

2020-03-17

Friday, March 13, 2020 5:45 PM

Date:	17/03/20	Place:	TC
Start:	3.00 PM CET	End:	4.30 PM CET
Topic: 4th AREB TC			
Participants: FGB: Annalisa Landi, Viviana Giannuzzi EJP RD coordination team: Yanis Mimouni, Daria Julkowska EJP communication manager: Eleonora Passeri ECRIN: Marta Del Alamo EMBL -DTL PROJECTS- ELIXIR/ELIXIR-NL: Rob Hooft CVBF: Giovanni Migliaccio DLR: Ralph Schuster ZonMw: Sonja van Weely			
Apologizes: <u>Mandatory participation:</u> ➤ BBMRI: Petr Holub, Michaela Th. Mayrhofer ➤ RaDiCo: Sonia Gueguen <u>Facultative participation:</u> ➤ INSERM [Orpha]: Ana Rath ➤ EURORDIS: Virginie Bros-Facer ➤ REPRESENTATIVE OF THE ERN RESEARCH GROUP: Alberto M Pereira ➤ EATRIS: Anton Ussi, Ben Lydall ➤ UKL-HD: Franz Schaefer ➤ AP-HP: Rima Nabbout ➤ DLR: Katarzyna Saedler, Michaela Fersh ➤ VUHSK: Biruté Tumiene			

TOPIC	DISCUSSION AND DECISIONS
1. Collaboration between the Ethics Advisor and AREB	<p>A. Landi asks EJP RD Coor team for an update on the appointment of the project Ethics Advisor and when the collaboration will start. Considering the imposing restrictions due to the spread of the COVID-19, a meeting in person is not feasible and she proposes to organize a web meeting in April.</p> <p>Information on the importance of signing the contract for hiring the Ethics Advisor was sent by EJP RD coordination to INSERM administration.</p> <p>Action:</p> <ul style="list-style-type: none"> <input type="checkbox"/> • The Ethics Advisor will be asked if she is available on April 2020 to start collaboration: starting with a TC for introduction to the AREB members @EJPRD coordination <input type="checkbox"/> • @EJP RD coordination will ask INSERM coordination if the contract of the Ethics Advisor can be retro-active (to allow her full involvement) <input type="checkbox"/> • @EJP RD Coordination will inform AREB on the advancement of the contract of the Ethics Advisor
2. Inclusion of a legal member among AREB members	<p>A. Landi reminds TC participants that, according to the specific recommendation of the Ethics Advisor, she prepared and shared (with the help of Yanis) a survey allowing WP4 members to suggest a legal expert to be included in the AREB. Nevertheless, she did not receive any reply. She asks EJP RD Coordination team how to proceed and if the survey should be</p>

She asks EJP RD Coordination team how to proceed and if the survey should be shared with all Consortium members.

Action:

- @Annalisa @ Yanis will adapt the survey for sharing with the EJP RD consortium
- @EJP RD Coordination will share the survey once adapted (provide more explanation):
 - on the "General" channel of the team "EJPRD-CENTRAL" that gathers now the whole consortium
 - and by email using EJP RD consortium mailing lists

3. AREB section on the EJP RD website

- A. Landi informs TC participants that she had a brief discussion with Eleonora Passeri related to this topic and she shares the proposal with Daria (no reply yet).
- The proposal is the following:
 1. To include the AREB in the Member page (next to ExCom) (<https://www.ejprarediseases.org/index.php/about/members/>) where adding a table with the list of "names, expertise, and institutions (with hyperlinks to their website)";
 2. To create a new WEBpage "Advisory Regulatory Ethics Board" on the menu. In this WEBpage we could include:
 - The list of names and hyperlink to the AREB Member webpage (to avoid duplication);
 - An intro on AREB;
 - The list of the activities performed by the AREB within EJP RD that can be disclosed
 - Contact info with a hyperlink to the helpdesk webpage;
 - A clear sentence stating that the AREB supports only requests received from members of the EJP RD Consortium;
 3. To add another category among the Helpdesk options: "Regulatory and Ethical issues" or "request for AREB members"
- A. Landi adds that after the obtention of the green light on the proposal from Daria, she will liaise with all AREB members for suggestions/help in producing contents to be validated by Daria/EJP Coor teams before the publication on the website.

TC update:

- Next week the reorganisation of the EJP RD website will be finished. The AREB sub-section/tab will be under a section gathering the different EJP RD services provided
- A Slider will be added on the main page of the website, it can be used to feature AREB services and information

Action:

- A. Landi will liaise with all AREB members for suggestions/help in producing contents to be validated by Daria/EJP RD Coordination teams before the publication on the website
- @EJP RD coordination will inform AREB on the availability of the section on the website

4. EJP RD JTCs 2019 projects: ethics

- V. Giannuzzi and Pillar 1 leaders give an update on the ethics monitoring of the EJP RD JTCs 2019.

