To: 5.1.2e [5.1.2e @epiconcept.fr]
Cc: 5.1.2e @epiconcept.fr[5.1.2e @epiconcept.fr]; 5.1.2e [5.1.2e @epiconcept.fr] 5.1.2e 5.1.2e [5.1.2e @gmail.com]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @nivel.nl]
From: 5.1.2e
Sent: Fri 9/4/2020 8:16:50 AM
Subject: [Spam] RE: [Spam] Fwd: [I-MOVE-COVID-19] Ethics work packages deliverables required SOON
Received: Fri 9/4/2020 8:17:52 AM
Nivel ethical clearance.pdf
Nivel Privacyreglement met technische toelichting pseudonimisering 2018.pdf

Dear 5.1.2e,

Please find attached a letter from Nivel director indicating that ethical clearance is not needed.
The second document is the privacy regulations for Nivel Primary Care Database, including a detailed description how data protection and data security has been organized in a practical/technical way (in Dutch).

All the best,
5.1.2e

Van: 5.1.2e [5.1.2e @rivm.nl]
Verzonden: donderdag 3 september 2020 10:03
Aan: 5.1.2e; 5.1.2e; 5.1.2e; 5.1.2e; 5.1.2e; 5.1.2e
CC: 5.1.2e @epiconcept.fr; 5.1.2e; 5.1.2e
Onderwerp: RE: [Spam] Fwd: [I-MOVE-COVID-19] Ethics work packages deliverables required SOON

Dear 5.1.2e,

For Deliverables 5.1.1, 5.1.2 and 5.1.3, we indeed would like to refer to the country-specific study protocol for primary care case-based surveillance (attached).

I am not sure how to go about the risk factor studies. As you know we do not formally participate in WP4, and I therefore assume that we do not need to submit any documentation on the risk factor studies. However, 5.1.2e (Nivel) would submit details on their participation in WP4 I guess.

In another attachment, please find the RIVM declarations for 5.2.1 and 5.2.2.

With respect to 5.2.3, 5.2.4 and 5.2.5, could you send an example?

Regards,
5.1.2e

From: 5.1.2e <5.1.2e @epiconcept.fr>
Sent: woensdag 2 september 2020 14:14
To: 5.1.2e <5.1.2e @rivm.nl>; 5.1.2e <5.1.2e @rivm.nl>; 5.1.2e <5.1.2e @rivm.nl>; 5.1.2e <5.1.2e @rivm.nl>; 5.1.2e <5.1.2e @nivel.nl; 5.1.2e <5.1.2e @nivel.nl>
Cc: 5.1.2e @epiconcept.fr; 5.1.2e <5.1.2e @epiconcept.fr>; 5.1.2e <5.1.2e @gmail.com>
Subject: [Spam] Fwd: [I-MOVE-COVID-19] Ethics work packages deliverables required SOON

Dear I-MOVE-COVID-19 teams from the Netherlands,

As mentioned below, **we require some ethics deliverables soon (by the 7th of September)**, as deliverables to the European Commission. We fully agree with 5.1.2e's sentiment that the amount of deliverables is quite heavy, but such is the unfortunate reality of the European Commission. **We will try and support you in any way we can with this**.

First of all thank you for letting us know that you do not require ethical approval for the I-MOVE-COVID-19 surveillance, the way you reference this in the protocol (version from the 14th of July 2020) is perfect.

I am not sure where we are with the ethical approval for the I-MOVE-COVID-19 risk factor study. Would it be possible for you to clarify if the letter you have stating ethical approval is not needed is also valid for the risk factor study? If yes, then we will need either a protocol, or a document stating this (on official letterhead, signed by the principle investigator (I believe this is 5.1.2e. I can send you a template for this if useful, just let me know).

Additionally we will need from you some more deliverables:

Deliverables **5.1.1, 5.1.2 and 5.1.3** are
- procedures for identifying participants
- procedures for informed consent
- templates for informed consent and patient information leaflets

In the protocol that we have received from you (dated 14th of July, 2020), these 3 deliverables are very nicely outlined. I believe we can use the protocol plus your sample form (annex 1) for these deliverables for the surveillance part. What is your advice for the risk factor study? Could we use the same parts of the protocol for it? An alternative is to write an official document stating that the data for the risk factor study have not been transmitted yet and therefore the ethical documents are not yet available, however they will be in line with the surveillance part of the project. Please let me know what you think will be best.

