STUDY INFORMATION AND INFORMED CONSENT FORM

**Instructions for Use**

Text in grey is not relevant for personal data protection, but is for your information only and meant to place the data protection provisions into context of the whole document.

Text in black is text required to fulfil personal data protection laws and regulations and must not be changed.

*[Text in green and italic is instructional and will have to be deleted while preparing the study specific ICF.]*

*Text in black and italic needs to be adapted for each study; it is either subject to a condition or requires choice/ customisation.*

**Introduction**

The following Study Information and Informed Consent Form (ICF) is an outcome of Work Package 4 (WP4) of the Innovative Medicines Initiative’s (IMI) Project “DO🡪IT”. DO🡪IT was the Coordination and Support Action (CSA) project within the IMI “Big Data for Better Outcomes” (BD4BO) programme (for more information see [www.bd4bo.eu](http://www.bd4bo.eu)). The DO🡪IT Consortium united partners from the pharmaceutical industry, academic research institutions and patient organisations.

WP4’s main outcome is this harmonised ICF template for clinical studies and further research. It is meant to cover all information required by the General Data Protection Regulation (GDPR) within a traditional (non-electronic) informed consent document to be signed by patients or healthy volunteers before participating in a clinical study; it does not address country specific requirements. This information aims to address the processing of personal data for (a) the conduct of a clinical study within a drug development programme (Part 1) and (b) future scientific research on personal data and biosamples collected in clinical studies, i.e. research beyond of the original drug development programme (Part 2).

Beyond the personal data protection provisions, this template proposes a full ICF structure to place the information into context. Both the content and the structure have been discussed with various stakeholders including representatives of several European data protection authorities and Ethics Committees, European Patient Associations, study sites as well as of service providers including CROs. It may however not necessarily reflect the position of each involved individual or institution, nor does it set a defined standard among them, but it has been developed to be a balanced compromise on a still shaky legal framework.

This document is a living document and not carved in stone. The main goal was to achieve as much harmonisation as possible across the EU and beyond to foster further alignment among all stakeholders in order to enhance transparency for research participants and to reduce bureaucratic burden for researchers. In this sense it is a starting point and not the end of the debate. It is expected to be tested and updated within either a following European project or another type of consortium and supplemented by further guidelines.

Therefore, this template is expected to be used as a starting point for further harmonisation of practices when informing and collecting consent from patients and healthy volunteers. In first place, it is a tool dedicated to clinical study sponsors, but moreover it is expected to be evaluated by local and European stakeholders (associations of patients, pharmaceutical companies, data protection authorities and ethics committees) while developing their specific standards (e.g. if developing a local ICF template or guidance).

The final structure and wording was tested by patient focus groups and considered to be understandable and transparent. If you have questions about this document, please contact Anne Bahr (Sanofi, [RnD-Data-Privacy@sanofi.com](mailto:RnD-Data-Privacy@sanofi.com)) and Irene Schlünder (TMF, [Irene.Schluender@tmf-ev.de](mailto:Irene.Schluender@tmf-ev.de)).

Further information about the content of this template and the reasoning behind most important topics can be found in the “Explanatory Information” document.

*[Include Sponsor’s logo]*

STUDY INFORMATION AND INFORMED CONSENT FORM

There are [4] parts to this document:

Part 1: the “**Study Information**” essential to your decision to take part in the clinical study,

Part 2: the “**Future Research Information**” which explains the possibility to contribute to future research, subject to an optional consent

Part 3: your “**Consent Form**” which summarise what you may agree to and

Part 4: supplementary information in the “**Additional Information for Patients**” section.

# PART 1: STUDY INFORMATION

[Study number & Product code]

[Title of study]

*[This section will contain an introduction, invitation, brief summary of study, general considerations, approval of EC/IRB, confidentiality of participation, introduction of participants (sponsor, site, major CROs), phase of study and information about the documents]*

|  |
| --- |
| *The overall description of this study (including the collection, storage and use of your data and biosamples as well as this document) has been reviewed in your country by an independent Ethics Committee to ensure that the rights, safety and well-being of study participants are protected.*  *Your condition may or may not improve if you join the study. But, the information we get from this study might help other patients with the same condition in the future.* |

## What is this study about?

*[This section will contain a description of the study participants’ condition(s) which is(are) evaluated, the type of study (experimental drug [please make sure to replace “drug” with appropriate terms such as “medical device” or “vaccine” throughout the document if needed] vs drug already on market, safety study vs new indications, etc.), an overview of the high-level purpose (all detailed purposes to be explained in the section related to the processing of personal data), the size of the study, a brief description of the study drug (e.g. route of administration such as tablet taken orally, comparator(s) vs placebo(s), how the study drug works.]*

|  |
| --- |
| *You have [Insert condition. For healthy volunteer studies, adapt as appropriate]*  *We are doing this study to learn more about [Explain experimental drug/ device/ procedure].*  *Some parts of this study are experimental which means [Insert: “they have not been tested yet, fully tested”, etc.].*  *The untested parts of the study are [Insert description of which parts of research are experimental].*  *About [number] [people/women/men] will take part in this study.* |

