DELIVERABLE 11.4

H - REQUIREMENT NO. 4

WORK PACKAGE NUMBER: 11

WORK PACKAGE TITLE: ETHICS REQUIREMENTS

ETHICS

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Lead beneficiary	BIU
Lead Author(s)	Jos Dumortier and Liesa Boghaert
Contributor(s)	

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Approvals

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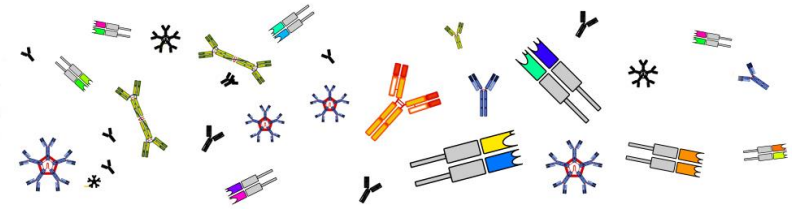
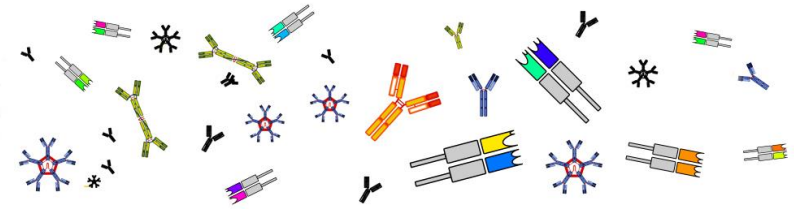


Table of Contents

This project is funded by the European Union's H2020 Research and Innovation Programme under Grant Agreement No. 825821 and Canadian Institutes of Health Research (CIHR)



Executive Summary

This deliverable shows that, in the context of iReceptor Plus, no activities of processing personal data will rely on informed consent as a legal basis. As such, there is no need to provide information on informed consent procedures, informed consent forms or information sheets.

Introduction

As a part of WP11 – Ethics requirements, Deliverable 11.4 is aimed at providing detailed information on the informed consent procedures that will be implemented for the participants in iReceptor Plus. D11.4 also requires that the templates of the informed consent forms and information sheets are kept on file.

In fulfilling this task, this deliverable first indicates the relevant provisions of the GDPR referring to informed consent and obligations to inform the data subject and assesses their applicability to iReceptor Plus. This leads to the conclusion that, as matters stand, informed consent will not be used as a legal basis within iReceptor Plus. As a result, no informed consent procedures should be put in place, nor should informed consent forms or information sheets be kept on file.

Informed consent under the GDPR and iReceptor Plus

The provisions of the GDPR

Under the GDPR, every activity of personal data processing requires a legal basis under Article 6 of the GDPR in order for this processing to be lawful. This legal basis can be:

- the consent of the data subject[1] (Art. 6.1 (a) GDPR)
- the necessity of the processing for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract (Art. 6.1(b) GDPR);

[1] The data subject is the identified or identifiable natural person to whom the personal data concerned relate. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier, such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (Art. 4(1) GDPR).

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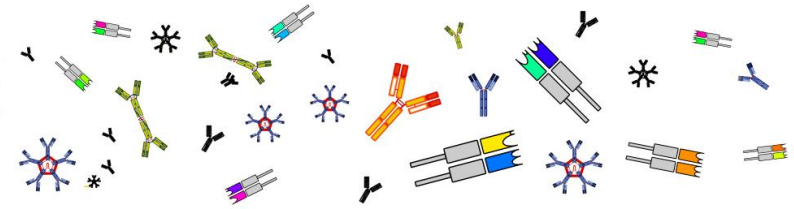

- the necessity of the processing for compliance with a legal obligation to which the controller[2] is subject (Art. 6.1 (c) GDPR);
- the necessity of the processing in order to protect the vital interests of the data subject or another natural person (art. 6.1 (d) GDPR);
- the necessity of the processing for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller (art. 6.1 (e) GDPR);
- the necessity of the processing for the purposes of the legitimate interests pursued by the controller or by a third party[3] (art. 6.1 (f) GDPR);

When 'consent of the data subject' is used as legal basis for a certain processing operation, the GDPR emphasizes that this consent should be given by a clear affirmative act establishing a freely given, specific, *informed* and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement […] (Article 4.11 and recital 32 GDPR).

