

WP1: Primary and secondary user involvement and pilot studies

D1.4: Privacy, security and GDPR compliance

Project acronym	ACESO
Project number	AAL-2019-6-137-ACESO
Project full name	Patient centric solution for smart and sustainable healthcare
Dissemination level	Public
Type of deliverable	Project Deliverable
Contractual Date of Delivery	M38
Actual Date of Delivery	M38
Deliverable Number	1.4
Deliverable Name	Privacy, security and GDPR compliance
Workpackage / Task	WP1 / Task 1.4
Work package responsible / Task responsible	MKS/JUMC
Number of Pages	8
Contributors	JUMC, LSDM, MKS
Version	10

Abstract

Ethical issues are paramount in all research involving living subjects, especially humans. As per the Study Protocol, an Ethical Advisory Board (EAB) has been named, which includes external members, including the Patient organization. The board was to oversee and advise the research team on ethical issues, and in cases of need, it was to take a position concerning possible ethical problems should they arise. The EAB convened 8 times and addressed issues ranging from ethical committee/institutional board agreements to perform the study or lack of need for such permissions (depending on a country), the GDPR policy, and the need to be prepared for potential issues in the post-marketing phase. On one

occasion, the EAB discussed and approved the solution by the Polish research team to address the query by one of the end users concerning data handling.

Table of Contents

Members	3
Purpose	3
Scope	3
In scope	3
Out of scope	3
Authority	4
Working method	4
Operations	4
Documents	5
MINUTES OF THE MEETINGS OF THE ACESO ETHICAL ADVISORY BOARD	5
Ethical Advisory Board Zoom Meeting Minutes, 10th Nov. 2021	5
Ethical Advisory Board Zoom Meeting Minutes, 23rd Nov. 2021	5
Ethical Advisory Board Zoom Meeting Minutes, October 17, 2022	6
Ethical Advisory Board Zoom Meeting Minutes, Apr 17, 2023	7
Ethical Advisory Board Zoom Meeting Minutes, May 11, 2023	7
Ethical Advisory Board Zoom Meeting Minutes, July 11, 2023	7
Ethical Advisory Board Zoom Meeting Minutes, Aug 4, 2023	8
Ethical Advisory Board Zoom Meeting Minutes, Sep 8, 2023	8

In the study proposal, we included the following passage:

“Ethical Advisory Board:

will be chaired by JUMC and will be responsible for all ethical issues arising from end-user involvement. It will consist of one member from each end-user organization in the project. Exploitation Board: will consist of representatives of all companies and will be chaired by SPH. The role of the Exploitation Board is the continuous assessment of the market, and exploitation planning (support and liaising to companies, SMEs, and other stakeholders). Work Package Leaders: Each WP Leader is responsible for his WP. This especially includes (1) assessment of progress reports and detailing of work plans; (2) coordination of research, development, and integration issues; (3) guaranteeing that the project tasks are carried out in time; (4) the translation of technical recommendations into action; and (5) conflict resolution within the respective Work Package. The Work Package group will convene as often as necessary, but between these meetings, stays continuously in contact via e-mail or telephone (video) conferences.”

Members

- Jerzy Gąsowski
- Ligia Muntianu
- Drago Rudel
- Dr Judit Katalin Nagy, MD, Buda Health Centre
- Katalin Mátics, leader of Újbuda Social Services, Municipality of the 11th district, Budapest

Purpose

The purpose of the Ethical Advisory Board (EAB) is to assess and advise the consortium on the ethical issues possibly arising from the involvement of the primary and secondary end-users.

Scope

In scope

The scope of the operations involves the scrutiny, assessment, and advice on the following issues:

- a) The proper informing and obtaining of informed consent from the participants
- b) The employment of the GDPR standards throughout the project
- c) The assurance of the appropriate handling of the sensitive data during the analyses

Out of scope

The scope of operations of EAB does not include preparation of the reporting to the AAL or the consortium, preparation of the consortium documentation, or direct involvement in the execution of the project. The latter concerns the EAB as a constituted body and not some of its members in their particular capacity as project participants.

Authority

EAB is purely advisory in nature and does not have decision-making authority, however, it may advise the consortium about the actions proposed to meet the potential ethical challenges both during the study period and in the marketing stage.