## Do I have to take part?

*[This section will contain voluntariness of participation and short description of alternative procedures / courses of treatment including time frame as well as their risks and benefits.]*

|  |
| --- |
| *You have a choice whether or not you would like to participate.*  *Please take as much time as you need to make a decision about whether or not you would like to participate in this study. It may be helpful to talk with your friends and family as you make this decision.*  *If you join the study, you can leave at any time. Leaving will not affect your care. If you choose to leave the study, please let us know as soon as possible.*  *If you don’t join the study, you will continue to receive care for your [Describe condition]. Your study doctor will talk to you about other possible treatments, their risks and benefits.* |

## What will happen if I join the study?

*[This section will contain a detailed description of the study including duration, planned procedures, prerequisites for participating (no pregnancy, no breast feeding, screening), information on possible discontinuation of the study, and information about treatment after the study.]*

|  |
| --- |
| *You will be in the study for [length of time].*  *You will not receive the study drug in any case [Explain placebo and comparator studies]. You will be randomly assigned a study treatment (“randomly assigned” means that whatever treatment you get will be by chance, like flipping a coin or drawing names out of a hat).*  *You will have [Describe number and type of procedures, such as “10 visits that will last between 1 and 3 hours”. Clarify what will happen at each visit such as things to observe, other medication etc.)]*  *To read more about this, turn to the additional procedures information provided in “Part 4: Additional Information for Patients”.*  *Please note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see “What will happen if I do not wish to carry on with the study?” for more details).* |

## What are the required tests and procedures?

To conduct the study, some tests and procedures will have to be performed on you.

The tests will include *[Complete the paragraph to describe all tests that are necessary for the study. The list and a brief description of each test must be provided here and details developed in the appendix, depending on its length & complexity.]*

The procedures will include *[Complete the paragraph to describe all procedures that are necessary for participating in the study. The list and a brief description of each test and procedure must be provided; additional details can be added in the appendix section. The number and type of biosamples and the amount of blood taken for any test should be provided in mL (tablespoon must be included too for the USA).]*

The complete list of tests and procedures, including their detailed schedule is available at the end of the document in “*Part 4: Additional Information for Patients*”. This section also provides more details on **biosamples** handling and storage locations.

*[Next section will be included if genetic analysis is planned in the study. If not planned, move it to either the “What are the optional tests and procedures?” or “Part 2: Future Research Information]*

***Genetic analyses***

*Some biosamples will be used to analyse your genetic information. You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body but some words or letters may be different from one person to the other. Some of those differences have no effect on your health but others can* *influence the likelihood of developing a disease or affect how medicine to treat a disease will work. If genetic analyses are done, they may involve all or part of your genetic information. [Description to be further developed based on specific planned tests. If whole genome sequencing is planned, it must be indicated].*

*[Next section will only be included if any optional test or optional procedures are proposed.]*

## What are the optional tests and procedures?

*[This section will list all tests and procedures which are optional but already planned in the protocol (e.g., pharmacogenetics blood sampling for drug metabolising-enzyme and transporter (DMET) analysis.) Specify that an optional checkbox confirming agreement to participate is required in the Consent Form. The use of biosamples for future research will not be discussed there”.]*

*[Insert test or procedures names] are optional in this study. If you agree, you may provide your consent by ticking the checkbox in the consent form. [Where extra biosamples are needed, add the following: An extra sample [Describe type and amount] may be collected during the study for optional tests. Where “genetic analyses” are not conducted as required tests, but are conducted as optional ones, copy their descriptions here.]*

## What are the risks of joining the study?

*[This section will contain the most common or serious side effects of all medications, tests and procedures that are planned to be used for this study as well as of those already known for the study drug (for the country ICF, this section might need adaption due to specific labelling in the country). This section will also describe the potential lack of effect when receiving a placebo. The list can be continued in the appendix section as appropriate.]*

|  |
| --- |
| *It is possible that some patients could have side effects that we do not know about yet.*  *If you have severe side effects from the study drug, the study doctor may ask you not to continue in the study.*  *To read more about the other risks, turn to the additional risk information provided in “Part 4: Additional Information for Patients”.* |

## Are there any other considerations or risks I need to know about?

*[This section will contain (1) any special warnings, (2) restriction of consumption of other medicines, food, drinks etc. whilst in the study, (3) restrictions on driving, using machinery, sport or other activities whilst in the study, and (4) instructions for pregnant study participants and those who may become pregnant, including breast-feeding and duration of contraception requirements.]*

*[The next section will be included if information on pregnancy/ birth/ health of a baby are relevant.]*

***Pregnancy***

*[For clarity, for data on the health of the baby once born, a separate ICF form will be applicable.]*