The controller should be able to demonstrate that the data subject has given consent to the processing operation (Article 7.1 GDPR and recital 42 GDPR). In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware of the fact that and the extent to which consent is given. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of the GDPR shall not be binding (Article 7.2 GDPR).

In addition, the data subject shall have the right to withdraw his or her consent at any time. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent (Article 7.3 GDPR).

In accordance with Council Directive 93/13/EEC[4] a declaration of consent pre- formulated by the controller should be provided in an intelligible and easily accessible form, using clear and plain language and it should not contain unfair terms. For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended (recital 42 GDPR).

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[2] The controller is the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data (art. 4(7) GDPR).

[3] Except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require the protection of personal data, in particular where the data subject is a child.

[4] Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, available in the consolidated version at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01993L0013-20111212&from=EN.

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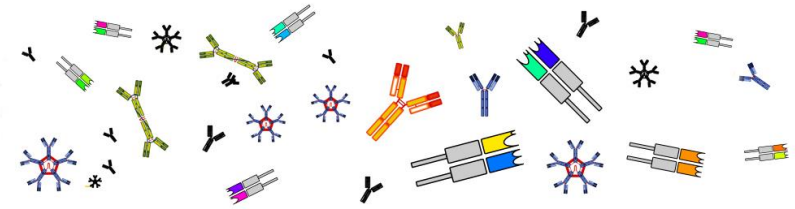

Moreover, under article 12 of the GDPR, data subjects have a right to transparent information, which means that controllers should take appropriate measures to provide any information referred to in Articles 13 and 14[5] and any communication under Articles 15 to 22 and 34[6] relating to processing to the data subject in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child. The information shall be provided in writing, or by other means, including, where appropriate, by electronic means. When requested by the data subject, the information may be provided orally, provided that the identity of the data subject is proven by other means. This providing of this information can be done through so-called 'information sheets' or 'privacy notices'.

Indeed, the principle of transparency requires that any information and communication relating to the processing of those personal data be easily accessible and easy to understand, and that clear and plain language be used. That principle concerns, in particular, information to the data subjects on the identity of the controller and the purposes of the processing and further information to ensure fair and transparent processing in respect of the natural persons concerned and their right to obtain confirmation and communication of personal data concerning them which are being processed. Natural persons should be made aware of risks, rules, safeguards and rights in relation to the processing of personal data and how to exercise their rights in relation to such processing (recital 39 GDPR).

The processing activities in iReceptor Plus

The objective of iReceptor Plus as a research and innovation action is to build a common scalable platform to integrate distributed repositories of Adaptive Immune Receptor Repertoire sequencing data (AIRR-seq data) for enabling improved personalized medicine and immunotherapy for diseases with an immune component.

iReceptor Plus will be designed as a network of federated repositories that facilitates data queries and advances analyses through a centralized web portal (the iReceptor Plus Scientific Gateway).

As was already indicated in previous deliverables (more specifically D11.2 and D11.12), the AIRR-seq data that will be shared and will thus be accessible through the iReceptor Plus platform will, in the first stage of the iReceptor Plus project, only be AIRR-seq data that have undergone anonymisation techniques, as they originate from scientific studies that were undertaken by the

[5] Articles 13 and 14 respectively lay down the information that needs to be provided where personal data are collected from the data subject or, where personal data have not been obtained from the data subject. This information includes a.o. the identity and contact details of the controller and its representative, the contact details of the data protection officer, the purposes of processing, the categories of personal data concerned, the recipients or categories of recipients of personal data…

[6] These provisions relate to the rights of the data subjects.

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academic research institutes and hospitals that are part of iReceptor Plus. These AIRR-seq data have already been made available in an anonymous form in open access repositories, since the data had to be published together with the studies they support, as is common practice in scientific research and such publishing should always be performed in an anonymized format.

Given that the AIRR-seq data that will be processed throughout the first phase (M1-M24) of the iReceptor Plus research action consequently consist only of public data that have undergone anonymisation techniques, to our understanding, these data cannot be qualified as personal data and consequently, no legal basis for the processing of these data (such as e.g. informed consent) is required (since it is impossible to ask consent from a person for processing data that do not (or no longer) relate to an identifiable person).