Working method

- virtual meetings, at least once during the implementation of each of the three stages of primary end-user involvement
- ad hoc meetings on demand in case of any significant ethical issues or risks
- targeted meeting agendas

Operations

During the end-user classification and the testing of individual components, the EAB has met twice (Nov 10, 2021, and Nov 23, 2021). The members from outside the consortium were acquainted with the project's particulars. The documents concerning the ethical issues and privacy matters were shared with the members. The EAB discussed the content of the documents, suggested necessary changes, and approved amended versions. It was further decided that most EAB input would be required during the final testing.

In the preparation and execution of the testing of the integrated ACESO platform, the EAB has met on seven occasions. The board deemed it necessary to hold the majority of the meetings during the final piloting to be able to identify and address any potential ethical issues proactively, should they arise during the testing phase. The board met on Oct 17, 2022, Jan 8, 2023, Apr 27, 2023, May 11, 2023, Aug 4, 2023 and finally Sep 8, 2023.

The first meetings dealt with the preparation of the end-user involvement. The potential ethical and GDPR issues were considered, and the project documentation concerning the ethical issues was screened. The JUMC prepared and presented its local Bio-Ethical Board clearing for this project stage. In the latter part, the EAB decided that practical issues might arise, and thus, the meetings should be more frequent. Indeed, some of the end-users had questions about data handling, which were answered and discussed during the EAB meetings.

During the meetings, we discussed the issue concerning the lack of the need for a formal ethics committee agreement in Slovenia. This stems from the specificity of legal arrangements in Slovenia ruling the need or lack thereof to obtain such a formal agreement. We condone the fact that the study is being executed in accordance with the Protocol and the fact that the participants (non-patient end-users) receive thorough information about the study and sign an informed consent document to take part. This, we think, is fulfilling the minimum ethical requirements usually needed for the conduct of similar studies. In Poland, a formal Bioethical Committee approval has been sought and obtained for both initial and final pilots (two separate rulings).

Overall, during the project, no significant ethical issues have arisen. On one occasion, there was a query from an end-user in Poland concerning data handling and analyses. The user was informed that all analyses are and will be performed anonymously. The case was reported

during the EAB meeting and the handling of the case was approved. The EAB also identified that the significant ethical challenges are yet to be expected in the post-marketing stage and that they might, among other issues, include the sustainability of pricing of the service, proper training of the users, etc.

Documents

1. Ethics manual:
https://docs.google.com/document/d/1_9gsFqGIW2lhFP9pjuMixbSx8c_JFnJ/edit?usp=sharing&oid=113105268360838635257&rtpof=true&sd=true
2. Meeting minutes

MINUTES OF THE MEETINGS OF THE ACESO ETHICAL ADVISORY BOARD

Ethical Advisory Board Zoom Meeting Minutes, 10th Nov. 2021

Present: Drago Rudel, Ligia Muntianu, Katalin Matics, Judit Nagy, Jerzy Gąsowski (chair), and Janos Csebfalvi (observer)

JG presented the members.

JG presented the ideas behind the ethical conduct of research and commercialization of its results as the basis for the operations of the ACESO Ethical Advisory Board.

It was decided that all existing documents would be shared with EAB members, and all would have a chance to comment and suggest the changes as deemed appropriate.

Next meeting of the Ethical Board: on 23rd November, 2021

Final remarks

Adjourn

Ethical Advisory Board Zoom Meeting Minutes, 23rd Nov. 2021

Present: Drago Rudel, Katalin Matics, Jerzy Gąsowski (chair)

JG presented all the existing documents

ALL: Generally: documents addressing the ethical issues and privacy are in place or in a preparatory phase.

JG will prepare the document "Information on the processing of personal data - Consent to the processing of personal data"

The "Patient's consent to participate" in Polish and Romanian needs to be prepared

It is expected that the documents will be ready for submission to the project officer before the Midterm review.

JG to visit the GDPR Officer at his university to discuss the ACESO approach

Next meeting of the Ethical board: in approx. 3 months' time

Final remarks

Adjourn

Ethical Advisory Board Zoom Meeting Minutes, October 17, 2022

Present: Judit Nagy, Jerzy Gąsowski (chair), Janos Csebfalvi (observer)

The agenda:

State of the project

The testing of the Integrated Platform

The JUMC Ethics Committee approved amendment

Identification of possible Ethical issues (data sharing, the interaction between end-users and ACESO Staff, etc)

Further plans

Next meeting: December 2022.