We will also need (see the details in yellow at the bottom of this email, this is just a summary):

Deliverables **5.2.1, 5.2.2, 5.2.3, 5.2.4, and 5.2.5** - they are
- 5.2.1: a declaration of compliance with respective national legal framework - **please see attached a template** for this (could you write this on a document with an official letterhead and have it signed by the principle investigator? It's very short.)
- 5.2.2: confirmation that you have a data protection officer (DPO), or if you do not have one, that the project has a data protection policy in place. Could you also write a letter to declare this? **Please see attached template**. Again, this needs to be on a document with an official letterhead.
- 5.2.3, 5.2.4 and 5.2.5: Information on data protection, data security and anonymisation procedures. Are you able to provide this? **Please let us know if you need an example.**

Deliverables 5.4.1 and 5.4.2: These are deliverables related to the lab, including security classification, GMO authorisation and declaration that health and safety procedures are being carried out according to national guidelines. **I attach two documents that Portugal sent that could be helpful examples. 5.1.2e would it be possible for you to send something similar?**

We really need these documents by Monday the 7th of September. Do you think this would be possible? Please let us know if there is any way we can assist you with this.

Apologies again for this burden to your already huge workload.

Wishing you all the best,

5.1.2e

-------- Forwarded Message --------

Subject:[I-MOVE-COVID-19] Ethics work packages deliverables required SOON

Date: Fri, 21 Aug 2020 15:56:49 +0100

From: 5.1.2e < 5.1.2e @epiconcept.fr>

To: 5.1.2e < 5.1.2e @epiconcept.fr>, 5.1.2e < 5.1.2e @epiconcept.fr>, 5.1.2e @nivel.nl < 5.1.2e @nivel.nl>, 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e @iplesp.upmc.fr < 5.1.2e @iplesp.upmc.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @iplesp.upmc.fr>, 5.1.2e < 5.1.2e @univ-corse.fr>, 5.1.2e @isciii.es < 5.1.2e @isciii.es>, 5.1.2e @isciii.es < 5.1.2e @isciii.es>, 5.1.2e @isciii.es < 5.1.2e @isciii.es>, 5.1.2e < 5.1.2e @isciii.es>, 5.1.2e @navarra.es < 5.1.2e @navarra.es>,

5.1.2e @rivm.nl < 5.1.2e @rivm.nl>, 5.1.2e @rivm.nl < 5.1.2e @rivm.nl>, 5.1.2e @rivm.nl < 5.1.2e @rivm.nl>, 5.1.2e @hse.ie < 5.1.2e @hse.ie>, 5.1.2e @hse.ie < 5.1.2e @hse.ie>, 5.1.2e < 5.1.2e @nhs.net>, 5.1.2e (NHS NATIONAL SERVICES SCOTLAND) < 5.1.2e @nhs.net>, 5.1.2e (NHS FIFE) < 5.1.2e @nhs.net>, 5.1.2e (NHS NATIONAL SERVICES SCOTLAND)' < 5.1.2e @nhs.net>, 5.1.2e < 5.1.2e @strath.ac.uk>, 5.1.2e @insa.min-saude.pt < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e @insa.min-saude.pt < 5.1.2e @insa.min-saude.pt>, 5.1.2e @insa.min-saude.pt < 5.1.2e @insa.min-saude.pt>, 5.1.2e @insa.min-saude.pt < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @dgs.min-saude.pt>, 5.1.2e @folkhalsomyndigheten.se < 5.1.2e @folkhalsomyndigheten.se>, 5.1.2e @folkhalsomyndigheten.se < 5.1.2e @folkhalsomyndigheten.se>, 5.1.2e @pasteur.fr < 5.1.2e @pasteur.fr>, 5.1.2e @pasteur.fr < 5.1.2e @pasteur.fr>, 5.1.2e < 5.1.2e @phc.ox.ac.uk>, 5.1.2e 5.1.2e < 5.1.2e @phc.ox.ac.uk>, 5.1.2e < 5.1.2e @phc.ox.ac.uk>, 5.1.2e (PUBLIC HEALTH SCOTLAND) < 5.1.2e @nhs.net>, 5.1.2e PUBLIC HEALTH SCOTLAND) < 5.1.2e @nhs.net> 5.1.2e < 5.1.2e @ucd.ie>, 5.1.2e @ucd.ie < 5.1.2e @ucd.ie>, 5.1.2e (5.1.2e @chu-rennes.fr) < 5.1.2e @chu-rennes.fr>, 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @vi-vi.org>, 5.1.2e < 5.1.2e @nhs.net>, 5.1.2e < 5.1.2e @chu-montpellier.fr>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com> 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e @insa.min-saude.pt < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @uzbrussel.be>, 5.1.2e < 5.1.2e @cantacuzino.ro>, 5.1.2e @yahoo.com < 5.1.2e @yahoo.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @vi-vi.org>, 5.1.2e 5.1.2e < 5.1.2e @cch.aphp.fr>, 5.1.2e < 5.1.2e @cch.aphp.fr>, 5.1.2e < 5.1.2e @chu-lyon.fr>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @uzbrussel.be> 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @gmail.com>

Dear I-MOVE-COVID-19 colleagues,

How are you? Hopefully back refreshed from a summer break and ready for the autumnal conjoint influenza and COVID season!

