DELIVERABLE 11.11

POPD – REQUIREMENT NO. 14

WORK PACKAGE NUMBER: 11

WORK PACKAGE TITLE: ETHICS REQUIREMENTS

ETHICS

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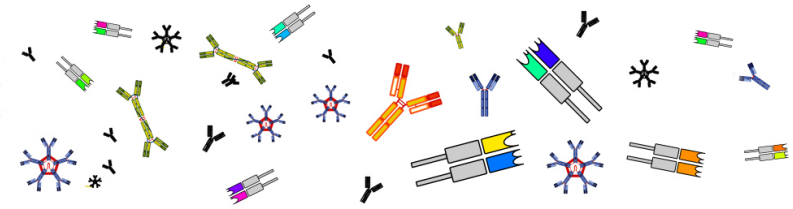

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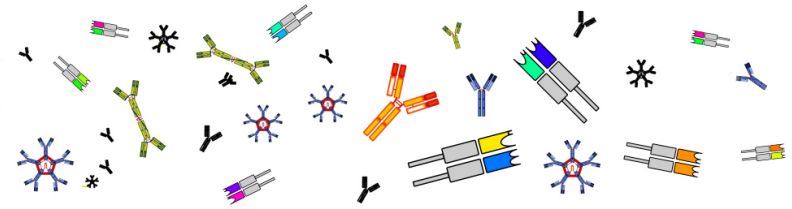

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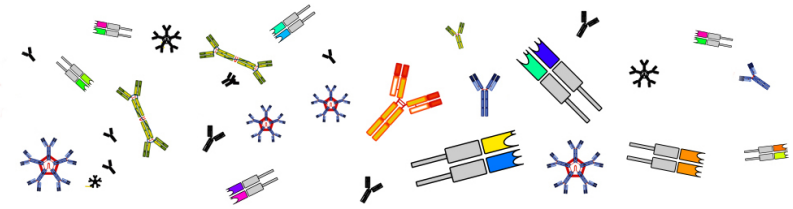

Executive Summary

This deliverable addresses POPD Requirement No. 14 which requires that individual participants with data introduced into the system are given a convenient way of accessing their data as well as rectifying and deleting their data from the system and that they are made aware of all the studies their data is being used for and provide their consent for each. If consent is given for their data to be used in a particular subject area research, they should moreover still be able to easily access information about all the studies involved. Additionally to the studies, individual participants should know the data protection officer governing the specific study.

This deliverable argues that it is impossible for the iReceptor Plus consortium to fulfil or facilitate all the data subjects rights listed in POPD Requirement No.14 given that the data processed in iReceptor Plus do not relate to an identified/identifiable natural person and the consortium is thus not able nor allowed to contact or retrace the individuals to whom the data related in the past.

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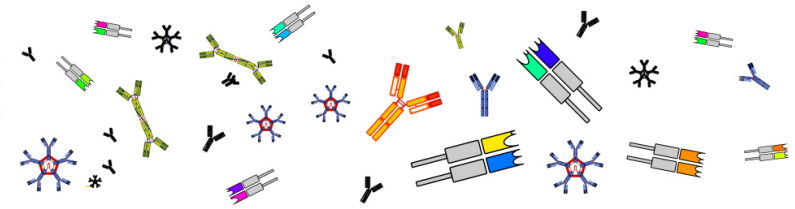

Introduction

As part of WP11, deliverable D11.11 addresses POPD Requirement No. 14, which requires that individual participants with data introduced into the system are given a convenient way of accessing their data as well as rectifying and deleting their data from the system. Individual participants should pursuant to POPD requirement No. 14 also be made aware of all the studies their data is being used for and provide their consent for each. If consent is given for their data to be used in a particular subject area research, they should moreover still be able to easily access information about all the studies involved. Additionally to the studies, individual participants should know the data protection officer governing the specific study.

First, the deliverable will reiterate the objectives of the iReceptor Plus project and will explain that the data processing activities in iReceptor Plus merely concern a further processing or secondary use of previously collected data, for research purposes. Then, the deliverable will link the different requirements listed in POPD Requirement No. 14 to the corresponding rights of data subjects laid down in the GDPR and will assess their applicability and feasibility in the context of the iReceptor Plus project.

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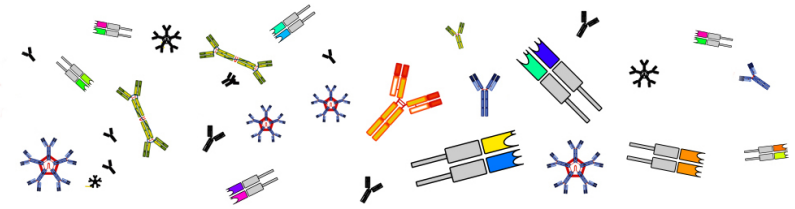

Objectives of iReceptor Plus and related data processing activities

The iReceptor Plus project essentially intends to lower the barrier to share, access and analyze large sets of Adaptive Immune Receptor Repertoire sequencing data (AIRR-seq data) from around the world and to ease the availability of these AIRR-seq data to academia, industry and clinical partners. This increased availability of AIRR-seq data will advance researcher's understanding of immune responses and may lead to the discovery of biomedical interventions (such as vaccines and other immunotherapies) that manipulate the adaptive immune system. Such advancements will enable improved personalized medicine and immunotherapy in cancer, inflammatory an autoimmune diseases, allergies and infectious diseases.