The EAB decided that the possible ethical issues during integrated testing of the ACESO platform should be considered. The EAB decided to discuss the issue in detail during its next meeting in December 2022 (date TBD).

The EAB discussed that the Romanian (to be confirmed) and the Polish end-user organizations have obtained or are in the process of obtaining or amending their ethics committee approvals to carry out the testing of the integrated platform.

The committee advises the Slovenian End-User organization to check again the need, or lack thereof, to obtain the local ethics committee approval to carry out the testing and report it back, in unequivocal terms, to the EAB.

End of the business of the October 17, 2022 ACESO EAB meeting.

Ethical Advisory Board Zoom Meeting Minutes, Apr 17, 2023

Today, we held an Ethical Advisory Board meeting with Drago and myself present. During the meeting, we discussed the status of possible ethical issues during the conduction of the pilots. In Poland, the research team received a query from an end-user concerning the handling of the personal details of the participants., in particular, who has access to those details. The end-user has been informed that the data are being analyzed anonymously and that the integration of within-participant data is achieved using consecutive anonymized logins. Only the local team, that is caring for the patients and at the same time overseeing the study can identify the health data with a given personnel. The end-user was satisfied with the explanation. The Board approved of the explanation. No issues were reported in Slovenia, and no report of any ethical issues was forwarded from Romania.

The Board agreed that another meeting be held on May 11 (ATTENTION, not on 16th May, as previously stated) at 1 p.m. CET. Besides that meeting, there will be a meeting in late June, mid-July, and the beginning of August - before the closing of the ACESO project. The meetings are part of fulfilling the project's contract, and I count on your participation.

Ethical Advisory Board Zoom Meeting Minutes, May 11, 2023

Today, we held a meeting of the Ethical Advisory Board, with DR and myself (JG) present. There were no current issues raised in the time between the previous session and today. DR and I discussed the issue reiterated during one of the earlier meetings concerning the lack of a formal ethics committee agreement in Slovenia. This stems from the specificity of legal arrangements in Slovenia ruling the need or lack thereof to obtain such a formal agreement. We condone the fact that the study is being executed in accordance with the Protocol and the fact that the participants (non-patient end-users) receive thorough information about the study and sign an informed consent document to take part. This, we think, is fulfilling the minimum ethical requirements usually needed for the conduct of similar studies.

The date of the next meeting that will take place in the second half of June will be announced later.

Ethical Advisory Board Zoom Meeting Minutes, July 11, 2023

Today, we held an Ethical Advisory Board meeting, with Ligia, Drago, Janos, and myself (chair) present. We reviewed the current status of the project. No imminent ethical issues were reported. We followed up on a thread initiated during previous meetings concerning data handling. We discussed the fact and ensured the Board of the fact that the individual patient has access to their measurements and that, on top of that customized feedback notes are sent to the patient based on the review of measurement data by the physicians affiliated with the ACESO pilots. In Kraków, on one occasion, the use of the ACESO system prompted medical attention to a patient

who had very high blood pressure values. This was seen by the Board as an example of the clinical usability of the system.

The next meeting will be held in the last week of July or the first week of August.

Ethical Advisory Board Zoom Meeting Minutes, Aug 4, 2023

We have just had a brief meeting of the Ethical Advisory Board with DR, JC, and myself (JG) present. There were no ethical issues reported since the previous meeting. As a result of our discussions earlier in the project, Inspiring Culture will prepare the customized version of the Code of Ethics document. Our last meeting is scheduled for September 8 at 9 a.m. CET.

Ethical Advisory Board Zoom Meeting Minutes, Sep 8, 2023

We have now held the final meeting of the ACESO Ethical Advisory Board with Janos, Drago, and myself (chair) present. We discussed the whole process of ethical screening and touched on the following points during the project itself, we did not encounter any significant ethical issues the form of constant monitoring with the majority of regular meetings taking place during the pilots seems to be an advisable form that enabled the committee to address the minor issues such as queries from the end users. We agreed that JG will prepare the document concerning the proceedings of the Board during the project Janos will lead the update of the official documents, such as the code of ethics, etc. We also identified that the major ethical challenges are yet to be expected in the post-marketing stage and that they might, among other issues, include the sustainability of pricing of the service, proper training of the users, etc.

I would like to thank all persons involved in our Ethical Advisory Board and with this, I close the proceedings and operations of the Board.

Jerzy Gąsowski