<p>monitoring</p>	<ul style="list-style-type: none"> • A dedicated Team "JTC Ethics Monitoring" was created on MS teams to allow an easy collaboration and communication among WP4 leader, AREB members and Pillar 1 members involved in the JTCs 2019. • In detail, the WP4 leader/AREB members were asked to verify if "Requirements to be addressed before grant agreement/before signature deadline: 31st January 2020" column "M" of the Excel file shared have been completed with the information received from the applications of the concerned nine projects. • The first comments were drafted by Viviana and Annalisa. Afterwards, they asked AREB members to provide them with a feedback on the draft comments for the projects. G. Migliaccio provided Viviana/Annalisa with his contribution. • The feedback is expected from Pillar 1 leaders by March, 20th. <p>Action:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> @V. Giannuzzi will send a reminder to Michaela Mayrhofer <input type="checkbox"/> @AREB members will provide Viviana/Annalisa with additional comments by March, 19th <input checked="" type="checkbox"/> @V. Giannuzzi will send the feedback to Pillar 1 leaders
<p>5. Update on Data Transfer Agreement being generated for WP13 work (task 13.2)</p>	<ul style="list-style-type: none"> • Agreement for the use of the Embassy Cloud (held by ELIXIR/EMBL-EBI) was put on hold. <ul style="list-style-type: none"> • The status of GDPR compliance still needs to be clarified • The cost of embassy cloud use is still under discussion <ul style="list-style-type: none"> ◦ Pillar 2 involved persons are going to be contacted to provide decision on the Embassy cloud Use • Meanwhile UMCG partner is setting up the environment in his university cluster to allow the partner Radboudumc to perform the analysis. A DTA was set between the data Provider (INSERM-Toulouse ERN ERKNet) and Radboudumc .
<p>6. Update on the ERN VASCERN REQUEST</p>	<ul style="list-style-type: none"> • The reply to the VASCEN request was provided on March 6th 2020 • The request part for registries was subdivided in four sub-parts. • In particular, for the sub-part on "data consent and control" VASCERN will be liaised with the following contact persons: Marco Roos [LUMC], Mary Wang [FTELE], Anthony Brookes [ULEIC], Petr Holub [BBMRI-ERIC], Heimo Müller [BBMRI-ERIC], Michael Nitzlnader [AIT]) and the contact-person from the "Advisory Regulatory Ethics Board" (AREB), Annalisa Landi [FGB]. <p>Action:</p> <p>None</p>
<p>7. GDPR Guidelines issued by BBMRI-ERIC for Pillar 2 - tbc</p>	<p style="text-align: center;">Postponed</p> <p>Associated documents (links):</p> <ul style="list-style-type: none"> • EJPRD Guideline GDPR Guiding Technical Principles for Pillar 2 • EJPRD Guideline Requirements for GDPR Implementation in Pillar 2 <p>Action:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> • A dedicated TC will be scheduled to gather FTELE (Stefano and Barbara) and BBMRI-ERIC partners members of AREB (Petr and Michaela) to discuss the adaptation of the guidelines to EU countries and to expand to a process for DTA generation: @Annalisa and @Yanis <input type="checkbox"/> ◦ AREB will be informed on the discussion results and actions agreed
<p>8. AOB</p>	<ul style="list-style-type: none"> ✓ EJP RD Networking Support Scheme ✓ S.van Weely involved FGB in the ethical evaluation of the 9 applications received for the EJP RD Networking Support Scheme to evaluate if one or more of the applications has to be evaluated by an independent expert in ethics. ✓ Annalisa/Viviana are starting the evaluation and ask if someone else from the AREB

would like to participate in the process considering that only issues related to the data protection may arise (it is not mandatory).

Action:

- ✓ **@A. Landi** will provide a feedback to S.van Weely by April 1st, 2020.

✓ **AREB members not participating to the AREB TCs**

V.Giannuzzi asks EJP Coo teams & AREB if any action should be undertaken for AREB members not participating in AREB TCs/meetings and/or not providing any feedback.

Action:

- ✓ For partners not having person months: discuss general participation and ask for a proxy/alternate if possible in case of non-availability **@Viviana**
- ✓ A rule needs to be defined for several successive non-participations: send a request for information (alternate) and reminder after X non-participation then send an exclusion notification after X+n non-participation **@Viviana**

✓ **Key Ethics & Regulatory documents for EJP RD consortium**

A.Landi reminds AREB members that she uploaded a folder [Key Ethics & Regulatory documents for EJP RD consortium \(link\)](#) including the key ethical and regulatory documents divided by topics (as extracted from D4.1 - First AREB report) in the MS Teams EJPRD-Central general channel.

Action:

- @AREB members** to add any new useful documents in the list (.doc file) and upload the pdf file in the relevant folder