To achieve this objective, the iReceptor Plus aims to build a common scalable platform to integrate distributed repositories of AIRR-seq data. 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). This Scientific Gateway will allow researchers to pose complex queries about AIRR-seq data, their metadata and annotated sequence data. The Gateway then, on behalf of the end-user, will send the query to each of the repositories (using the REST API), will federate the results from each repository and present these federated results to the end-user. But the Gateway will go even further, as it will be able to stage federated data resulting from a query to an advanced analysis tool that uses computational methods on the aggregated data, such as relational datamining algorithms and deep learning techniques (AI), to facilitate complex analysis of the federated data and integrate it with other types of human health and genomic data.

The data in the distributed repositories originate from scientific and clinical studies that were undertaken by academia, industry or clinical partners. In accordance with common practice in research, these academia, industry and clinical partners deposit all data supporting their research findings in an open access repository upon publication of their research findings in scientific journals. The data concerned will be deposited in these repositories in an anonymous form, since this is required by most data protection laws and will in any case be obliged by the competent supervisory ethics committees.

A key characteristic of the project is thus that it will **facilitate a secondary use of data that was previously collected and deposited in a repository by other researchers/clinicians or industry partners**. As such, the iReceptor Plus project will not actively collect data from research or clinical trial participants. Rather, it will only provide access to data of research participants that already sits in a repository set-up by researchers/clinicians or industry partners. Those researchers and clinicians are the only ones that will have been in contact with the research or clinical trial participants at the stage of data collection, but neither they nor the iR+ consortium partners will

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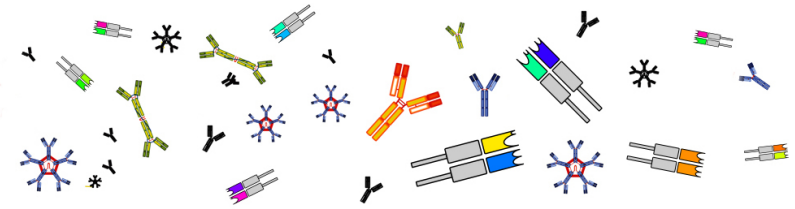

still be able to retrace or contact those participants, given that the data have been anonymised in the meantime. The data that will be accessible through the iReceptor Plus platform will thus only be data that have undergone anonymisation techniques. As such, these data cannot be considered as personal data in the sense of the GDPR since they no longer relate to an identified or identifiable natural person.

It is not yet clear if the iReceptor Plus consortium will at a later stage in the project also enable the sharing of AIRR-seq data that researchers have not yet uploaded to a repository in an anonymous format and that are thus, personal data. If so, the contents of this deliverable will have to be revised.

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Data subject rights under the GDPR

POPD Requirement No. 14 provides that individual participants with data introduced into the system should have a convenient way of **accessing their data** as well as **rectifying** and **deleting their data from the system**. They should **be made aware of all the studies their data is being used for** and **provide their consent for each**. If consent is given for their data to be used in a particular subject area research, they should still be able to easily **access information about all the studies involved**. Additionally to the studies, individual participants should **know the data protection officer governing the specific study**.

This description touches upon several rights of data subjects laid down in the GDPR. However, not all of these rights apply categorically in case of a further processing/secondary use of previously collected personal data. Moreover, as was clarified above, as matters stand, the iReceptor Plus project will only process non-personal, anonymous data. This means that the rights of data subjects are not applicable, since there are no data subjects who could exercise their rights.

Below the different requirements of POPD Requirement No. 14 will be linked to the corresponding rights of data subjects laid down in the GDPR and their applicability and feasibility in the context of the iReceptor Plus project will be assessed.

Requirement 1: Individual participants with data introduced into the system should have a convenient way of accessing their data

This requirement relates to the right of access of data subjects laid down in Article 15 GDPR. Article 15 provides that the data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the certain information, such as:

- The purposes of the processing;
- The categories of personal data processed;
- The recipient or categories of recipients to whom the personal data have been or will be disclosed (in particular recipients in third countries or international organisations);
- The envisaged period for which the personal data will be stored or the criteria used to determine that period;
- The existence of the right to request from the controller rectification or erasure of personal data or restriction of the processing of personal data concerning the data subject or to object to such processing;