*You (or your female partner if you are a man) must not get pregnant or breastfeed a child during the study. You must use effective birth control during the study and up to [include duration in months or weeks] after you have finished the study. The study doctor can discuss acceptable birth control methods with you.*

*If you or your partner becomes pregnant, you must tell the study doctor within 24 hours of finding out. You will have to stop taking the study drug immediately and you and your partner will be asked under a separate consent to provide information about you and your baby for at least [include duration in years, months or weeks] after the birth.*

## What are the possible benefits of taking part?

*[This section will describe if study participants shall expect their condition to benefit from the study drug or not, as well as the potential benefit for others.]*

|  |
| --- |
| *There is no certainty that you will have any benefit from the study drug. However, it is expected that [\_\_\_].*  *The information the study sponsor receives from this study may help to treat study subjects better with [\_\_\_].*  *It is not certain that you will directly benefit from the participation in the study. Your participation may, however, help other patients in the future by improving the knowledge of diseases and improving medical care.* |

## What happens if something changes while I am in the study, e.g., if new information is found?

*[This section will describe what will happen if there are new medical findings related to the studied conditions, either during or after the study, including the possibility to stop participating in the study and take the newly discovered treatment.]*

|  |
| --- |
| *Changes may happen in the study that could make you change your mind about continuing to take part. If something changes, we will tell you as soon as possible.*  *You can choose to leave the study at any time. For more details see section below “What will happen if I want to quit the study?”.*  *The study doctor can also choose to take you out of the study if they believe that it is best for you.* |

## What happens if I am harmed or injured during the study?

*[This section will describe what to do in case of emergency.]*

|  |
| --- |
| *If there is an emergency, call [applicable emergency number to be inserted] right away or go to [insert applicable reference e.g.: the emergency room] and contact your study doctor as soon as you can.*  *For other medical problems, contact your study doctor right away. They will treat you or contact another doctor.*  *The costs of your care resulting from an injury or illness during the study will be billed to [complete as appropriate e.g.: you or your insurance].* |

## What will happen to my data and biosamples gathered in the study?

### Which data and biosamples are collected?

In order to conduct the study, the **study site** will have to collect and register information about your identity (such as your name, address, telephone number, and health insurance number) as well as data that is necessary to assess your health conditions (such as *[Describe categories of data, adapt as needed: your medical condition and medical history (this may include information from your physicians/ available in your medical records), your life style, [where applicable and collected, make sure you also list: your sexual life,]) your demographics (age, gender, [where applicable and collected, make sure you also list ethnic and racial background]), your images (e.g. x-rays) and your genetic information]).*

*[In rare cases where no biosamples are being taken, delete the next paragraph.]*

In addition, the study site will collect biosamples from you (such as blood or body tissue). These will be analysed and the data derived from the analysis will be part of your **coded data** *[where applicable and collected, make sure you include the following: which will also include genetic data.]*

### What are my data and biosamples needed for?

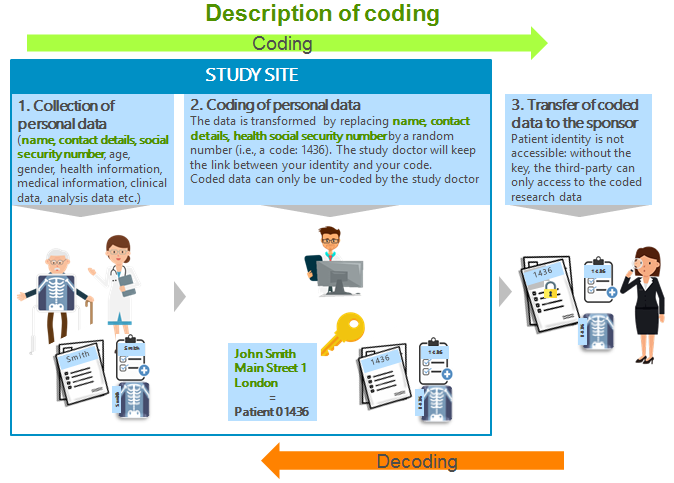
*[The next section summarises the purposes of use of clinical data throughout the drug development programme. Please make sure it is properly reflected in the study protocol.]*

Your data and biosamples are needed for the **sponsor** to develop the drug, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances, i.e., throughout the drug development programme. Therefore, they will be used as planned in this study as well as within related research activities necessary for this drug development programme in order to:

* understand how the study drug and similar drugs work in the body (i.e., evaluate the study drug mode of action),
* better understand the studied disease and associated health problems,
* *[unless you are sure that this may never be done, also add: develop diagnostic tests for the disease,]*
* learn from past studies to plan new studies or improve scientific analysis methods,
* publish research results in scientific journals or use them for educational purposes,
* *[where other purposes of use are necessary for the drug development programme and not subject to a choice (i.e., no separate consent), add them here]*.

