D7.2: POPD Requirement No. 2

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CONTRIBUTORS

- Xuanye Gu
- Hugh Martin
- David Wright
- Peter Coveney

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1 One-page summary

Work Package 7 of the VECMA project was created in response to the Ethics Summary Report [800925-VECMA-Ethics_Summary_Report.pdf] produced during the review of the project proposal to set out the 'ethical requirements' for the project. The review raised a number of issues related to the protection of personal data (POPD) which we address in this document:

- What kind of anonymized data will be used for VECMA's health-related application scenarios?
- Relevant documentation (i.e. authorizations for secondary use of anonymized patient's data) must be provided prior the execution of Trials.
- It is not expected that any new datasets will be collected during the project lifetime.

VECMA is primarily a software development project and the concerns above have been addressed through the establishment of an ethics advisory board (EAB) along with documentation of the initial datasets and procedures for adding new datasets in deliverable D4.5. The initial datasets to be used in VECMA were confirmed to have no personally identifiable data and present no other ethical concerns. Future datasets will be reviewed by the EAB to ensure that all relevant documentation (i.e. information sheets, informed consents) and authorizations are in place (the execution of Trials was never intended within the project). In addition to these provisions, we have added a further task to Work Package 4, Task 4.7, to ensure that any ethical concerns are recorded in a living document and all necessary documents are provided to the relevant EC & REA services.

We believe that the three steps outlined above address all of the ethics concerns of the project and eliminate the need for the extra Work Package (WP7) and two deliverables [VECMA_D7.2_POPD Requirement No.2 and VECMA_D7.2_POPD Requirement No1] added within the EC portal. In summary, these steps are:

1. Addition of ethics deliverable D4.5 in WP4
2. Addition of ethics task (Task 4.7) in WP4
3. Creation of an Ethics advisory board (detailed in D4.5)

So we herein clarify the structure we have put in place to address the Ethics Summary Report, as agreed with the EC Project Officer for the VECMA project.

The above summary is supported by the provision of scanned email discussions of the agreements between the Project Officer and ourselves, if required.

2 Appendices

The file name of the Ethics Summary Report is “800925-VECMA-Ethics_Summary_Report.pdf”.