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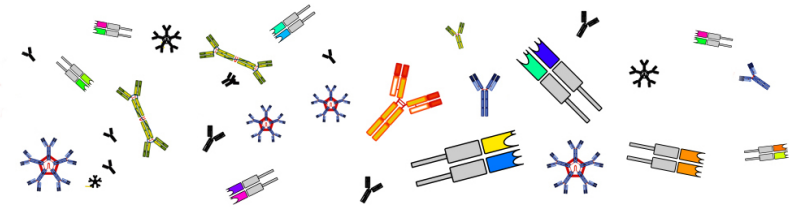

- The right to lodge a complaint with a supervisory authority;
- Where the personal data are not collected from the data subject, any available information as to their source;
- The existence of automated decision-making, including profiling and at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject;
- Information on the appropriate safeguards relating to a transfer of personal data to a third country or international organisation;

Moreover, the controller should provide a copy of the personal data undergoing processing (where requested, in a commonly used electronic form).

In essence, the right of access thus gives individuals the right to obtain (1) confirmation that their personal data are processed by the controller, (2) a copy of their personal data as well as (3) other supplementary information. It is an important data subject right, as it helps individuals to understand how and why a controller is using their data, and check if this controller is doing it lawfully.

Applicability in iReceptor Plus

As was previously mentioned, one of the key characteristics of the iReceptor Plus project is that it will facilitate a **secondary use** of data that was previously collected and deposited in a repository by other researchers/clinicians or industry partners. The data in those repositories are **anonymized**, which means that no personal data will be processed in iReceptor Plus. In fact, the researchers and clinicians that originally collected the samples are the only ones that have been in contact with the research or clinical trial participants at the stage of data collection, but neither they nor the iR+ consortium partners are able to retrace or contact the individuals behind the datasets, once the data relating to these samples have been deposited in the repositories in an anonymous way. Consequently, the right of access does not apply as regards the data processed in iReceptor Plus, since these data are non-personal and therefore, there are no data subjects who can exercise these rights.

Moreover, Article 89 of the GDPR, which concerns the ‘safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes’ is relevant in this context. Pursuant to the second paragraph of this Article, where personal data are processed for scientific research purposes, Union or Member State law may provide for a derogation from the right referred to in Article 15 of the GDPR (i.e. the right of access) subject to the conditions and safeguards in paragraph 1 (i.e. technical and organisational measures to ensure respect for the principle of data minimisation) in so far as this right is likely

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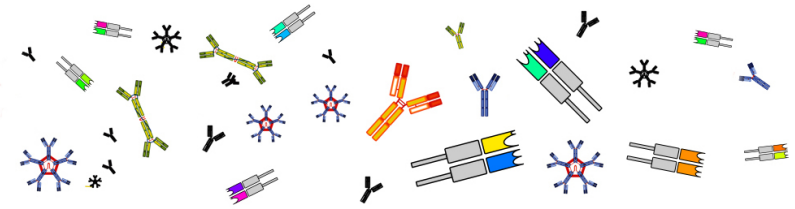

to render impossible or seriously impair the achievement of the specific purpose and such a derogation is necessary for the fulfilment of that purpose.

This means that Union or Member State laws can foresee a derogation from the right of access where personal data are processed for scientific research purposes subject to certain safeguards and in so far as providing data subjects access to their personal data is likely to render impossible or seriously impair the achievement of the specific purpose and such derogation is necessary for the fulfilment of that research purpose. Even if personal data would be processed in iReceptor Plus, Union or MS law derogations might thus apply.

Lastly, even if the data processed in iReceptor Plus would still be identifiable to some extent due to the fact that genetic data are concerned, Article 11 of the GDPR explicitly states that if the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the GDPR. Where the controller is able to demonstrate that it is not in a position to identify the data subject, the controller shall inform the data subject accordingly, if possible. In such cases, Articles 15 to 20 shall not apply except where the data subject, for the purpose of exercising his or her rights under those articles, provides additional information enabling his or her identification.

This means that even if the iReceptor Plus consortium would receive a request to exercise the right of access from an individual claiming that his/her personal data are processed in iReceptor Plus, the consortium would not have to comply with this request as the consortium is not obliged to maintain additional information in order to identify the individuals to whom the data processed in iReceptor Plus previously related.

Requirement 2: Individual participants with data introduced into the system should have a convenient way of rectifying their data

This requirement relates to the right of rectification of data subjects laid down in Article 16 GDPR. Article 16 provides that “The data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have incomplete personal data completed, including by means of providing a supplementary statement.”

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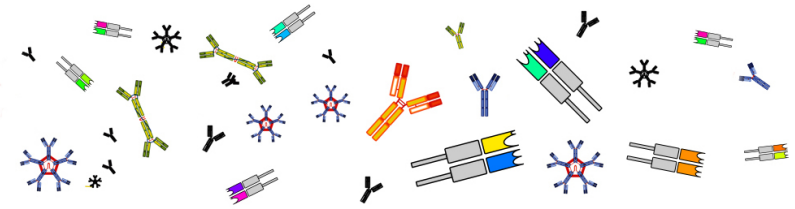

Applicability in iReceptor Plus

Also in regards of this data subject right, the same reasoning applies. Given that the data processed in iReceptor Plus are anonymized and the consortium thus has no way of retracing or contacting the research/clinical trial participants, the right of rectification cannot apply. It would also be contrary to the GDPR to maintain additional information in order to identify the data subject to whom the data previously related, for the sole purpose of meeting data subjects' requests to exercise their rights.