### Who can access my data and biosamples?

Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the sponsor and being bound by a duty of confidentiality as well as **health authorities** *[where required add: and Ethics Committees]* may also be given access to this data only to verify that the study is carried out in compliance with legal and quality requirements.

The study site will share your data and biosamples with the sponsor but only after they have been coded (which means that your name, contact details or health insurance number, have been replaced by a code. For more details about coding, see the diagram below or further details at the end of this document in “*Part4: Additional Information for Patients*”).

The sponsor may share your coded data and biosamples with its **research partners** and **service providers** for the purposes of the drug development programme.

In order to ensure proper conduct and accurate results of the study and to get permission to market the drug, the sponsor will share your coded data with authorities and possibly with Ethics Committees. They may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results.

In **none** of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards than your country, appropriate **safeguards** (such as contracts and technical **security measures**) will be adopted to protect and maintain the confidentiality of your data and biosamples as further described at the end of the document in “*Part4: Additional Information for Patients”*.

In case another organisation takes over development or commercialisation of the study drug, your coded data or biosamples may be transmitted to them. They will then have to protect your data and biosamples in the same way as described herein.

### Who else may have access to my data and why?

*[The next section related to access to “name and contact details” will be included if people other than the investigator’s team or other authorised person as listed in section 11.c may have access to study participant’s fully identifiable data.]*

#### Access to my name or contact details by service providers

*[If applicable, describe other parties who will collect or access study participant’s fully identifiable data where necessary for the study (e.g., call-out centres that have access to study participants’ names and phone numbers); adapt as necessary: Your name or contact details may leave the study site and be sent to service providers, in order to:*

* *[Include if applicable: reimburse you for your time, effort and certain expenses related to your participation.]*
* *Allow call-centres to reach you for telephone interviews related to the study.*

*[The next section will only be included if people other than the investigator’s team and those listed above may have access to the study participant’s fully identifiable data, for optional services subject to consent on the signature page which require access to their identity.]*

* *Offer you the following additional services to ease your participation in the study: [Specify which ones, e.g.: courier service for delivering the drug to you at home, home nurses to make it unnecessary to travel to the study site, optional text messaging service to remind you of your visits, biosamples pick-up from your home to be taken to the central lab, transportation and study logistics support, etc.).] [Provide all useful details related to the optional services, explain each service and who will have access to which data including where possible, the name of companies which will have access to the study participant’s name or contact details; also add the following: If you agree to register to [this/ these service(s)], a tick-box available in “Part 3: Consent Form” will allow you to make this choice.]*

The service providers must keep your name or contact details private and will **NOT** share any information that can directly identify you with the sponsor.

*Next section will only be included if study participants are to be registered in a national registry (e.g. for healthy volunteers).]*

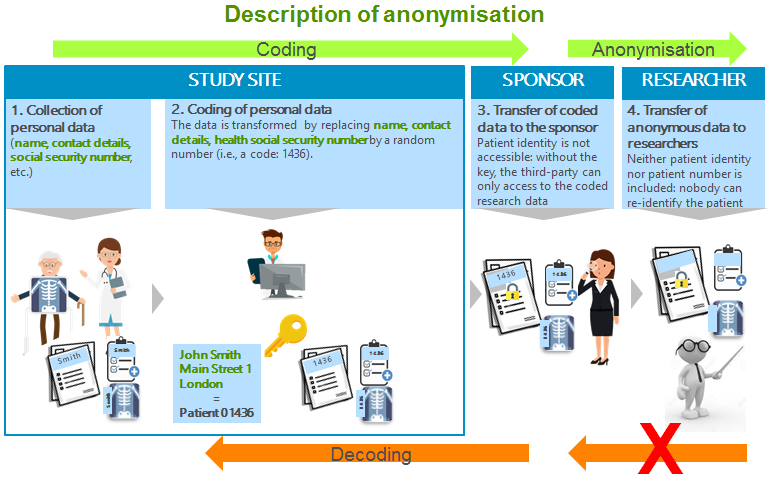
#### Transfer of my [adapt as needed: name and/or contact details or coded data] for National registry

*Your data will be entered in the [Specify the national register] as required by [Specify applicable law, e.g. Public Health Code]. You can check the accuracy of the data with the [Specify the body, e.g. Health Ministry] and enquire about the deletion of these data at the end of the applicable retention period.]*

### How long will my coded data and biosamples be kept?

The study site and the sponsor are obliged to keep all study data for *[Insert applicable retention period. For studies involving European countries, indicate 25 years to comply with the Clinical Trial Regulation. If you know that other countries require more than Europe, indicate the longest known period: 25 years after the end of the study],* unless there is a legal requirement for keeping them longer. Your coded data will then be deleted or anonymised, and your biosamples destroyed as soon as possible after their analysis unless you authorise the sponsor to use them for future research (a tick-box available in “*Part 3: Consent Form*” will allow you to make this choice).

