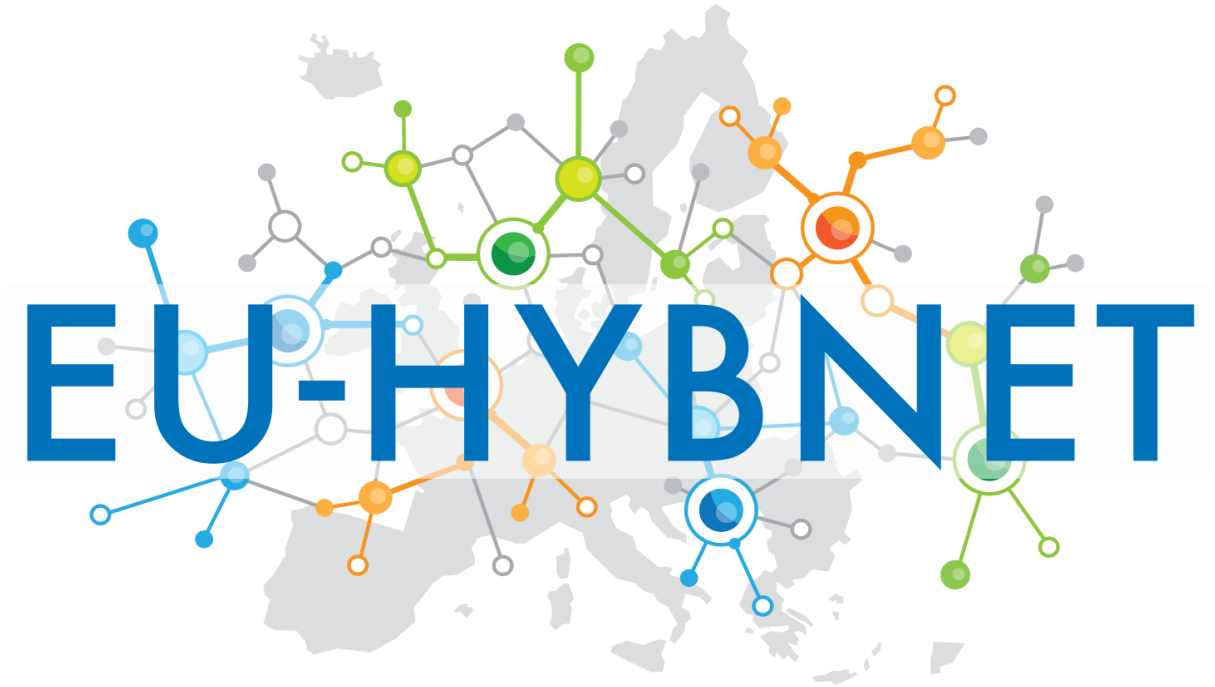

INFORMED CONSENT FORM TEMPLATE

DELIVERABLE 1.16

Lead Author: Laurea

Contributors: KEMEA-

Deliverable classification: PU

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0.3	27.6.2020	Georgia Melenikou/ KEMEA	Text review and text editing
0.4	28.6.2020	Tuomas Tammilehto/ Laurea	Incorporation of comments of the KEMEA
1.0	29.6.2020	Tuomas Tammilehto/ Laurea	Ready to submit

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TABLE OF CONTENTS

1. INTRODUCTION

1.1 OVERVIEW

The DoA describes this deliverable of the WP1 “Coordination and Support” simply as a document that presents the informed consent forms. There are two informed consent procedures:

The first one is for the participation of humans in the research , and it includes (a) an information sheet that is provided to the individuals prior to the start of the research activity/ies and (b) a consent form through which the individuals consent to participate to the research activity/ies.

The second one is for the personal data processing, and it includes (a) an information sheet that is provided to the individuals prior to the start of the research activity and (b) a consent form with which individuals express their consent for the processing of their personal data, if and when personal data is needed to collect.

