if your study doctor needs to find out he/she can do so)], randomisation process [definition - i.e.: Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance. The randomisation method is set up so that you have a X in X chance of receiving study drug/treatment and a X in X chance of receiving placebo/comparator drug; therefore, you have a X times greater chance of receiving study drug/treatment than receiving placebo/comparator drug as your treatment], study drug/treatment regimen, duration of treatment, duration of the research study and follow-up, if relevant, etc), including explanations for what 'blinding' and/or 'randomisation' means. You should tell the subjects what chance they have of getting the study drug/treatment>

<Explanation of study drug(s)/treatment(s)>
<If applicable, enter flowchart or table with visit schedule>

<Study procedures for all study participants :>
<List all study specific key procedures that apply to all study participants e.g. medical history, current health status, activities status (e.g. work, social, travel), blood sampling (total amount of blood in ml and teaspoon)[ Conversion of mL to teaspoons: 1 milliliter = 0.2 Teaspoon [metric].], electrocardiogram (ECG) [definition - i.e.: This is a test that looks at the electrical activity of your heart by putting small sticky patches on certain areas of your body while you are lying down. These patches have small wires that connect to a machine which will read and print a report. The test takes about 5 minutes.and for any other procedure] which will be assessed during the study.>

<List all planned physical examinations and the procedures which they comprise (e.g. measuring of body temperature, pulse rate and blood pressure, laboratory measurements).>

<List all diaries and/or questionnaires that will have to be completed by the subjects during the study and give an estimation of the time needed to complete these.>

<Treatment-arm specific study procedures for participants :>

<Enter all information regarding specific procedures or treatments which only apply to certain treatment groups of subjects.>

**Expenses and payment**

There will be no cost to you for taking part in this study. You will be provided with all study drugs, examinations and medical care related to the study at no cost to you.

<A simple sentence explaining that the subject (and carer, if applicable) will be reimbursed for their travel and parking (if Sponsor is offering this reimbursement), if applicable >
<If subject will be paid for their participation, include explanation here and amount. If not, state that the subject will not be paid for participating.> <Please note that any form of payment to the participant must be justified e.g. compensation for loss of earnings, for the cost of a meal or for childcare. The Research Ethics Committee will review how ethical such payments are.>

**What will you have to do?**

- You will have to go to the study visits, follow the instructions the doctors give you and take the study drug as directed.
- You must not take part in any other studies while you are taking part in this study.
- If applicable: <Please do not give blood for non-study purposes, unless medically required, while you are taking part in this study or for X days/weeks after you have finished. >

<Explain (if appropriate) that the participants should take the study drug/treatment regularly as directed and whether they can continue to take their regular drug/treatment or other prescribed or over the counter drugs.><Any lifestyle, medical health product or dietary restrictions should be stated.> <Explain other essential study requirements, e.g. keeping diaries, completing questionnaires, etc., and remind the participant that he/she should return all unused study treatment as well as any relief medication (if applicable) to the study centre at the next visit etc>

**What will happen to any samples you give?**

Your samples may be kept for research purposes for several years after the end of the study. For carrying out any new analysis on the samples not connected to this study, your permission will be required – you will be asked to sign a new consent form to allow further use of the samples. You have the right to refuse.

Samples will be used to <insert details>. In addition, may also require following info:

<The location [with exact address only for countries where it is required] where the samples will be shipped to, analysed and stored and the period of storage (this period should be as for essential documents)

To whom the data and samples are accessible [Note that if samples are being stored in the UK, the Human Tissue Act comes into effect].

Procedure for handling any retained identifiable samples, including intended use in the future for research that cannot yet be specified.

Plans to anonymise or destroy samples after analysis.

Handling of samples and data after withdrawal of the consent>

**What alternative treatments are available?**

Taking part in this study is voluntary – you do not have to take part to be treated for your condition. Your study doctor will discuss with you any other treatments or investigational drugs or treatments that may be available, and will also discuss their risks and benefits. If you decide not to take part in this study it will not affect your ability to receive medical care.

**What could be the side effects of the study drug?**

<Enter all information regarding expected risks and discomforts ("side effects"/adverse events) for study drug/treatment and/or comparator medication (in terms the subjects will clearly understand), including seriousness, severity and frequency (include an example of frequency, which a subjects will clearly understand).>
The level of detail should be influenced by the expected benefit from the drug/treatment and the underlying prognosis of the condition.

*If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately* (see 'Who should you contact for more information?').

Any side effects or other health issues occurring during the study will be followed up by the study doctor.

**What are the possible disadvantages or risks of taking part?**

It is possible that the symptoms of your condition will not improve during the study or may even worsen. Treatment with this study drug may also involve risks to your future health that we currently don't know about.