### What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge, and is in the best interest of patients and public health, provided that Patient privacy is protected. Therefore, the sponsor may generate and share internally or with other researchers an anonymised set of your data collected in the study (e.g., on [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com)). This means your coded data will be stripped of your Patient code as well as of any other information that could reasonably be used to identify you such as your exact size.

### What are my rights under data protection law?

*[The study participant rights provided by the GDPR depend on the legal basis you chose and on the local implementation of the GDPR (especially of article 89.2).]*

You have the right to review which of your data are collected and being used; you can also ask for a copy of this data, ask for restriction of use of this data, *[to be added only where the right to object has to be mentioned: object to the use of your data]* or ask to have incorrect data rectified. *[To be added where the right to portability applies: You can also ask the study doctor to receive a copy of the data you have provided for the study in a standardised electric format or to have them transmitted to another person of your choice.]*

To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends, because in this study, *[Adapt as needed neither you nor the study doctor know if you are receiving the study drug or the [insert appropriate term, e.g. “placebo” or “standard therapy”]].*

To exercise these **rights**, please contact preferably the study doctor. Contact details of the Data Protection Officer (**DPO**) are provided in “*Part 4: Additional Information for Patients*”. If there are issues related to the use of your data, you have the right to file a complaint with your local data protection authority or with the sponsor’s one (*[Add the name of the sponsor’s supervisory authority, e.g.: CNIL, the French data protection authority]*).

## What will happen to the overall results of the study?

*[To be included when the EMA website for lay summary is available: A summary of the study results will be made available at the latest one year from the end of the study in all countries. You will be able to find it here [Insert appropriate URL].*

*[Include reference to the publication of studies and results on websites from health authorities or others. For studies conducted in the US, the following wording is mandatory: A description of this study will be available on* [*www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results.]*

You can search *[Select as needed: this/ these]* website*(s)* at any time, using the number of this study as indicated on the first page of this document to ease your search.

## What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop your participation, you should tell the study doctor.

*[Insert appropriate language related to how and by whom the study participant will then be treated e.g. that this may have no effect on standard medical care].* If you stop participating in the study *[Be aware that this is a “study discontinuation”, and not a withdrawal of/ objection to consent for processing personal data]*, the study doctor will stop the collection of your data but your previously collected data and biosamples will be kept and used to guarantee the validity of the study and comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don’t show up at a planned visit, the study doctor will try to reach you. If the study doctor cannot reach you, official public sources will be consulted to verify your wellbeing. It is not mandatory but would be helpful for the study if you explain to your study doctor why you wish to stop your participation, in particular if you have experienced discomforts.

If you would like your data or biosamples not to be used after you quit the study, you must inform the study doctor. In such case, your remaining biosamples will be destroyed as soon as possible, but your coded data previously collected will be kept as required by clinical regulations.

## Who can answer any questions I may have?

Remember, there are no stupid questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this study *[Insert the following only if biosamples are collected and therefore future research on them is possible: as well as in the future research proposed in Part 2*.*]* You can contact the study doctor at any time at the address indicated in “*Part 4:* *Additional Information for Patients*”.

Additional information about the study can be found in “*Part 4: Additional Information for Patients*”.

# PART 2: FUTURE RESEARCH INFORMATION

*[This part will be included for all studies, even if future research is not yet concretely planned at that time.*

*This optional consent is to be collected alongside the consent for the study, preferably within the same document. If this optional consent is obtained at a later point in time than the consent for the study, please add additional wording with respect to the controller’s identity, contact details (and where applicable its representative) as well as details related to ethical review, patient rights and foreseeable risks and benefits. To do so, use “Part 4: Additional Information for Patients”].*

In addition to participating in the clinical study, we would like to know if you would be willing that your coded data *[add unless no biosamples is collected: and leftover biosamples]* are used in future research projects. *[Add only if additional biosamples will be collected: Your consent to future research means that you also consent to provide additional biosamples for use in these same future research projects.]*

You are free to consent to the use of your coded data and biosamples for future research. If you decide not to do so, you may still take part in the clinical study.

## What is future research?

Future research is important to advance science and public health. At present, however, it is not possible to foresee all details of future **scientific research** projects.

Your coded data *[Add if biosamples will be used too:* and biosamples*]* may only be used for scientific health-related research *[domain restrictions should not be added, but where absolutely required to restrict the scope further, list all the fields in which you may operate by inserting the following: limited to [list all potential areas e.g.: Oncology, Cardiovascular Diseases and Neurodegenerative Diseases]* to find new ways to detect, treat, prevent or cure health problems.

They may also be used jointly with information from other sources outside typical clinical research settings, e.g. from public research databases such as *[list examples]*. However, they will not be combined with other information in a way that could identify you.