This email is a follow-up to the initial one about ethics requirements and deliverables, sent to you by 5.1.2e on 11 June (see below).

In light of the forthcoming deliverables, most of which concern ethical approval documentation, we wanted to send this gentle reminder for the following documents. These will be required both for the primary care and hospital setting; so, if you participate in both, each document will need to cover both settings (alternatively, you may have separate documents for primary care and hospital settings). In addition, the documents are required for **surveillance and** for the **risk factor study**, so if you are participating in both, then we need separate documents for each of surveillance and research (or one document which covers both surveillance and research). ***For labs, please see D5.3 and D5.4 below for details of the four deliverables applicable to you.***

We do need to have all of these documents by **Monday 07 September 2020**, which is just around the corner. Note that the documents may be provided **in any language**.

We have copied and pasted below the table listing all the deliverables, highlighting those you need to provide, but we also summarise them for you here:

D5.1 – four deliverables. The following three may be / have already been provided within your surveillance/study protocols:

- Procedures and criteria for participant recruitment/selection
- Procedures for informed consent (or waiver of same e.g. for surveillance)
    - Copies of the templates for informed consent/patient information sheets (can be an Annex of your protocol)

In addition to these, the fourth deliverable under D5.1 is a **copy of the certificate of ethical approvals**, for both surveillance and for the risk factor study. Some of you have already provided these.

D5.2 – eight deliverables. The first **six** are applicable to participating primary care and hospital sites.

- **Declaration of compliance** with national legal framework(s), indicating any special exemptions pertaining to personal rights or processing of genetic, biometric and/or health data under the national legislation
- **Confirmation of appointment of a Data Protection Officer** (DPO) and that the DPO's contact details are available to all data subjects involved in the research. [*If your institution is not required to appoint a DPO under GDPR, you must submit instead a detailed data protection policy for the surveillance and the risk factor study*]. ***It is very important for you to make a connection with your institute's/hospital's DPO as soon as possible, if this has not already been done***
- The next three deliverables may also be part of a study/surveillance protocol methodology:
    - **Description of technical and organisational measures** to safeguard the rights and freedoms of the data subjects/research participants
    - **Description of security measures** to prevent unauthorised access to personal data or the equipment used for processing data
    - **Description of the anonymisation/pseudonymisation techniques** implemented
- The **sixth deliverable** of D5.3 *only concerns Albania and the UK:* confirmation that **transfer of personal data to the EU complies with the laws** of each of those countries

D5.3 and 5.4 – two deliverables each. These are applicable to participating **laboratories** and refer to requirements to keep the following information on file:

- Details on **cell/tissue types** collected
- Copies of relevant documents for using, producing or collecting human cells or tissues (e.g. **ethics approval, import licence, accreditation/designation/authorisation/licensing**)
- Copies of **authorisations for relevant facilities** (e.g. security classification of laboratory, GMO authorisation)
- Evidence of **appropriate health and safety procedures** conforming to relevant local/national guidelines/legislation for project staff.

Please let us know if there is any way we can assist you in getting these deliverables together. For those who have sent your site-specific protocols, we can look through these to obtain the deliverables related to methodology, but will contact you if we are unable to locate them.

Warm regards

5.1.2e on behalf of the WP2 and WP3 I-MOVE-COVID-19 teams

***

Here is the table listing the details, with yellow highlight for those applicable to participating sites:

D5.1	1. The procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable. 2. The informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable. 3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file. 4. Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans must be submitted as a deliverable.	Confidential, only for members of the consortium (including the Commission Services)	**15 Sep 2020**	Please, send copies of each document to Epiconcept before 1st September 2020
D5.2	1. The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).	Confidential, only for members of the consortium (including the Commission Services)	**15 Sep 2020**	Please, send copies of the documents required to Epiconcept before 1st September 2020

	2. The host institution (ALL PARTNERS collecting data) must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be submitted as a deliverable. 3. A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable. 4. A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable. 5. Description of the anonymisation/pseudonymisation techniques that will be implemented must be submitted as a deliverable. 6. In case personal data are transferred from a non-EU country to the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected must be submitted as a deliverable. 7. In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be submitted as a deliverable. 8. The beneficiary must evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion must be submitted as a deliverable.			
D5.3	1. In case human cells/tissues are obtained within the project, details on cell/tissue types must be kept on file. 2. Copies of relevant documents for using, producing or collecting human cells or tissues (e.g., ethics approval, import licence, accreditation/designation/authorisation/licensing) must be kept on file. 3. In case human cells/tissues are obtained from a biobank, details on the cell/tissue types and on the biobank and access to it must be kept on file.	Confidential, only for members of the consortium (including the Commission Services)	**15 Sep 2020**	Please keep the relevant documents archived
D5.4	1. Copies of authorisations for relevant facilities (e.g., security classification of laboratory, GMO authorisation) must be kept on file. 2. The applicant must demonstrate that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. This must be kept on file.	Confidential, only for members of the consortium (including the Commission Services)	**15 Sep 2020**	Please keep relevant documents and send to Epiconcept