Moreover, Article 89.2 GDPR, also provides that in regards of the right of rectification, Union or Member State laws can foresee a derogation to the right of rectification where personal data are processed for scientific research purposes subject to certain safeguards and in so far as providing data subjects right to rectify their personal data is likely to render impossible or seriously impair the achievement of the specific purpose and such derogation is necessary for the fulfilment of that research purpose. Even if personal data would be processed in iReceptor Plus, Union or MS law derogations might thus apply.

Requirement 3: Individual participants with data introduced into the system should have a convenient way of deleting their data from the system

This requirement relates to the right to erasure of data subjects laid down in Article 17 GDPR. Article 17 provides that "the data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

- The data subject withdraws consent (when the lawfulness of processing is based on consent) and there is no other legal ground for the processing;
- The data subject objects to the processing pursuant to Article 21(1) GDPR and there are no overriding legitimate grounds for the processing, or the data subject objects to the processing pursuant to Article 21(2);
- The personal data have been unlawfully processed;
- The personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject;
- The personal data have been collected in relation to the offer of information society services referred to in Article 8(1).

Where the controller has made the personal data public and is obliged pursuant to the foregoing paragraph to erase the personal data, he shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data that the data subject has

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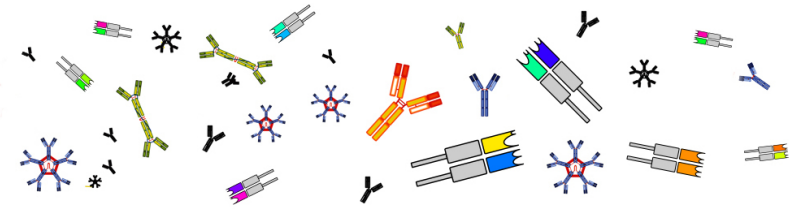

requested the erasure by such controllers of any links to, or copy or replication of, those personal data.

In a third paragraph, Article 17 however indicates that the right to erasure shall not apply to the extent that processing is necessary for a.o.:

- Archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing;

Nevertheless, it should be mentioned that pursuant to Article 21.6GDPR "where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89.1, the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, unless the processing is necessary for the performance of a task carried out for reasons of public interest.

Applicability in iReceptor Plus

Again in regards of this data subject right, the same reasoning applies. Given that the data processed in iReceptor Plus are anonymized and the consortium thus has no way of retracing or contacting the research/clinical trial participants, the right of erasure cannot apply. It would also be contrary to the GDPR maintain additional information in order to identify the data subject to whom the data previously related, for the sole purpose of meeting data subjects' requests to exercise their rights.

Moreover, Article 17.3(d) GDPR explicitly provides that the right to erasure shall not apply to the extent that processing is necessary for scientific research purposes in accordance with Article 89.1 in so far as the right to erasure is likely to render impossible or seriously impair the achievement of the objectives of that processing. Even if personal data would be processed in iReceptor Plus, this exemption might arguably apply.

Requirement 4: Individual participants with data introduced into the system should be made aware of all the studies their data is being used for

This requirement relates to the right of data subjects to be informed about the collection and use of their personal data in accordance with Articles 13 and 14 of the GDPR.

Article 13 and 14 of the GDPR require that the data subjects be informed of a.o.

- The identity and contact details of the controller and the controller's representative;
- The contact details of the data protection officer (DPO);

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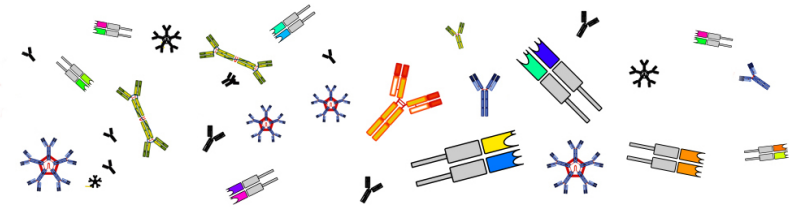

- The purposes for processing their personal data;
- The legal basis for the processing;
- The retention periods;
- The recipients or categories of recipients of the personal data;

These Articles distinguish between two situations. Whereas Article 13 applies to the situation in which the controller obtains the data from the data subject, Article 14 applies to the situation in which the data have not been obtained from the data subject by the controller.

In a research context, the first situation will most often occur if health data are specifically collected to be used for research. Then, data subjects must evidently be informed. This rule also applies if a hospital providing health care to a patient wishes to further process the health data collected in the clinical context for its own research projects or to transfer the data to a third party. As a controller, the hospital obtained the health data from the patient and consequently must inform the patient for example about the purposes for which the data will be used.