The informed consent forms are related to the Work Package 1 objective number 2): “To ensure that all project ethical, legal and quality aspects of the project are thoroughly addressed and conducted”, since the informed consent forms are an essential part of ethical research, they constitute a legal obligation of the researcher, and ensure quality too.

The information sheets along with the informed consent forms are to be used by the consortium, and thus they are stored in EU-HYBNET’s online document repository (Eduuni). Here, in this document they are presented in the annexes, while description of the informed consent procedures and reasoning for the templates can be found in the following chapters.

1.2 STRUCTURE OF THE DELIVERABLE

This document includes the following sections:

- Chapter 2: In this chapter, the purpose of consent is explained together with the details of the content of the information sheet and the consent form, as well as the process how to ensure the consent.
- Chapter 3: In this chapter, consent processing personal data is explained along with the necessary information that needs to be included in the documents.
- Chapter 4: In this chapter, the storage of the templates is revealed and the responsibility of the organiser is touched.
- Section Annexes: In the Annexes are included the Information Sheets and the Informed Consent Forms

2. DEFINITION AND PURPOSE OF INFORMED CONSENT FOR THE PARTICIPATION OF HUMANS IN RESEARCH ACTIVITIES

What is informed consent then? Why we need consent forms? In the Directive 2001/20/EC Informed Consent is defined in relation to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

> "Informed Consent is the decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation."

Regardless that EU-HYBNET is not carrying any clinical studies as such, nor studying medicinal products this viewpoint is valid for our project's purposes too, since the aforementioned definition is based on the principle of *informed and free decision* that is fundamental for any kind of research activities, and also touches the practical embodiment of it, i.e. written dated signature, informing the participants, documenting necessary details etc. [1]

Free and voluntary participation, ensured with consent is pivotal for research, since without free consent the risk of e.g. distorted data would be significant and devastating for the validity of the research findings. Therefore too, it goes without saying that research activities can only be carried out based on the consent of the research participants. Inasmuch as EU-HYBNET intends to be ethical, this project too, like every other H2020 funded project, must guarantee respect for people and for human dignity, and fair distribution of the benefits and burden of research. Research must comply with ethical principles and applicable international, EU and national law.[2] Moreover, protection of the freedoms, rights and interests of the research participants is of paramount significance.

Thus, informed consent forms are obligatory. In EU-HYBNET, we provide for the participants' sufficiently detailed information on the research activities, so that they can make an informed, voluntary and rational decision to participate. The Information Sheet includes at minimum:

- Details of the project in general and of the type and purpose of the specific research activity
- Confirmation of the voluntary character of the research activity
- Information on their right to decline or withdraw at any time without any consequences
- Location and expected duration of the specific research activity

[1] During the COVID-19 crisis when people are working remotely, not face-to-face in same physical space, this has and can be been problematic. Consent is therefore sometimes the action itself: if someone participates willingly on a discussion online, knowing their sayings may be used for research purposes etc., the consent is then asked orally (or in a chat of the online working tool), and the permission has been given orally and confirmed by the participant's continuous participation in the research activities.

[2] The obligation is stated in legislation, but the true compulsion comes from the principles of responsible conduct of research. The principles of voluntary participation and informed consent have been stressed by various scholarly associations practically on every research field long before they epitomised as laws and regulations.

- Potential risk, discomfort or adverse effects
- Prospective research benefits
- Information on whom to contact for questions and for the exercise of their rights related to the research

Also, sufficient time must be allowed for the participants to ask questions on their participation, however not compromising the research objectives.

Therefore, when carrying out the EU-HYBNET research activities in which human participation has any role, e.g., interviews, questionnaires, workshops, brainstorming events etc. the informed consent procedures must be followed . This is regardless the fact that for the most the participants are foreseen to be members of the consortium, possibly members of other similar projects, or other legally competent adults who participate to the activities based on their personal or work related interest, and understanding well their role and their needed input.

Thus, the researcher shall inform before any EU-HYBNET research activity that the participation is voluntary, and anyone has the right to refuse to participate, and to withdraw the participation at any time, without consequences .[3] In addition, sufficient information on the participation and the research activities themselves will be given in a form of an Information sheet. This document will be distributed prior to the participation. Naturally, a written Consent form on the participation will be provide, to be signed before the commencement of the activities.