*[Genetic analysis must always be included in the scope of future research because genetic analysis is really common nowadays and necessary for most research. Study participants who would not agree to the possible use of their biosamples for genetic analyses should refuse to participate in future research using biosamples. Always include the following except for studies where no biosamples were collected:* Some research projects may require the analysis of your genetic information.*]* *[If genetic analysis was not planned in the clinical study, copy the text provided in the “Genetic analyses” section: The text starts with “You can think of” and ends with “all or part of your genetic information.”]*

Information can be provided about the research and the general results of the research by contacting [*adapt as needed: the sponsor*]. *[Where possible, replace by existing means available, for instance: [on this website: [Insert website URL]].*

## *[If additional biosamples must be collected for future research, include this section; if not, discard this section.]* Which additional biosamples do I have to provide?

*If you consent to future research, we will collect additional biosamples from you as follows: [Include description, as appropriate, of (1) specimen type, (2) amount to be taken (per sample and total), (3) when, (4) from where and (5) how it will be taken, and any risks involved in the collection procedure. Please adjust according to your needs.]*

*Your additional biosamples will be coded like the ones collected for the purposes of the clinical study.]*

## How will my coded data and biosamples be handled?

All biosamples will be securely stored *[add as appropriate: on behalf of the sponsor] [when required by law, specify the exact location of storage of biosamples]* for up to *[indicate period, or if that is not possible, indicate criteria used to determine that period; local requirements may apply] and will be destroyed thereafter. [When location is indicated, add the following: Please note that the location of the biosamples may change at the request of the sponsor.]*

Any additional data generated from your biosamples will be stored for up to *[indicate period] OR if that is not possible, indicate criteria used to determine that period or indicate: as long as necessary for scientific research objectives and allowed by law]* and will be destroyed or anonymised thereafter.

## May my coded data and biosamples be shared?

The sponsor may share your coded data and biosamples with research partners *[remove only if required: or* **deposit** *them in scientific databases]* as described at the end of the document in “*Part 4: Additional Information for Patients*”. This may include researchers *from [Insert institutions if known], as well as universities, research hospitals, and drug- or health-related companies [Add any other category of organisations that may apply].*

*[Add unless you exclude any data to be transferred outside the EU:* Some of the above-mentioned recipients may be located outside your country. The data protection laws which apply in those countries may not be as stringent as the laws in your country. Nevertheless, appropriate safeguards and security measures will be taken in order to protect and maintain the confidentiality of your biosamples and coded data as described at the end of the document in “*Part 4: Additional Information for Patients*”.]

## How will my privacy be protected?

Your coded data and biosamples will be subject to appropriate safeguards, as specified in “*Part 4: Additional Information for Patients*”, and will only be used for the purpose of scientific health related research. They will not be used to contact you or to affect your care or any other decision affecting your life such as insurance rates or employment opportunities.

You have the same rights as the ones described in the section “*What are your rights under data protection law?”.*

## What if I want to withdraw from future research?

Your participation in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without giving a reason and without a negative effect on your standard of medical care. If you wish to withdraw, please inform *[adapt as needed: e.g. your study doctor, the DPO of the sponsor]*.

You may still continue to participate in the clinical study even if you choose to withdraw from future research.

If you withdraw from future research, your coded data and biosamples will not be used for future research and will be destroyed as soon as possible. Your coded data (either copied from the clinical study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications.

## What happens if there are unexpected findings?

We may have to study coded data and biosamples from many people over many years before we can know if the results of future research are meaningful.

Therefore, you should not expect to receive individual results from future research projects. We will not give any such data to your doctor and we will not put them in your medical record as they are not individual valid results.

However, there is a small chance that we could one day discover something that might be very important to your health or medical care. If this happens while your data is still coded (i.e. not anonymised), we will use reasonable efforts to inform your study doctor, so that he/ she can discuss further options with you to confirm the findings. In case you do not want to be informed about such findings, please *[Select one option depending on applicable laws/ regulations and internal policy: tell the study doctor/ do not consent to future research].*

**You are free to consent to the use of your coded data and biosamples for FUTURE RESEARCH. If you agree, you can indicate this in the CONSENT FORM.**

# PART 3: CONSENT FORM

*[Include clinical consent wording such as:]*

*I confirm that:*

* *The study doctor [in case local law permits consenting by personnel other than investigators, insert: or study personnel delegated by the study doctor] [has/ have] explained the study to me comprehensively.*
* *I have had the opportunity to discuss the study with the study doctor and all my questions were answered.*
* *I have had an adequate amount of time to consider the study.*
* *I have read and understood all the above information related to the study.*
* *I understand that I will receive a copy of this document once I have signed it.*
* *I understand that my decision to take part in the study is entirely voluntary. If I decide not to participate in the study or to stop my participation during the study, this will not affect my standard medical care.*
* *I have truthfully answered all questions about my medical history and will follow all rules listed in the document.*

I consent to take part in the clinical study and study procedures described herein. I understand that my participation also entails:

* My name and contact details being collected during the study as described to me, and accessed and reviewed by listed authorised people;
* My coded data being used by the sponsor or by people or companies acting on its behalf or working with the sponsor;
* My coded data being used by persons or organisations located in countries that do not have data protection rules equivalent to those of my country. I understand that the sponsor monitors these uses and takes all possible measures to protect my privacy;
* My biosamples being collected and analysed as described herein *[Add where applicable: and that this includes genetic analyses]*.