If the hospital provided the health data, collected in a clinical context, to another controller, for example a private or public research institution, the question rises whether also the latter institution has the duty to inform the data subjects. This research institution did not obtain the data from the data subject, so Article 14 GDPR comes into play. Article 14.5.b GDPR waives the obligation of controllers to inform the data subject if one of the following conditions is fulfilled: (a) “the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes”, or (b) the duty to inform “is likely to render impossible or seriously impair the achievement of the objectives of that processing”. The provision stipulates that in such cases the controller shall take appropriate measures to protect the data subject’s rights and freedoms and legitimate interests, including making the information publicly available”.

Condition (a) often applies when researchers process large volumes of historical health data, relating to patients who cannot be contacted anymore either because their contact details are unknown or outdated or the patients have deceased in the meantime.

Again, it is important to refer to Article 11.1 GDPR which states that if the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the GDPR. In other words, controllers are not obliged to collect (updated) contact details exclusively for the purpose of addressing information to the data subject about the personal data processing.

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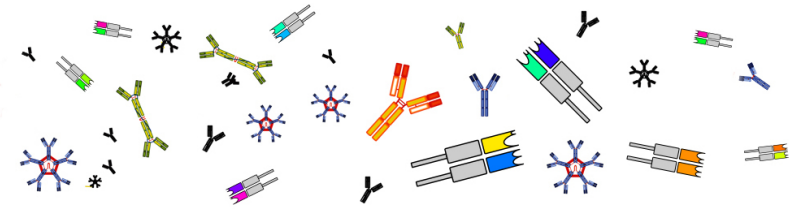

Condition (b) applies, for example, to research projects including double blind tests. Providing prior and full information to the data subject would result in biases and account for other effects that might influence results such as the placebo effect, where the belief one is being treated has an effect on results itself.

Applicability in iReceptor Plus

Given that the data processed in iReceptor Plus are anonymized and the consortium thus has no way of retracing or contacting the research/clinical trial participants, the right of data subject to be informed in accordance with Articles 13 and 14 cannot apply.

Moreover, even if the data processed in iReceptor Plus would still be identifiable to some extent due to the fact that genetic data are concerned, in iReceptor Plus, the provision of the information laid down in Article 14 to the data subjects would arguably involve a disproportionate effort in particular taking into account the scientific research purposes of iReceptor Plus, so the obligation of controllers to inform the data subjects would be waived pursuant to Article 14.5(b) GDPR.

Besides that, providing the information listed in Article 14 to data subjects would require iReceptor Plus to acquire or process additional information to identify the data subject for the sole purpose of complying with the GDPR, which would run counter to Article 11.1 GDPR.

Requirement 5: Individual participants with data introduced into the system should provide consent for each of the studies their data is being used for

Requirement 5 does not relate to the rights of the data subjects, but rather to the fundamental principle laid down in Article 5.1(a) of the GDPR that each processing of personal data shall be lawful and should thus be based on one of the legal grounds listed in Article 6 GDPR. It also relates to Article 9.2 of the GDPR which lists the circumstances in which the processing of genetic data (and other special categories of personal data) is not prohibited.

While the initial text of the GDPR, as it was proposed by the Commission in 2012, provided the option to carry out scientific research on a legal basis other than consent, the Civil Liberties Committee (LIBE) of the European Parliament proposed a provision requiring that *"consent should always form the correct basis for the processing of personal health data in a research context unless research serves a purpose of exceptionally high public interest"*. The LIBE Committee justified its revision by arguing that *"the current proposal for Article 83 appears to allow processing of health data, in identifiable form, for research purposes without reference to*

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consent. The only safeguards (that identifiable data must be kept separate and that researchers can use identifiable data only if research cannot be fulfilled by using non-identifiable data) significantly lowers the protection of health data. There is a risk that the current proposal will allow for researchers to use identifiable data without consent."[1] This proposed amendment by the LIBE Committee raised serious concerns that it would hinder health research significantly.[2] Finally, the Council of Ministers did not agree with the approach favoured by Parliament, and the text of the GDPR, as it was ultimately approved in 2016, provides for major derogations.

Yet, GDPR commentators often still refer to consent as the first possible legal ground for the processing of health data and all other grounds as exceptions.[3] This assumption that consent of the data subject is always necessary for the processing of health data probably stems from the culture of consent developed in the context of clinical trials. Consent to participation in a study or a trial must however be distinguished from consent to the processing of personal data.[4] Data protection legislation only governs the processing of personal data, not the actual participation of individuals in research projects. This participation is subject to other legal rules, in particular the European Clinical Trial Regulation and to ethical standards, such as the Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects of the World Medical Association.

To understand how the GDPR regulates the processing of health data for research purposes, a distinction must be made between research as a primary purpose of processing and research s a secondary purpose.