Moreover, even if at a later stage, the iReceptor Plus consortium decides to allow for the sharing of personal data, in particular special categories of personal data such as data concerning health and genetic data (through data sharing and data transfer agreements), iReceptor Plus will not rely on the explicit consent of the data subject as a legal basis for processing health/genetic data under the GDPR and informed consent procedures, nor informed consent forms or information sheets will be required.

This because, in terms of the GDPR, the data processing activities of iReceptor Plus would constitute a 'further processing' or 'secondary use' of the personal data that were collected and processed by the research institutions and hospitals that give access to their data through the iReceptor Plus platform for scientific research purposes.

According to Article 5.2 (b) of the GDPR, which introduces the principle of 'purpose limitation', 'personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes'. This implies that every activity of processing personal data should have a specific purpose and should be legitimized by a legal basis. If personal data are 'further processed' for another purpose that the initial purpose, a separate legal basis should legitimize that other purpose.

However, the second sentence of Article 5.2(b) GDPR clarifies that 'further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes. This 'assumption of compatibility' entails that whenever personal data are further processed for scientific research purposes in accordance with the safeguards that are put forward in Article 89.1 of the GDPR, this further processing for scientific research purposes will not be considered incompatible with the initial purpose and no 'extra' legal basis is required for this processing operation. This reasoning is spelled out in recital 50 of the GDPR, which notes that 'the processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes

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for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required' (recital 50 GDPR).

Under the GDPR, the processing of special categories of personal data, such as data concerning health and genetic data, is in principle prohibited. Nevertheless, Article 9.2 of the GDPR provides for 10 exceptions, in which case the prohibition to process special categories of personal data does not apply. One of these exceptions, laid down in Article 9.2(j) allows for the processing of special categories of personal data if 'the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'. In that case, according to the assumption of compatibility, no separate legal basis from the one that was relied upon for the initial purpose of processing the special category of personal data will be required for this further processing activity for scientific research purposes.

It is thus clear that even when iReceptor Plus at a later stage would process personal data, in particular health or genetic data, originating from research institutes and hospitals, this processing would constitute a 'further processing' or 'secondary use' for scientific research purposes which can rely on the legal basis foreseen for the initial purpose of processing of the data and iReceptor Plus would not be required to legitimize these processing activities by a separate legal basis.

What legal basis the research institutions and hospitals will choose to process the health/genetic data for their initial purpose is however up to them. These research institutions and hospitals are free to choose the legal basis that is most appropriate under their national (EU MS, Canadian, USA) law for the initial processing purpose concerned.

As indicated above, under the GDPR, processing special categories of personal data is only allowed if one of the ten exceptions listed in Article 9 GDPR applies. One of these exceptions is the 'explicit consent of the data subject' (art. 9.2(a) GDPR). If a data subject has explicitly consented to the processing of a special category of personal data (such as health or genetic data) relating to him or her, processing of this special category of personal data is lawful.

Research institutions and hospitals that decide to base their activities of processing special categories of personal data (as a primary use) on the explicit consent of the data, will however have the responsibility to ensure that informed consent procedures, consent forms and information sheets are put in place. From a legal point of view, these information notices do not necessarily have to include the fact that the data might be used for (additional) scientific research purposes through iReceptor Plus later on. From an ethical point of view however, this may be nevertheless be beneficial.

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Conclusion

In the first stage of iReceptor Plus, only anonymised data will be processed. As such, no informed consent procedures, consent forms or information sheets will be required.

To the extent that iReceptor Plus at a later stage would process personal data, in particular data concerning health or genetic data, iReceptor Plus will be further processing these data as a secondary use and will be able to rely on the assumption of compatibility for scientific research purposes. This entails that the further processing of these special categories of personal data for scientific research purposes will not require a legal basis separate from the one provided by the research institutions and hospitals for the initial processing purposes. Consequently, even in this instance of further processing of special categories of personal data, iReceptor Plus will not have to rely on the explicit consent of the data subject, given the research purposes envisaged in iReceptor Plus. As such, no informed consent procedures, consent forms or information sheets will be required.

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