<Include reference to risks and discomforts of scheduled procedures (e.g. ECG [i.e. some areas where the electrodes will be placed may need to be shaved; the test is painless], X-Ray [i.e. The radiation exposure is equivalent to approximately 10 of days natural background radiation exposure], blood draw [i.e. May cause discomfort, bruising and very rarely infection at the site where the skin is punctured by the needle. You may also experience dizziness, nausea or fainting during blood taking. Please tell the study doctor or study staff if you do not feel well after having your blood drawn.] and possible risk of drowsiness (e.g. don't drive, etc), if applicable. Also, include any inconveniences, e.g. overnight stays or fasting for any length of time.> <Add risk or receiving placebo (if placebo controlled), washout (if applicable) and any invasive procedures such as drawing of blood must be listed.>

Harm to the unborn child *Complete this section carefully, in certain circumstances it would be deemed to be inappropriate*

For women: Currently we are not fully aware of the effects of the study drug on unborn babies, or pregnant or breastfeeding women. If you are pregnant, or may become pregnant, treatment with the study drug may lead to new, previously unknown, side effects that we currently don't know about and this may involve risks to you or your unborn baby. Because of this, women who can have children <insert appropriate text: "are not allowed to take part in this study" OR "will be asked to take a pregnancy test, at the start of the study>. You must be using an effective form of birth control before you start the study drug and while you are taking part in the study. You must also agree to continue to use an effective form of birth control for X months after taking the study drug. Effective birth control includes birth control pills, intrauterine devices (IUDs), condoms, sponges, diaphragms with spermicide, or just avoiding sexual activity that could cause you to become pregnant." <Sponsor and/or protocol may require double-barrier birth control. If so, insert "You will be asked to use condoms as well as any other method of birth control during this study">.

If you become pregnant during the study or within X months of you stopping the study drug or treatment, you should immediately tell the study doctor. <Make special reference to the effects of the study drug/treatment on the unborn child or the pregnant woman. Make reference that treatment with a new substance may lead to the occurrence of new, previously unknown side effects/adverse events, which are currently unforeseeable and may involve risks to the subject (or to the unborn child, if the subject is or may become pregnant).>
For men: We do not know if the study drug will affect sperm or semen so you should not father a child during this study or for X months after treatment. If your partner might become pregnant, you must use effective, reliable forms of birth control during the study and for X months afterwards. Effective birth control includes birth control pills, intrauterine devices (IUDs), condoms, sponges, diaphragms with spermicide, or just avoiding sexual activity that could cause your female partner to become pregnant." <Sponsor and/or protocol may require specific birth control – specify

If your partner becomes pregnant during the study or within X months of your stopping the study drug or treatment, you should immediately report the pregnancy to the study doctor.

In case of pregnancy of female patient and/or partner: <Information must be provided about follow-up in the event of pregnancy.><If pregnancy will be followed, it should be stated that the subject's partner will be asked to give information about her pregnancy.>

**What are the possible benefits of taking part in this study?**

<Enter information regarding possible benefits for the subjects (e.g. any interim illnesses will be treated at no charge to you). Add statement that there is no guarantee that subject will receive a medical benefit from participating in this study. If no benefits are expected, this should be stated along with: 'The information we get from this study may help us in the future to treat people with [disease] better'.>

<Enter information about possible extension studies or if subjects, once they have completed the study participation, need to return to usual care (see also "What alternative treatments are available?").>

**What happens when the research study stops?**

During the study you will receive the study medication or treatment free of charge. The study drug or treatment may not be available as a prescription paid for by the health care system immediately after the end of the study. There is no guarantee that you will continue to receive this particular drug or treatment when you have finished taking part in the study. The care you receive after the study has ended may involve a different drug or treatment, which the hospital, together with your study doctor, considers to be the most suitable alternative.

<It must be clear whether the subject will have continued access to any benefits they may have obtained during the research study. If the study drug/treatment will not be available after the research finishes, this should be explained to the participant with information on what treatment will be available instead.>

If you have a reaction to the study drug, your participation may be stopped at any time by the study doctor or sponsor without your consent.

If the study is stopped, you will be told and your study doctor will make arrangements for continuation of your care.

**What if you have a question?**

If you have a question, concern or complaint about any part of this study, you should ask to speak to the study doctor or a member of the research team, who will do their best to help (see 'Who should you contact for more information?').

If you have any questions about your rights as part of the research, or any concerns or complaints about the research that you do not want to discuss with the study doctor or research team, see 'Who should you contact for more information?'.

If you suffer a serious illness or injury during this study, please contact your study doctor immediately (see 'Who should you contact for more information?').

**Compensation for study related injury**

Any compensation payable for any injury caused to you by taking part in this study will be in line with local guidelines. The Sponsor will pay for the cost of medical treatment for any injury that is directly due to treatment with the study drug or study procedure (that has been used as described in the study protocol). The Sponsor will not compensate you where the injury has happened because a procedure has been carried out that is not in line with the study protocol or where the study doctor has acted negligently.

The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from your taking the study drug, provided such personal injury is not due to fault or negligence of the study doctor or his team.