- Research as a **primary purpose** refers to the situation where research is the primary purpose for which health/genetic data are collected from the data subject.
- Research as a **secondary purpose** refers to the situation where health/data are initially not (or not necessarily) collected for research purposes but, for instance, for the provision of health care and are later on further processed for research purposes.

Collecting health and genetic data specifically for research purposes (as a **primary purpose**) is regulated by Article 9 of the GDPR which deals with 'special categories of personal data'. Article 9 essentially states that the processing of health and genetic data (among other categories of

[1] European Parliament, Committee on Civil Liberties, Justice and Home Affairs, Report on the proposal for a regulation of the European Parliamnet and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)) (COM(2012)0011-C7-0025/2012-2012/0011(COD)), Rapporteur: Jan Philip Albrecht, p. 24, *in fine*.

[2] M. PLOEM, M. ESSINK-BOT and K. STRONKS, Proposed EU data protection regulation is a threat to medical research, British Medical Journal (2013), Vol. 346, 3534; E. S. DOVE et al., Data protection and consent to biomedical research: a step forward?, The lancet, Vol 384 September 6, 2014, p. 855.

[3] E. DOVE and G. LAURIE , Consent and Anonymisation: Beware Binary Constructions, British Medical Journal 350 (2015) 1139.

[4] EDPB, Opinion 3/2019 concerning Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR).

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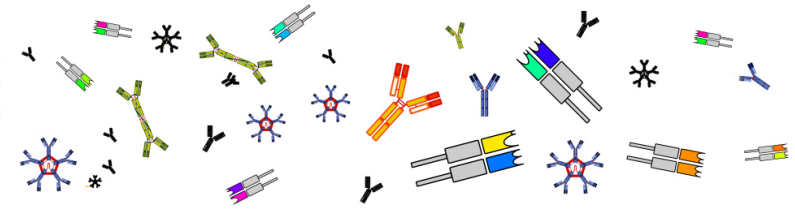

'sensitive' data) is prohibited except if the processing can be justified under one of the 10 exceptions listed in that article. One of these exceptions, overruling the prohibition to process sensitive personal data, is the necessity of processing "for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes" (Art. 9.2(j) GDPR). As a consequence of this article, the prohibition to process health data does not apply if the processing of health data is necessary for scientific research and under the condition that all other provision of the GDPR are respected. In other words: if scientific research is the purpose of processing, health and genetic data can be processed under the same conditions as "common" personal data.

One of those conditions is the requirement of having a legal basis in accordance with Article 6 of the GDPR. Article 6 of the GDPR determines that processing of personal data is only lawful if it is based on one of the six legal grounds listed in that article These are:

- the data subject has given **consent** to the processing of his or her personal data for one or more specific purposes;
- processing is **necessary 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;
- processing is **necessary for compliance with a legal obligation** to which the controller is subject;
- processing is **necessary in order to protect the vital interests** of the data subject or of another natural person;
- processing is **necessary for the performance of a task carried out in the public interest** or in the exercise of official authority vested in the controller;
- processing is **necessary for the purposes of the legitimate interests pursued by the controller or by a third party**, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Among those six possible legal grounds, the most obvious one when collecting health and genetic data specifically for research purposes, is the consent of the data subject. Other legal grounds, listed in Article 6 may be applicable as well, such as the performance of a task carried out in the public interest or the legitimate interest of the controller, but, in practice, these legal grounds are much less obvious in this situation. In most cases, researchers collecting health data in the context of the research project or a series of research projects, will collect the data directly from the data subjects and there will be no practical obstacles to obtain consent for the processing of the data.

For consent to be a valid legal basis, it must be freely given, specific, informed and unambiguous. Recital 32 of the GDPR states that "*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*

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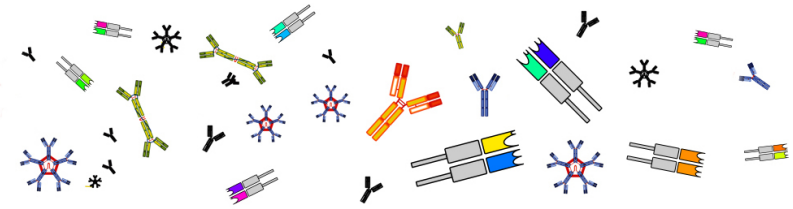

the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent."

Informed consent means that adequate information must be provided to the data subject to enable him or her to make an enlightened choice. For there to be informed consent, data subjects must at least have information on e.g. the controller's identity, the purpose of each processing operation, the type of data collected etc.