**I further understand that I can make a choice about the topics listed below and that by ticking “Yes” I do give consent and that by ticking “No” I do not give consent:**

|  |  |  |
| --- | --- | --- |
| *[Include where applicable: My participation to optional tests/ procedures ([Specify all optional tests/ procedures described in Part 1 - section 5])]]* | *Yes* | *No* |
| *[Include where applicable: My registration to “Optional Services” ([Specify all optional services described in Part 1 - section 11-d ])]* | *Yes* | *No* |
| The use of my coded data and biosamples for future research, as described in “*Part 2:* *Future Research Information*”, *[Add where applicable: including the collection of additional biosamples] [Add unless the study does not require any biosamples: and where necessary for the research, possible analyses of my genetic information]* | Yes | No |
| The study doctor may notify your physician of your participation in the study and may share relevant medical information with him/ her if necessary for managing your health and safety throughout. If you agree, please indicate name and contact details of your physician here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

|  |  |  |
| --- | --- | --- |
|  | **STUDY PARTICIPANT** | **PARENT’S or Legally Acceptable Representative’s (LAR)** |
| FULL NAME (capital letters) |  |  |
| DATE  (dd-Mmm-Year) |  |  |
| SIGNATURE |  |  |

|  |  |  |
| --- | --- | --- |
|  | **PERSON OBTAINING CONSENT** | |
| FULL NAME (capital letters) |  | |
| DATE  (dd-Mmm-Year) |  | SIGNATURE |

*[The signature block may be appropriately placed before or after the detailed reference section. Its placement may vary based on the contents of the informed consent document (i.e., inclusion and placement of all elements required by federal regulation) and study complexity. Placement of the signature block and factors affecting it should be considered.]*

# PART 4: ADDITIONAL INFORMATION FOR PATIENTS

## Detailed list of visits

*[INSERT TABLE(S)]*

## Detailed Study Tests and Procedures Schedules

*[INSERT TABLE(S) – The number and type of biosamples and the amount of liquid such as blood taken for any test should be provided in mL (tablespoons must be included too for USA). The list and a brief description of each test must be provided either here or in the core section, depending of its length and complexity.]*