It is important that the participants are given enough time to read the documents to ensure that they understand them, but also that the participants do not feel coerced into giving consent.

The name and contact details of the persons responsible for the research action are also vital to announce.

[3] There is some ambiguity to this when individuals are participating to research activities as part of their occupation and/or representing their organisations, i.e., whether the involvement is truly voluntary. Therefore, the principle of voluntary participation is stressed to all partners to avoid such situations, e.g., that the organisations will not force anyone unwilling to participate in EY-HYBNET activities to begin with.

3. INFORMED CONSENT FOR PROCESSING OF PERSONAL DATA

At times, personal data needs to be collected for research or other purposes, and that data needs to be processed. We do not envisage that further processing of personal data has any significant role in the activities of EU-HYBNET, however, if there would be a case, clear guidelines for that need to be set, along with necessary information sheets and informed consent forms.

The grounds for this is are in the General Data Protection Regulation (GDPR). According to GDPR, the procedures which shall be followed for the participants' personal data processing, the researcher/data controller carrying out interviews/questionnaires/other activity with healthy volunteers, as we do in EU-HYBNET, must inform the participants in advance via a detailed Information sheet about the following:

According to Article 13 (1) and (2) GDPR, where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:

a) the identity and the contact details of the controller and, where applicable, of the controller's representative;

b) the contact details of the data protection officer, where applicable;

c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

d) where the processing is based on point

(f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;

e) the recipients or categories of recipients of the personal data, if any;

f) where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.

In addition to the information referred to above, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:

(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

(b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;

(c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

(d) the right to lodge a complaint with a supervisory authority;

(e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;

(f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) 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.

According to Article 7 of GDPR, where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language.

Any part of such a declaration which constitutes an infringement of the GDPR shall not be binding.

The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent. The language of the Information Sheet will be English which is considered to be a language familiar and intelligible to all participants. In case of any questions, the point of contact/ethical manager/researcher/data controller will be there ready to respond and make clarifications.

A copy of the Information Sheet will be given to the research participants, in order for the data controller to be sure that they will be able to read the information therein at any time and that they will exercise their rights whenever they see the need to do so.

Similarly to the consent to participate, informed consent is a key element of data processing too. Therefore, EU-HYBNET ensures that the participants will receive adequate information on the data processing activities and that their consent will be given freely via the filling in and the signing of an Informed Consent Form.

Then consent will be expressed as a rule in writing, but an oral statement might be used. Much like with the participation consent, after ensuring that the participant has read and understood the information included in the Information Sheet, the researcher/data controller provides the participant with an Informed Consent Form for Data Processing. This will be signed by the participant. The participants can withdraw their consent at any time without consequences. The personal information on the consent form must be processed in compliance with the General Data Protection Regulation.

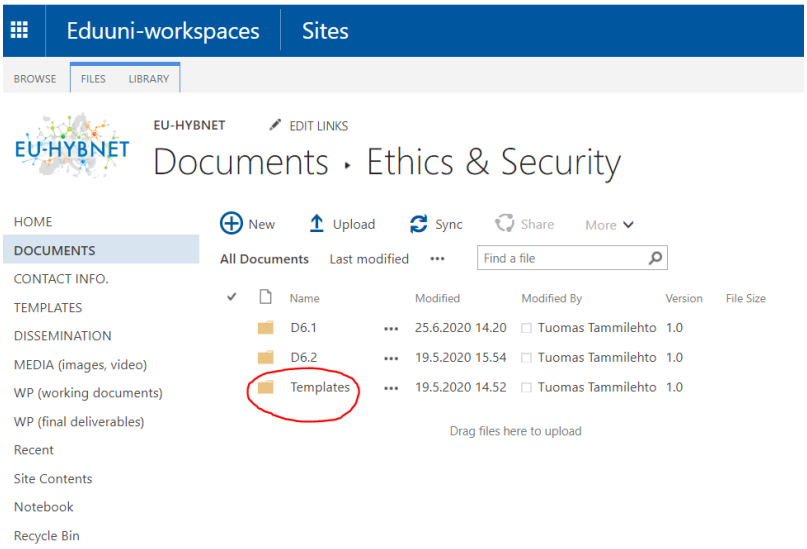
The language of the informed consent form will be English which is considered to be a language familiar and intelligible to all participants and, if needed, it will be translated to the language of the participants.

In case of any questions, the responsible person/researcher/data controller will be present ready to respond any questions and make clarifications.

Finally, after taking into account the nature of the data collected in EU-HYBNET, we do not foresee that the personal data collected will be made available for future research purposes, nor for purposes other than our research. Thus, no explicit consent of the data subjects for secondary use is needed.

4. STORAGE

The templates and information sheets will be stored in the online repository of EU-HYBNET (Eduuni) so that all the consortium partners will have access to them. The partners can ask them to be sent via email too.



As what comes to filing the signed consent forms, that is the responsibility of the organiser of the research activity to store and handle them properly. The signed informed consent forms will be stored securely by the data controller for the time-period mentioned in article 18.1 of the EU-HYBNET Grant Agreement (five years after the completion of the project) for accountability reasons.

Technical, organisational and security measures will be implemented by the data controller for secure storage to be ensured.

5. CONCLUSION

Taking both the consent to participate in any research activities and the consent for the processing of personal data into serious consideration, procedures have been put in place, and related templates have been formulated. They are for the consortium to use.

Of course, this deliverable alone does not make the ethical work of e.g. Ethical Manager redundant, quite the opposite, since the Ethical Manager will provide guidance throughout the project, e.g. on how to fill in the blanks. And, if needed, to rephrase templates altogether. In ethics, it is more important that the actual action is ethical than formalities, although they also need to be taken care of.

ANNEX I. GLOSSARY AND ACRONYMS

Table 1 Glossary and Acronyms

Term	Definition / Description
DoA	Description of Action
EU	European Union
EU-HYBNET	Empowering a Pan-European Network to Counter Hybrid Threats
GDPR	General Data Protection Regulation
WP	Work Package

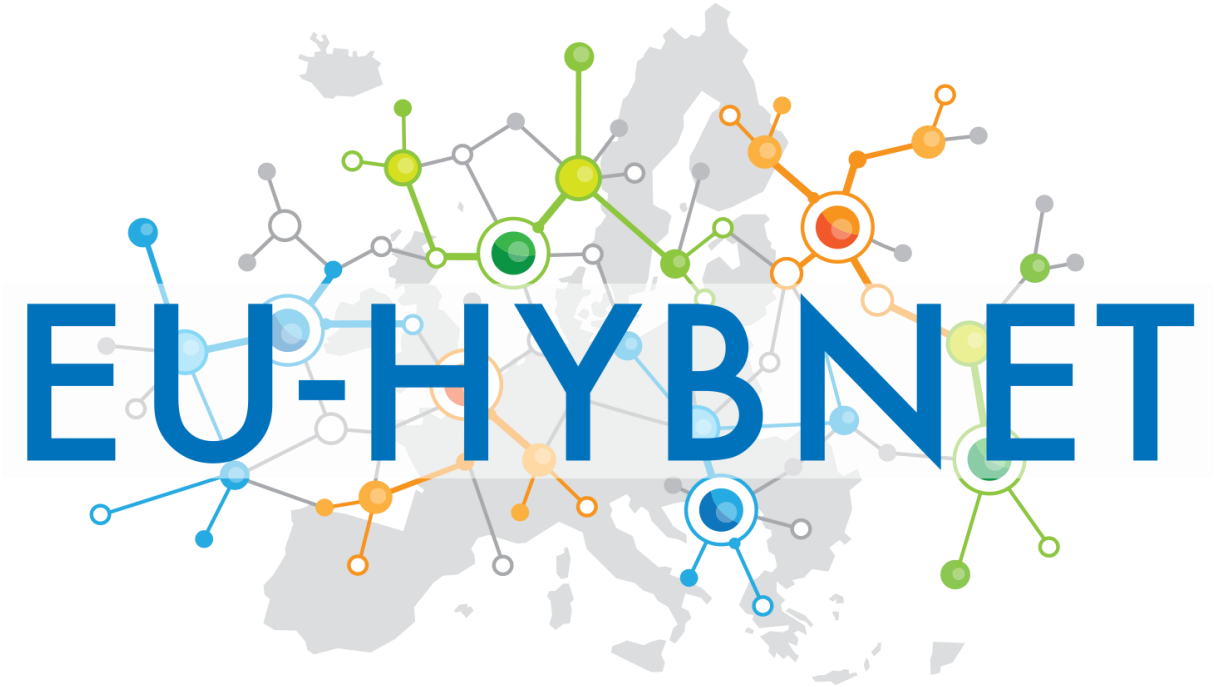
ANNEX II. REFERENCES

[1] Regulation (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[2] DIRECTIVE 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001.

ANNEX III. TEMPLATE OF INFORMED CONSENT FORM FOR PARTICIPATION IN RESEARCH (INCLUDING THE INFORMATION SHEET)

(Starting from the next page)



INFORMED CONSENT FORM FOR DATA PROCESSING FOR [INSERT THE RESEARCH ACTIVITY HERE + TASK & DELIVERABLE]

This project has received funding from the European Union's Horizon 2020 – Research and Innovation Framework Programme, H2020-SU-SEC-2019, under grant agreement No. 883054

INFORMATION SHEET FOR THE PARTICIPATION IN RESEARCH

[COPY THE INFORMATION SHEET TO BE GIVEN TO THE PARTICIPANTS TOO]

"Empowering a Pan-European Network to Counter Hybrid Threats" (EU-HYBNET) is a five year project funded by the European Commission (No. 883054). The EU-HYBNET is a Pan-European network of security practitioners, stakeholders, academics, industry players, and SME actors across EU collaborating with each other in ever increasing numbers to counter hybrid threats.

EU-HYBNET aims to build an empowered, sustainable network beyond the scope of the project through its on-going association with a key partner, The European Centre of Excellence for Countering Hybrid Threats (HCoE).

EU-HYBNET's activities comprise:

- define common requirements that can fill knowledge gaps, deal with performance needs, and enhance capabilities of innovation endeavours;
- monitor significant developments in research and innovation;
- deliver recommendations for uptake and industrialisation of the most promising innovations, that address the needs of practitioners, and determine associated priorities for standardisation;
- establish conditions for enhanced interaction among its members; and
- persistently strive to increase its membership and continually build network capacity through knowledge exchange, including exercises.

The EU-HYBNET consortium has 25 partners from 14 different EU Member States and associated countries. The consortium comprises of 12 Practitioner partners from 10 different EU MSs (FR, DE, NL, PL, ES, IT, RO, EE, FI, NO) and the remaining Partners represent industry, SMEs, academia and other organisations and reside additional 4 EU MSs (GR, SE, LT, BE).

The specific activity of EU-HYBNET concerning your participation is [INSERT THE RESEARCH ACTIVITY HERE in the context of < Task and Deliverable name and number >], and it aims to [INSERT THE AIM AND GOAL OF THE RESEARCH HERE].

Your participation in this research activity is voluntary, and the purpose for the participation is to [INSERT THE REASONING FOR THE PARTICIPATION HERE].

The duration of your participation will be from ___.___._____ to ___.___._____.

The responsible organisation of this activity is: [ADD YOUR ORGANISATION NAME HERE].

The contact person is [ADD THE NAME OF THE POINT OF CONTACT].

The participation to the activity may contain the following risk(s), discomfort(s) and/or disadvantage(s):

- [ADD HERE THE FORESEEN RISK(S), DISCOMFORT(S) AND/OR DISADVANTAGE(S)]

The participation to the activity may benefit you in the following way(s):

- [ADD HERE THE POSSIBLE BENEFIT(S)]

CONSENT FORM FOR THE PARTICIPATION IN RESEARCH

[THIS PAGE IS FOR THE RESPONSIBLE ORGANISATION]

I **have read the Information Sheet** for this research activity that will be carried out as part of <deliverable number and title> of the H2020 EU-HYBNET project: YES / NO

I understand that I may ask **further questions** at any point: YES / NO

I understand that I am **free to withdraw** from the research at any time without giving a reason for my withdrawal without any consequences to my future treatment by the researcher: YES / NO

I **wish to participate** in the research under the conditions set out in the Information Sheet: YES / NO

I have received a copy of the details of this particular activity in which I am participating (Information Sheet for the participation in research).

Location: ……

Date: ……

Name and signature of the participant:

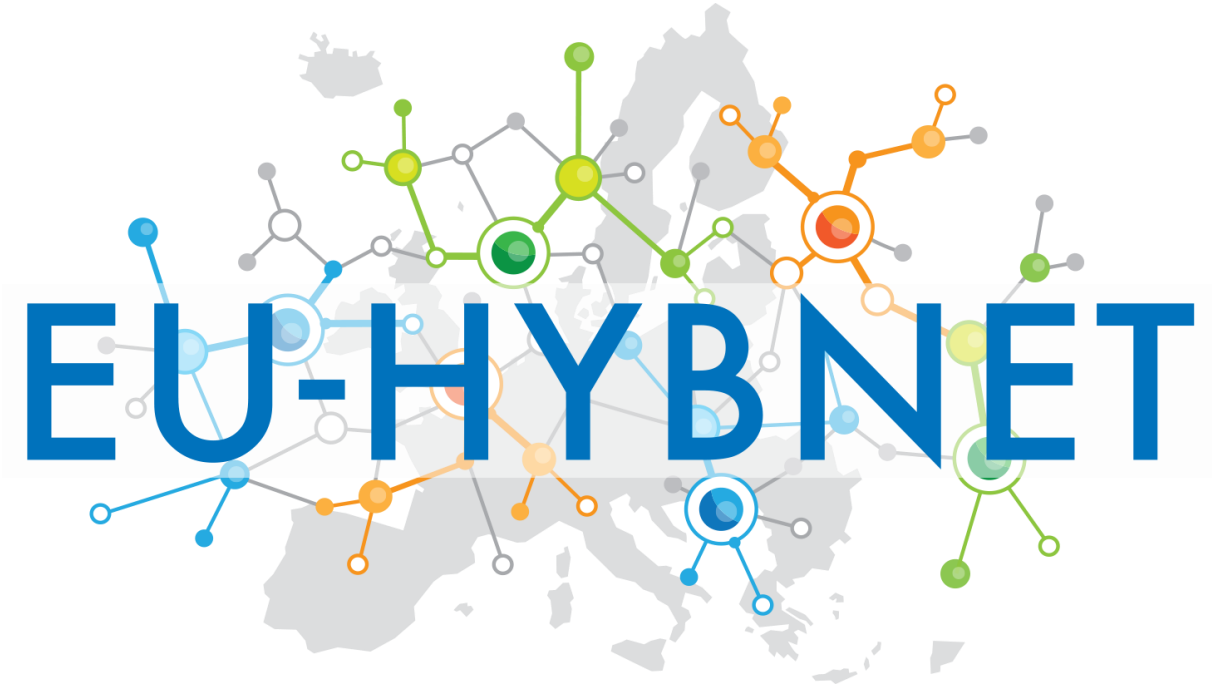
Name: _____

Signature: _____

The personal information on this Informed Consent Form will be retained in hard copy by the researcher/data controller during the lifecycle of the project and for a five (5) year period after its completion according to Article 18.1 of the EU-HYBNET Grant Agreement.
For any information and for the exercise of your rights with respect to the personal data on the consent form, you may contact the Data Protection Officer ([ADD THE DETAILS OF THE DPO HERE]) or the data controller ([ADD THE DETAILS OF THE DATA CONTROLLER]).

ANNEX IV. TEMPLATE OF INFORMATION SHEET OF DATA PROCESSING

(Starting from the next page)



INFORMATION SHEET OF DATA PROCESSING

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Dear participant,

We inform you that in the context of Task <number of the task> Deliverable <name and title of the deliverable>of the EU-HYBNET project (Task Leader <name of the partner leading the task>), a specific report/research action ...<description of the report/research action according to the task>. will involve processing of your personal data.
Please, delete the unnecessary

DATA CONTROLLER:

<Name of the partner responsible> <contact details>

DATA PROTECTION OFFICER:

<Name of the DPO> <contact details>

TYPES OF PERSONAL DATA TO BE PROCESSED:

Your **<**types of personal data, e.g. name, email address, voice, other**>** will be processed by the data controller for the purposes mentioned below.

PURPOSES OF THE PROCESSING:

Personal data will be processed for the purpose of carrying out an interview/questionnaire/ in the context of <deliverable number>.

1. <type of personal data and specific purpose>

2. <type of personal data and specific purpose>

We will not use personal data for any other purpose, unless a new legal basis exists, in which case you will be notified accordingly or asked for renewed consent.

LEGAL BASIS FOR THE PROCESSING:

Personal data which is collected as part of the interview/questionnaire/training pilot is processed by the data controller **based on your consent** (see attached the Informed Consent Form to be signed).

RECIPIENTS:

<name of the recipient(s) if any>

TRANSFER TO NON-EU COUNTRIES/INTERNATIONAL ORGANISATIONS:

The personal data is processed in Europe. No transfer to non-EU countries or international organisations is foreseen. Please, delete the unnecessary

STORAGE PERIOD:

Personal data (e-mail address, voice, other) is retained by the data controller for as long as it is necessary to fulfil the purposes for which it was collected, and in any case no more than the lifecycle of the project. After this period, the information will be permanently deleted.

Personal data on the attached Consent Form will be retained by the data controller during the lifecycle of the project and for a five-year period after its completion according to Article 18.1 of the EU-HYBNET Grant Agreement.

RIGHTS OF THE DATA SUBJECT:

You have the right to:

- Request information about whether we hold personal information about you, and, if so, what that information is and why we are holding it.
- Request access to your personal information. This enables you to receive a copy of the personal information we hold about you and to check that we are lawfully processing it.
- Request rectification of the personal information that we hold about you. This enables you to have any incomplete or inaccurate information we hold about you corrected.
- Request erasure of your personal information. This enables you to ask us to delete or remove personal information where there is no good reason for us continuing to process it.
- Request the restriction of processing of your personal information. This enables you to ask us to suspend the processing of personal information about you.
- Request transfer of your personal information in an electronic and structured form to you or to another party (right to “data portability”). This enables you to take your data from us in an electronically useable format and to be able to transfer your data to another party in an electronically useable format.
- Lodge a complaint with a supervisory authority.
- Withdraw your consent at any time. Please note that the withdrawal does not affect the processing of your data which is based on the consent you have given before the withdrawal. Once we have received notification that you have withdrawn your consent, we will no longer process your personal information for the purpose/purposes you originally agreed to.

CONTACT

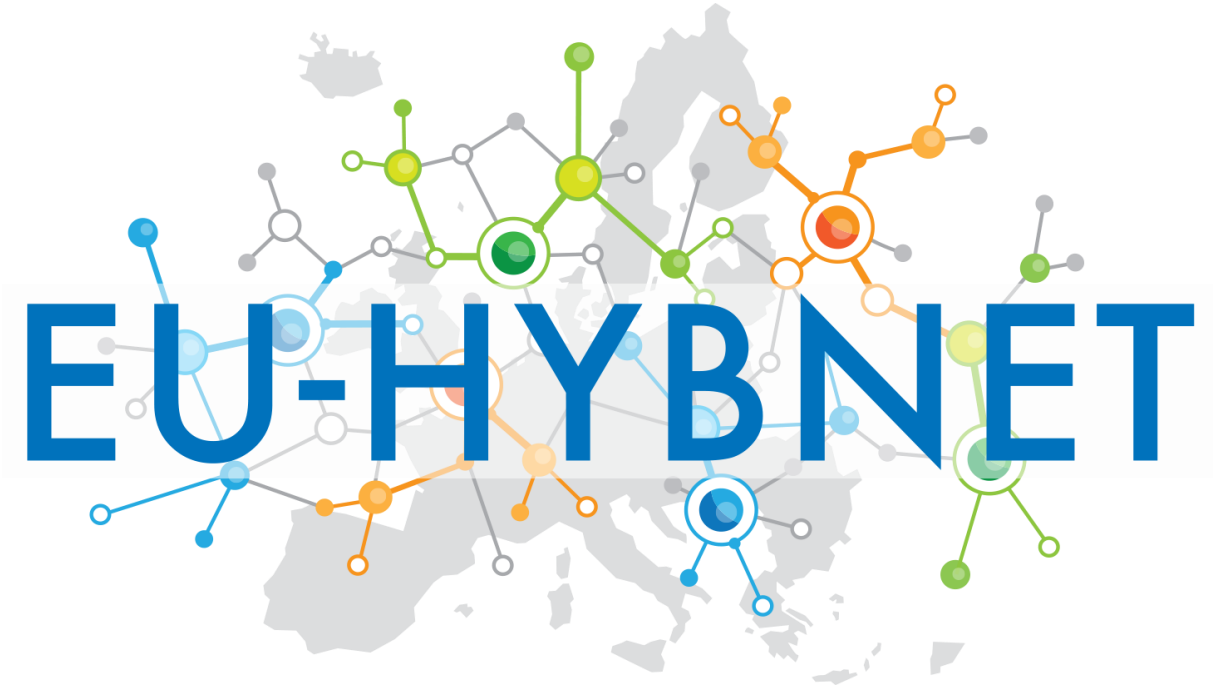
For the exercise of your rights and for any other data-related information, you may contact:

the **Data Protection Officer** of <name of the partner being the data controller> by sending an e-mail to <name and e-mail address of the DPO of the partner> or calling <telephone number of the DPO of the institution> or, alternatively,

the **data controller** <name of the partner> by sending an email to <name and e-mail address of the person responsible on behalf of the data controller> or calling <telephone number of the person responsible on behalf of the data controller>.

ANNEX V. TEMPLATE OF INFORMED CONSENT FORM FOR DATA PROCESSING

(Starting from the next page)



INFORMED CONSENT FORM FOR DATA PROCESSING

This project has received funding from the European Union's Horizon 2020 – Research and Innovation Framework Programme, H2020-SU-SEC-2019, under grant agreement No. 883054

Giving my consent, I undersign that:

1. I have carefully read and understood the Information Sheet for about EU-HYBNET and the activities I am taking part.
2. I am fully aware of all my rights and, especially, of my right to withdraw this consent at any time without consequences by contacting the Data Protection Officer either by sending an e-mail to <e-mail address of the DPO> or by calling <telephone number of the DPO>

or, alternatively, the data controller by sending an e-mail to <name and e-mail address of the person responsible on behalf of the data controller> or calling <telephone number of the person responsible on behalf of the data controller>.

Hereby I, …… (name, surname)

☐ **consent**
☐ **do not consent**

for the collection and further processing of my personal data (email address/voice/other) as part of the interview/questionnaire/action carried out for <number and title of the deliverable> of the EU-HYBNET project.

I have received a copy of the Information Sheet for Data Processing for the exercise of my rights.

Location: ……

Date: ……

Signature of the participant:

_____

The personal information on this Informed Consent Form will be retained in hard copy by the data controller during the lifecycle of the project and for a five (5) year period after its completion according to Article 18.1 of the EU-HYBNET Grant Agreement.
For any information and for the exercise of your rights with respect to the personal data on the consent form, you may contact the Data Protection Officer (see contact details in the Information Sheet) or the data controller (see contact details in the Information Sheet).