Finally consent must be specific for a particular purpose .This may be problematic in the context of research, since health data may be collected from data subjects at a moment when the specific research project for which the data will be used, is not yet fully clear. In other cases, health data may be collected in view of a long-term research programme or to feed a repository of health data to be made available to the research community. The GDPR recognises this problem. Recital 33 provides a certain flexibility in the specification of the research purpose, stating that *"it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research".* This is often qualified as "broad consent" but it should be kept in mind that it "*does not disapply the obligations with regard to the requirement for specific consent to the processing of data for scientific research purposes".* The data protection supervisory authorities assembled in the former Article 29 Working Party have specified in one of their opinions that broad consent may be an option, when explaining that the purpose cannot be fully determined at the outset of the project, but that this should be strictly interpreted in these case of processing of sensitive data and will be the object of a high degree of scrutiny.[5]

Dynamic consent is another possible option. It often consists of using a technical solution, such as a mobile application or a server platform to engage individual and active participants. This allows the researcher to easily inform research participants and ask for re-consent or additional consent. However, it is a solution which is not apt to apply in every research situation.

The rules outlined above apply when the data processed have been collected expressly for the purpose of scientific research. However, very often the data used for scientific research were initially not per se collected for research purposes, but researchers re-use health data that have been obtained from patients in a clinical context. Health data are often provided to researchers

[5] Article 29 Working Party, Guidelines on consent under Regulation 2016/679, WP 259 Rev.01, p. 27-29.

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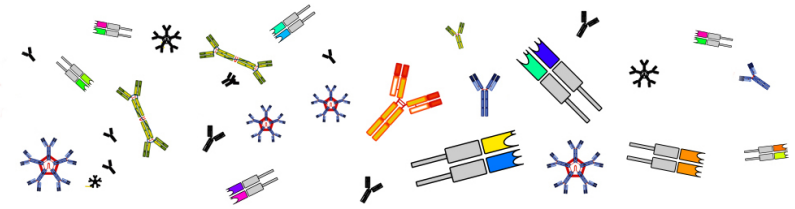

by hospitals, extracted from e-health records or obtained from health data repositories set up by public authorities. In these situations, research is a **secondary purpose** of the data processing.

As a general rule, secondary use of personal data is not prohibited by the GDPR insofar as the secondary purpose for which the data is re-used is not incompatible with the original purpose for which the data have initially been obtained.

This follows from the 'principle of purpose of limitation' as enshrined in article 5.1(b) of the GDPR. Pursuant to this provision, personal data shall be "collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes".

The limit between what is qualified as compatible and at which stage a secondary purpose becomes incompatible is not always easy to determine. Article 6.4 GDPR however contains some guidelines on how to ascertain whether the processing for another purpose is compatible with the original purpose for which the personal data were initially collected.

Yet, if **the secondary purpose of the processing of personal data is scientific research, compatibility with the initial purpose is legally presumed**. This 'legal presumption of compatibility' follows from article 5.1(b) GDPR which states: **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**.

The main consequence of this legal presumption of compatibility is that no separate legal basis is needed for the secondary use of genetic data for research purposes. This is confirmed in recital 50 which provides 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 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. […] Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing."

In other words: the further processing can be done relying on the same legal basis as the one used for the primary purpose. In practice, this means that in the case of secondary use of genetic data for research purposes, the initial legal basis on which the collection of the genetic data was grounded remains valid. It should however not be forgotten that, in such case, appropriate safeguards for the rights and freedoms of the data subject that should be in place in accordance with Article 89.1 GDPR.

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The processing activities performed in iReceptor Plus constitute a secondary use or further processing of data that were initially collected by academia, clinical and industry partners and that were deposited in repositories in an anonymous way.

While it is clear that the controllers that originally collected the data from the research participants for research as a primary purpose should have a legal basis for all processing of personal data (that stands next to the derogation of Article 9.2.(j) GDPR) and that legal basis will most likely have been the consent of the research participant, it is the responsibility of that controller to have a legal basis (such as consent) for each of the studies for which the data were originally collected.

It is however not required that iReceptor Plus has obtained the consent of the original research participants for all of the data processed, since (1) the data are anonymized, so that they no longer relate to an identifiable individual and consent could not be asked for any research studies that would be undertaken relying on the data accessed via the iReceptor Plus Scientific Gateway (2) even if the data processed in iReceptor Plus would still be identifiable to some extent, iReceptor Plus would not have to indicate a legal basis separate from that of the original research, given that the processing activities in iReceptor Plus constitute a further processing of data for scientific research purposes, which means that the purpose of processing is presumed to be compatible with the original purpose for processing, if appropriate safeguards for the rights and freedoms of the data subjects in accordance with Article 89.1 GDPR are put in place.

Requirement 6: Individual participants that have given consent for their data to be used in a particular subject area research should be able to easily access information about all the studies involved

This requirement relates to the right of data subjects to be informed about the collection and use of their personal data in accordance with Articles 13 and 14 of the GDPR (as was also the case in requirement 4). It requires data subjects to be informed of all the studies their data is being used for, when they have consented to the use of their data in a particular subject area of research. Essentially, requirement 6 thus demands that the purpose of processing (namely the studies in which the data of a data subject will be used are described as detailed as possible).