## Complete List of Risks and Side Effects

*[INSERT TABLE(S)]*

## HIPAA/Protected Health Information

*[Where applicable, insert mandatory US text]*

## Additional guidance to know more about the confidentiality of your data and biosamples

|  |  |
| --- | --- |
| **Your** **biosamples** | All your biological samples collected during this study and related to you, such as blood, urine, biopsy, surgical waste, as appropriate and listed in section 4: “*What are the required tests and procedures?*” *[add if applicable:* *and in section “Which additional biosamples do I have to provide?”].* All your biosamples are coded which means that your name will never be associated with them. |
| **Your** **coded data[[1]](#footnote-2)** | All your data collected at the study site with your name and contact details have been replaced by a code. This is done by the study doctor who keeps the link between your name/ contact details and the code to ensure your safety and confidentiality.  Coded information cannot identify you unless your study doctor provides your name or contact details, where allowed by applicable law. |
| **Sponsor details** | Sponsor: *[complete name and contact details; for large companies, indicate “[exact legal entity name], a [group name] company”]*  *[If the study is fully outsourced to a CRO, it is recommended to specify its name and insert the following: For this study, your coded data will be managed by [Insert CRO name (e.g. XYZ, an international company headquartered in France)].*  The sponsor has the overall responsibility for a clinical study. |
| *[Include only for non EEA sponsors:* ***EU representative of the sponsor****]* | *[Complete name and contact details of the EU representative of non-European sponsors. Please consider Art. 74 of the EU Clinical Trial Regulation 536/2014[[2]](#footnote-3)]* |
| **Study site details** | Study site: *[Insert name and contact details]*  The place where the clinical study is taking place and where you will have to go for the planned visits.  Study Doctor: *[Insert name and title]* |
| **Health authorities** | Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries. |
| **Research partners** | Any organisation which collaborates with the sponsor within the drug development programme or for future research. |
| **Service providers** | Any organisation bound to the sponsor by a contract, which may conduct activities on behalf of the sponsor under its strict instructions. This may include other researchers including so-called “contracted research organisations” (CROs) and IT companies hosting clinical data or providing IT services. |
| *[Include only if applicable:* ***Call centres****]* | *[Adapt as necessary: Your year of birth, phone number and schedule preference] will be sent to [Add call centre company name and country]. Your fully identifiable data will be entered directly into the study’s web application hosted [add location, e.g., on a French server, which means these data will remain in France at all times or in the US, and will be protected as explained in section 11b.]* |
| **Safeguards** | Appropriate safeguards will be implemented to protect coded data during and after the study and may include that:   * Access to the coded data will be limited to specific individuals subject to confidentiality obligations (including the obligation to not attempt to re-identify individuals/ decode the clinical data). * The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and further de-identification techniques may be applied. * A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. * When required by applicable law, scientific research is subject to the approval of Ethics Committees. * The coded data will not be shared for direct marketing purposes or other purposes that are not legal duties or are not considered scientific research according to the applicable data protection legislation. In particular, it will not be used to make decisions about future services available to you, such as insurance. |
| **Security measures: How is my data protected in other countries?** | The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data and biosamples coded, your data is also protected by high standard technical security means such as strong access control and encryption. They are also protected legally by the following means:   * Within the **European Economic Area** (EEA), the data privacy laws and regulations are the same as *[adapt as needed, in particular for non-EEA countries:* *in your country]*. * Outside the EEA, those countries are recognised by the European Commission as providing an equivalent level of data protection: Andorra, Argentina, Canada, Faroe Islands, Guernsey, Israel, Isle of Man, Jersey and New Zealand *[People developing ICF must verify at the following link that the list is still up-to-date:* [*https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries\_en*](https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en)*]* * *[To be included only if the group has implemented BCR which covers clinical studies: Within the sponsor group, your coded data are protected by* ***Binding Corporate Rules*** *(BCR).]* * In all other cases, your coded data are protected by contractual arrangements, Codes of Conduct or certifications which set the rules for personal information protection to those available in European countries (this could for instance be the case if the sponsor stores all its data with a US hosting company) or other alternatives set forth in the law.   You may obtain further information as well as a copy of these measures by asking your study doctor. |
| **Restricted** **rights** | Please note that the rights provided by the GDPR to get data discarded (i.e., the right to be forgotten) *[Include the following unless the right of portability applies: as well as to get data transmitted in a standard electronic format (i.e., right of portability)]* do not apply to such studies. |
| **DPO details** | Study site DPO: *[Where required insert contact details of the site DPO or of the person responsible for privacy if there is no DPO; this could be the case for studies taking place outside of the EU but sponsored by an organisation based in the EU]*  If you wish to contact the DPO of the sponsor, please be aware that your name is not known there. You would need to link your identity to your study participant number which may compromise the coding of your data.  Sponsor DPO: *[Insert contact details of the DPO or of the contact person for privacy if there is no DPO]* |
| **Scientific research** | Scientific research includes technological development and demonstration, fundamental research, applied research and privately funded research as well as studies conducted in the public interest in the area of public health. This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and treatments, for outcome research activities and to aid in pricing and reimbursement activities. |
| **Deposit in scientific databases** | *[This section will be included unless you exclude any data from being shared in scientific databases]*  To do more powerful research, it is helpful for researchers to share data by placing data into one or more scientific databases. Researchers can then study the data combined from several research projects and learn even more about health and disease.  If you agree to take part in future research, some of your coded data *[add only if the case may be:* *including* *genetic data]* might be placed into one or more scientific database.  Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people.  Your name and other information that could directly identify you (such as address or social security number) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential. |
| *[Include only if BCRs are listed as a security measures for transfers outside the EU:* **Binding Corporate Rules***]* | *[To be included only if group has implemented BCR which scope covers clinical studies: Internal rules of multinational groups which set the minimum rules for data protection to those available in European countries]* |
| **EEA (****European Economic Area)** | All European Union Member States as well as Norway, Liechtenstein and Iceland. |
| **Legal basis** | You will participate in the clinical study only if you consent to it. If you do so, data related to your health and to the study drug must be collected and processed to evaluate the efficacy and the safety of the tested drug, in accordance with legal requirements from:   * The clinical trials (i.e., the EU clinical trial regulation 536/2014 which requires the sponsor to collect and analyse such data before they are submitted to health authorities), * The EU regulations on pharmacovigilance[[3]](#footnote-4) which requires follow-up and reporting of adverse events to the health authorities, and * Any other applicable law.   The use of your coded data and biosamples for future research will only be possible if you provide optional consent for it. |

1. Coded data is just another term for “pseudonymised data”, which is used in the GDPR, which was preferred to render the document more readable. [↑](#footnote-ref-2)
2. Where the sponsor of a clinical trial is not established in the Union, that sponsor hast to ensure that a natural or legal person is established in the Union as its legal representative. Such a legal representative will be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and will be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative will be deemed to be a communication to the sponsor. [↑](#footnote-ref-3)
3. Regulation N° 1235/2010 of the European Parliament and of the Council of 15 December 2010 [↑](#footnote-ref-4)