---------- Forwarded message ---------
From: 5.1.2e < 5.1.2e @epiconcept.fr>
Date: Thu, Jun 11, 2020 at 12:29 PM
Subject: [I-MOVE-COVID-19] Ethics advisor appointment
To: 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e < 5.1.2e @phe.gov.uk>, 5.1.2e < 5.1.2e @iplesp.upmc.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @iplesp.upmc.fr>, 5.1.2e < 5.1.2e @univ-corse.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @chu-lyon.fr>, 5.1.2e (5.1.2e @chu-rennes.fr) < 5.1.2e @chu-rennes.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @chu-montpellier.fr>, 5.1.2e < 5.1.2e @aphp.fr>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @yahoo.com>, 5.1.2e @CANTACUZINO.RO < 5.1.2e @cantacuzino.ro>, 5.1.2e < 5.1.2e @isciii.es>, 5.1.2e < 5.1.2e @isciii.es>, 5.1.2e < 5.1.2e @isciii.es>, 5.1.2e <5.1.2e @isciii.es>, 5.1.2e (ISP) < 5.1.2e @navarra.es>, 5.1.2e < 5.1.2e @rivm.nl>, 5.1.2e < 5.1.2e @rivm.nl>, 5.1.2e < 5.1.2e @rivm.nl>, 5.1.2e < 5.1.2e @nivel.nl>, 5.1.2e < 5.1.2e @hse.ie>, 5.1.2e < 5.1.2e @hse.ie>, 5.1.2e (NHS National Services Scotland) < 5.1.2e @nhs.net>, 5.1.2e (NHS NATIONAL SERVICES SCOTLAND) < 5.1.2e @nhs.net>, 5.1.2e (NHS FIFE) < 5.1.2e @nhs.net>, 5.1.2e (NHS NATIONAL SERVICES SCOTLAND) < 5.1.2e @nhs.net>, 5.1.2e < 5.1.2e @strath.ac.uk>, 5.1.2e < 5.1.2e @vi-vi.org>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @insa.min-saude.pt>, 5.1.2e < 5.1.2e @dgs.min-saude.pt>, 5.1.2e < 5.1.2e @folkhalsomyndigheten.se>, 5.1.2e < 5.1.2e @folkhalsomyndigheten.se>, 5.1.2e @gmail.com < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e < 5.1.2e 5.1.2e @santepubliquefrance.fr>, 5.1.2e < 5.1.2e @pasteur.fr>, 5.1.2e < 5.1.2e @pasteur.fr>, 5.1.2e < 5.1.2e @phc.ox.ac.uk>, 5.1.2e < 5.1.2e @phc.ox.ac.uk>, 5.1.2e < 5.1.2e @uzbrussel.be>, < 5.1.2e @gmail.com>, 5.1.2e 5.1.2e <5.1.2e @sjdhospitalbarcelona.org>
Cc: 5.1.2e (5.1.2e) < 5.1.2e @epiconcept.fr>, 5.1.2e <5.1.2e @epiconcept.fr>, 5.1.2e < 5.1.2e @gmail.com>, 5.1.2e [5.1.2e < 5.1.2e @epiconcept.fr>, 5.1.2e < 5.1.2e @epiconcept.fr>, 5.1.2e < 5.1.2e @epiconcept.fr>

Dear Colleagues,

As you know, the European Commission adds a Work package in all proposals on Ethics and includes related deliverables.
Please find attached a table so that you know what each study site should submit and the deadlines.

One of the requirements is to appoint an independent Ethics Advisor by 15 June 2020 to monitor the ethics issues of the project and how they are addressed. There will be an evaluation of the ethics risks related to the data processing activities of the project. This includes also an opinion on the need for a data protection impact assessment under art.35 General Data Protection Regulation 2016/679.

The risk evaluation and the opinion will be submitted as deliverable. The Ethics Advisor must submit a report as a deliverable at the end of the 1st reporting period and at the end of the project.

We are pleased to welcome 5.1.2e who will be our Ethics Advisor.

5.1.2e

5.1.2e will work directly with Epiconcept to carry out her mission, however if necessary, she may need to ask you questions directly.

With very many thanks for your time and for your participation in WP5.

Best wishes,

5.1.2e 5.1.2e

#GlobalResponse
#UnitedAgainstCoronavirus
#StrongerTogether