As was explained above, consent as a legal basis must in principle be specific for a particular purpose. This may however be problematic in the context of research, since health data may be collected from data subjects at a moment when the specific research project for which the data will be used, is not yet fully clear. In other cases, health data may be collected in view of a long-term research programme or to feed a repository of health data to be made available to the research community. The GDPR recognises this problem in recital 33 which provides a certain

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flexibility in the specification of the research purpose, stating that *"it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research".* This is often qualified as "broad consent" but it should be kept in mind that it "*does not disapply the obligations with regard to the requirement for specific consent to the processing of data for scientific research purposes."*

This means that when a 'broad consent' is given, researchers can arguably give a more 'generic description of the research purpose, i.e. the studies in which the data will be used. According to the Article 29 Working Party however, transparency is an additional safeguard when the circumstances of the research do not allow for a specific consent. A lack of purpose specification may be offset by information on the development of the purpose being provided regularly by controllers as the research project progresses so that, over time, the consent will be as specific as possible. When doing so, the data subject has at least a basic understanding of the state of play, allowing him/her to assess whether or not to use, for example, the right to withdraw consent pursuant to Article 7(3).

While the researcher who has originally collected the data from the data subject must evidently inform the data subject as much as possible in accordance with Article 13 GDPR, the controller who did not obtain the data from the data subject can be waived from the obligation to inform the data subject under Article 14.5.b GDPR if one of the following conditions is fulfilled: (a) "the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes", or (b) the duty to inform "is likely to render impossible or seriously impair the achievement of the objectives of that processing". The provision stipulates that in such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available"

Applicability in iReceptor Plus

Given that the data processed in iReceptor Plus are anonymized and the consortium thus has no way of retracing or contacting the research/clinical trial participants, the right of data subject to be informed in accordance with Articles 13 and 14 cannot apply.

Moreover, even if the data processed in iReceptor Plus would still be identifiable to some extent due to the fact that genetic data are concerned, in iReceptor Plus, the provision of the information laid down in Article 14 to the data subjects would arguably involve a disproportionate effort and would even require the consortium to acquire or process additional

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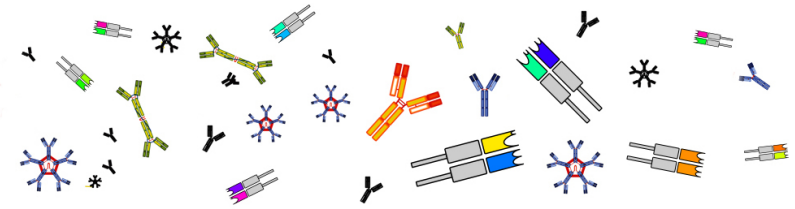

information to identify the data subject for the sole purpose of complying with the GDPR, which would run counter to Article 11.1 GDPR.

Requirement 7: Individual participants should know the data protection officer governing the specific study

This requirement relates to the right of data subjects to be informed about the collection and use of their personal data in accordance with Articles 13 and 14 of the GDPR and more specifically, to be informed of the data protection officer governing a specific study.

Article 13 and 14 of the GDPR require that the data subjects be informed of a.o.

- The identity and contact details of the controller and the controller's representative;
- **The contact details of the data protection officer (DPO)**;
- The purposes for processing their personal data;
- The legal basis for the processing;
- The retention periods;
- The recipients or categories of recipients of the personal data;

Requirement 7 is thus similar to requirement 4 listed above. Therefore, the assessment of the applicability of this right above applies mutatis mutandis.

Applicability in iReceptor Plus

Given that the data processed in iReceptor Plus are anonymized and the consortium thus has no way of retracing or contacting the research/clinical trial participants, the right of data subject to be informed a.o. about the data protection officer in each of the studies in accordance with Articles 13 and 14 cannot apply.

Moreover, even if the data processed in iReceptor Plus would still be identifiable to some extent due to the fact that genetic data are concerned, in iReceptor Plus, the provision of information on the data protection officer governing each of the studies to the data subjects would arguably involve a disproportionate effort in particular taking into account the scientific research purposes of iReceptor Plus, so the obligation of controllers to inform the data subjects would be waived pursuant to Article 14.5(b) GDPR.

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Conclusion

This deliverable clarified that the objectives of iReceptor Plus entail a processing of anonymous data. More specifically, the iReceptor Plus consortium will further process data that were originally personal but have been anonymised prior to the processing activities of iReceptor Plus. Consequently, it is impossible for the iReceptor Plus consortium to fulfil POPD Requirement No. 14 which requires the consortium to meet and facilitate the exercise of several kinds of data subject rights, as the consortium is not able nor allowed to contact or retrace the individuals to whom the data ever related.

The deliverable moreover shows that even if some of the data in iReceptor Plus would still be found (re-)identifiable, the obligation to meet the data subjects rights would most likely fall under the derogations foreseen in many of the rights and would in any case run counter to the GDPR principle that the controller should not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the GDPR if the purposes for which a controller processes personal data do not or do no longer require the identification of the data subject.

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