If you have medical insurance please check with your insurance company that taking part in this study will not affect your policy.

**What if new information about the study drug becomes available?**

Sometimes new information about the study drug is received. You will be told if any relevant new information becomes available that may affect your willingness to carry on taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained and arrangements made for your care to continue.

**What will happen if you don't want to carry on with the study?**
You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you stop taking part, please tell your study doctor immediately. You will be asked to return to the study centre for an end-of-study assessment and to return all unused study medication. You may also be asked for permission to be contacted at a later date by your doctor to collect minimum additional data about your condition.

**Will your taking part in this study be kept confidential?**
Your privacy and your personal information will be protected using measures which follow the requirements applicable in your country for the protection of your personal information. Any information about you that is collected during this study will remain confidential. Your records will be identified by your study subject number (in line with local law). These records will not include your full name or any address details. The information from the study may be published or sent to regulatory authorities or health insurers in your country or other countries where regulatory approval or payment for the medication is required. Your identity will not be released except with your permission, unless necessary for the vital interests of your safety.

The Sponsor and its representatives, monitors, auditors, government, regulatory health authorities and possibly an independent ethics committee or institutional review board will be entitled to review your medical files at the hospital (or study doctor's office) to check the clinical study procedures and information, without breaking your confidentiality.

By signing this consent form, you are giving permission for the processing and use of your personal information for this study.. You are also giving permission for processing of your coded personal information in a database and transferring of the same or any part of it to people and organisations outside your country, where personal data protection laws may be less strict. You may use your rights under your local data protection laws to access and correct your personal information or ask for it to be deleted. You can object to any further processing of your information by applying to your study doctor.

Your study doctor may tell your family doctor about you taking part in the study and ask them for medical information about you.

For your information, because this trial is run under a US IND, the following statement is required: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

<Include an expiration date on data or statement that there is no expiration date.>

**<If applicable: Will you do any genetic tests?**

*If genetic testing will be conducted, it is recommended that a separate brief PIS/ICF be used.*
If genetic testing is to be done then please state in the main information sheet "*Please refer to separate genetic testing information sheet*".>

**What will happen to the results and this clinical study?**
<If the results of the study are to be used to inform clinical decision making or the development of another study this should be mentioned. The author should state what will happen to the results of the research, whether it is intended to publish the results and how the results will be made available to participants (usually, the participant may approach the study doctor for published materials if they wish). You should add that they will not be identified in any report/publication.

The results of this study will be used to make informed clinical decisions for developing this new medication. If you want the results to be made available to you, please talk to your study doctor.

**Who has reviewed the study?**
All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion by <insert name> Research Ethics Committee.

The Sponsor, Regulatory Authorities or the Ethics Committee may stop the study at any time where there is good reason.

**Who should you contact for more information?**
For more information please contact:

Name: _____

Phone: _____

**Thank you for reading this and considering if you will take part in this study.**

## Consent form

**Study title:** <Study Title [verbatim as per protocol, with any acronyms spelled out]>
**Study protocol:** <Protocol Name and/or Number [verbatim as per protocol]>
**Study drug:** <drug name> referred throughout the document as the study drug
**Sponsor of the study:** <Sponsor Name>
**Investigator:** <Investigator's Name>

I confirm the following:

| | |
|---|---|
| • I have read and understand the information sheet for the above study, and have had enough time to think about taking part. | *Patient initial* |
| • I am satisfied with the answers given to all of my questions. | *Patient initial* |
| • I voluntarily agree to be part of this research study, to follow the study procedures and to provide the information the study doctor, nurses or other staff members ask from me. | *Patient initial* |
| • I understand that I am free to withdraw from this study at any time without giving a reason and without my medical care or rights being affected. | *Patient initial* |
| • I have received a copy of this information sheet and consent form to keep for myself. | *Patient initial* |
| • I agree, if my study doctor is not my family doctor, my family doctor may be told about my taking part in this study and asked for medical information about me. | *Patient initial* |
| • I agree to my samples being taken and used as described in this information sheet | *Patient initial* |
| • I give permission for my personal information collected as part of this clinical study to be:<br>- identified only with my subject ID number;<br>- reviewed, processed and transferred by and to the Sponsor and its authorised representatives for the purposes described in the study protocol;<br>- reviewed or audited by the central or local ethic committees;<br>- published and sent to regulatory authorities or health insurers in my country or other countries; and<br>- transferred if required to any country, where data protection laws may be less strict. | *Patient initial* |
| • I understand I may also be contacted at a later date(s) for my permission in connection with this or any related sub study... | *Patient initial* |

By signing this document I agree to take part in this study, as set out in this information sheet and consent form.

My name (or the name of my representative):

Signed (by me or my representative): Date:

**Investigator/Authorised Designee:**

- ✓ I have fully and carefully explained the study to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study
- ✓ I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.
- ✓ I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- ✓ I confirm they have been given a copy of this information sheet and consent form.

My name:

Signed: Date: