

Appendix I

Protection of Human Rights in Biomedicine II

Business and Technical Requirements for Design and Development of the Medical Ethics
Committee Platform in Armenia

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1. Background

1.1. Purpose of the document

The document describes the main business and technical specifications for developing a comprehensive platform for the recently established Medical Ethics Committee in Armenia.

1.2. Project reference

The project “Protection of Human Rights in Biomedicine II” is the logical continuation of a successful cooperation project “Protection of Human Rights in Biomedicine I”. The project aims at contributing to enhance awareness of European human rights’ and ethical standards in the field of biomedicine (e.g. informed consent to any medical intervention, the importance of medical secret and confidentiality, voluntary non-remunerated organ donation, preservation of genetic heritage) and to support national authorities in their efforts to align national legislation and practice in the field of biomedicine and healthcare with the European human rights’ and ethical standards in the field of biomedicine.

The project along with other activities, envisages creation of the communication platform for the Medical Ethics Committee, which was established according to the Law “On Medical aid and population services”.

1.3. Objectives and key results

One of the primary objectives of this assignment is to design and develop a website to ensure transparency, accountability, and visibility of the Medical Ethics Committee's operations. The creation of the website will ensure enhanced public access to committee information, improved communication between the committee and stakeholders, and increased awareness of the committee's role and activities.

The website should comply with the digitization standards and design system adopted by the Ministry of High-Tech Industries of Armenia.

The second goal is to examine how the committee communicates with beneficiaries, how it internally handles the cases it receives and to provide a platform that will enable:

- efficient and secure digitalization of their internal document exchange processes.
- protection of sensitive data circulated among the members and the beneficiaries.
- Collection of all data in one secure environment

For the second goal, the Supplier should use the platform operated by the Government of Armenia for digitizing state services. The platform will be provided to the Supplier for configurations according to the Committee's needs, thus there is no need for development of a new platform. However, alternative solutions can be considered and are subject to approval.

The key results which are expected to be achieved are the following:

- The website
 - A clean, comprehensive, user-friendly visual representation of the website's layout, user interface, and design elements is developed and submitted to MEC for approval.
 - Compliance of the website with accessibility and digitization standards is approved by the Ministry of High-tech Industries.
 - The website including the whole scope of functionality requested by MEC is developed.
 - The CMS, which enables easy content updates and management is developed.
 - The website and the CMS are hosted in Armenia, taking into account the sensitivity of data.
 - Website administrators are trained and provided with detailed documentation for managing and updating the site.
 - The website is tested and fully operational.
 - The smooth transition from development to live status is ensured.
 - Support is available to address any issues post-launch.
- The e-gov platform
 - The business processes of communication between the Committee and the beneficiaries are mapped using advanced BPMN tools like Lucidchart or equivalent.
 - The platform is hosted in Armenia, taking into account the sensitivity of data.
 - The platform provided by the Government is configured relevant to the business processes
 - The platform provides with opportunity to submit structured complaints to the Committee
 - The Committee processes the cases fully in digital format
 - Committee members are trained to operate the platform.
 - The platform is tested and fully operational.
 - Support is available to address any issues post-launch.

1.4. Main Legal acts

The supplier should familiarize themselves with the key legal regulations governing the Medical Ethics Committee's functions, as well as the official websites of state institutions to gain a comprehensive understanding on expected scope of works.

- [The Law on Medical Aid and Population Services](#)
- [Government Decree N 182-N dated 17.02.2022](#) "On the Rules of Ethics of Medical Professionals".
- [Government Decree N 1521-N dated 26.12.2013](#) "On minimum requirements for official web pages of the state entities".

- [Government Decree N 572-N dated 25.05.2017](#) defining the acceptable means of identification through online platforms of state institutions.
- [Order of the Minister of Health N 75-N dated 08.11.2022](#) “On defining the order of contest for the members of Ethics Committee, the working order of the Committee, the Declaration on presence or absence of conflict of interest.”
- [Order of the Minister of Health N 3470-A dated 13.07.2023](#) “On the approval of the composition of the Medical Ethics Committee”.
- [Digitization standards](#) developed by the Ministry of High-tech Industries.

1.5. Glossary

Term	Explanation
MEC	Medical Ethics Committee
CMS	Content Management System
CoE	Council of Europe
BPMN	Business process modeling notation
UAT	User acceptance testing

2. Business requirements

2.1. Overview

The law “On Medical Aid and Population Services” establishes MEC to investigate violations of professional ethics by healthcare workers. The committee, composed of seven members on public basis, includes healthcare representatives, patient rights advocates, lawyers, medical researchers, and a psychologist. The committee reviews non-criminal, non-administrative ethics violations and can recommend actions such as warnings, severe reprimands, or temporary suspension of medical licenses for repeated offenses.

The committee's communication with its stakeholders is structured through various channels: firstly, proactively providing comprehensive information about its operations, and secondly, ensuring efficient interactions with beneficiaries who have submitted complaints for review. Currently, the interactions with the beneficiaries are conducted through email, and the distribution of cases, as well as notifications about the committee's resolutions, are handled in paper format using traditional postal services. This raises serious security and efficiency concerns given that during the exercise of their functions, the Committee members deal with sensitive data.

The creation of a website will increase the awareness of MEC activities and improve the communication between the committee and all stakeholders.

At the same time, analysis of the communication processes and the configuration of the e-gov platform will ensure seamless, efficient, and secure processing of the complaints submitted for the Committee's review, ensuring high-security measures.

2.2. General requirements for the website

The Committee will supply the content for the website before the product is approved. However, if there is an unexpected delay in providing the content, the Supplier should hand over the website with placeholder content to ensure a realistic visual representation.

Below are the general functional requirements of the website:

- Multilingual. Website should support multiple languages.
- Intuitive design. The website should have a drop down mega menu on the homepage to enable users to directly navigate the page they choose. The website should have a link to the e-gov service provision platform.
- Responsive. Website viewing and interaction should adapt to the screen size layout on desktops, tablets, and mobile devices.
- Search functionality. Users should be able to search for content on the website using keywords and filters to find relevant information quickly.
- Content Management: Administrators should be able to create, edit, delete, and organise content (text, images, videos) through the CMS.
- Security: The website should include security measures: Implementation of SSL certificate, captcha, and protection against common vulnerabilities.
- Social Media Integration: The website should include features to share content on social media platforms.
- Subscriptions: The website should allow users to subscribe to news and announcements by providing an e-mail address.
- Analytics. The website should be able to integrate with analytics packages like Google Analytics.
- Flexibility: The website should ensure the possibility of extending the functionality.

2.3. Requirements for CMS

Below are the general functional requirements of the Content Management System

- The CMS system should support non-IT-literate users in operating the content within the overall rules and workflow laid down. This will include creating content, editing (with a rich text built-in editor), and publishing in all modes, including text, video, pictures, etc., across all pages on the site or in specific areas of the site.
- Adding, modifying, and deleting information in all available languages on the website should be implemented within CMS.

- Navigation must be simple and easy to use.
- Download and upload features should be supported.
- Display of content in selected order should be supported.
- Drag, drop, cut, and paste options should be easily supported.
- CMS should provide at least the following security features: Implementation of SSL certificate, Captcha, Login History, audit trail.
- CMS should offer to preview content before publishing
- The CMS should have a detailed logging of all activities performed by the Backend user on the CMS and features to track changes and actions in the system.
- The CMS should be integrated with the “Yes Em” National Authentication portal, to ensure the secure identification of the users.

2.4. General requirements for configuration of e-gov platform

Below are the general requirements for the e-gov platform

- Forms submission. Beneficiaries should be able to reach out with structured inquiries, and support requests to the Committee.
- Processing: The Committee should be able to process the received case in a digital manner
- Notifications: The Committee should be able to notify the beneficiary about the need for resubmission of the form, provision of additional evidence, and communicating the final resolution through the same platform.
- Database: The Committee should be able to create a database of all the cases to ensure institutional memory
- Security: The website should include security measures: Implementation of SSL certificate, captcha, and protection against common vulnerabilities.
- Reporting: The committee should be able to create various reports with the data collected in the platform.

3. Technical requirements

3.1. User Interface

The website should follow the principles of universal design:

- Equitable use: The design is useful and marketable to people with diverse abilities.
- Flexibility in use: The design accommodates a wide range of individual preferences and abilities.
- Simple and intuitive use: The design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level.
- Perceptible information: The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.

- Tolerance for error: The design minimizes hazards and the adverse consequences of accidental or unintended actions.
- Low physical and cognitive effort: The design can be used efficiently and comfortably and with minimum fatigue.
- Size and space for approach and use: The design provides appropriate sizing and spacing of elements, allowing the user to interact successfully.

The website should follow the web accessibility principles, on which level AA WCAG is based.

The main accessibility principles are the following:

- Perceivable: Information and user interface components must be presentable to users in ways they can perceive.
- Operable: User interface components and navigation must be operable.
- Understandable: Information and the operation of the user interface must be understandable.
- Robust: Content must be robust enough that it can be interpreted reliably by a wide variety of user agents, including assistive technologies.

During the acceptance, the website should be checked against the WCAG using relevant tools.

3.2. Hosting and Database backup

3.2.1. Hosting

The Supplier should host the product in Armenia during the whole period of support, which is 36 months. The hosting conditions should be compliant with the Government Decree 1069-N dated 20.10.2016.

3.2.2. Backup policy

- Incremental backups should be implemented on a daily basis to capture changes since the last full backup, which should be implemented on a weekly basis, reducing storage needs and speeding up the process.
- Encryption: The backup data should be encrypted during the transit and at rest to ensure protection of sensitive data.
- Regular Testing: The supplier should regularly test backup files to ensure that they can be restored accurately and within maximum 24 hours.
- Lifecycle management: The Supplier should develop the backup lifecycle management plan, including the proposal for back-up storage media to be utilized and submit for Committee's approval.

3.3. Documentation

3.3.1. Deliverables

1st Phase:

Within the first phase of the implementation, the Supplier should develop a detailed action plan based upon the initial plan outlining all the phases of the implementation and investigation during the first stage.

The supplier should organize kick-off meetings and workshops to discuss MEC's requirements and approaches. During this phase, the Supplier should also familiarize themselves with the e-gov platform and map all of the Committee's business processes.

As a result, the Supplier should come up with proposals for a user-friendly and optimal website design and the optimal implementation of the end-to-end digital service for submitting structured complaints to the Committee.

The deliverables for the 1st phase are the following:

- Detailed project plan, including implementation schedule, organization, testing and quality assurance, training, warranty, and support plans.
- Technical and business specifications of the product with all components
- Visual experience and design
- Site map detailing
- Detailed business processes map for interactions with the beneficiaries

2nd Phase:

During the second phase, the Supplier should develop the initial version of the website and the initial configuration of the e-gov platform and make them available for testing by the end-user.

The deliverables for the 2nd phase are the following:

- Report on main activities implemented during the second phase

3rd Phase:

In the third phase, the Supplier should amend the products based on the feedback received by MEC, test the products, and conduct training.

The deliverables for the 3rd phase are the following:

- Reviewed and finally confirmed mockups and layouts
- Testing results

- Training materials, attendee's list
- Report on main activities implemented during the third phase

4th Phase:

In the fourth phase, the Supplier should finalize the product (including operational acceptance) and transfer to live mode.

The deliverables for the 4th phase are the following:

- The final version of the software package (including all source codes), all sub-systems, installer packages, configuration files, and all those components that are necessary for the product's operation (final tested and corrected version).

These activities should be followed by Warranty and Support services.

3.3.2. Reporting

The supplier shall develop and submit to MEC narrative and Phase reports on progress achieved, issues identified, and solutions proposed accompanied by the relevant documentation(s).

3.4. Security requirements

The following security-related minimum requirements should be implemented for the provided product.

- System interaction protocol: HTTPS protocol (TLS 1.3) should be used for all communication and interactions with the website and CMS and other information environments
- Authentication: Multi factor authentication mechanisms should be enforced using a combination the following:
 - "YesEm" National Authentication portal
 - OTP
 - Other identification means prescribed by Armenian regulations.
- Authorization: CMS should implement Role Based Access Control (RBAC) ensuring actions are restricted unless they are explicitly assigned to the user.
- Protection of sensitive data: The website and the CMS should ensure the protection of personal data in accordance with applicable rules and the requirements of the RA Law on Protection of Personal Data. Personal data exchange should be compliant with the Government Decree N 1093-N dated 31.08.2015.
- Logs: The system should support different logging levels for all nodes and components which should be stored in a database. Any unauthorized attempt to edit data shall be logged with further possibility to be subjected to audit.
- All login/logout sessions should be logged, keeping the IPs and date and time.

- The CMS administrator should be able to enable/disable users accounts. The user account should be automatically disabled in case of a prescribed number of failed attempts to login.
- Data entered into the CMS may not be edited, damaged or deleted without authorization.
- Availability: The system should guarantee full data storage on predefined, configurable periods which shall not exceed Recovery Point Objective (RPO) and Recovery Time Objective (RTO) defined by the Committee.

3.5. Training

3.5.1. Training aim

The aim of the training is to provide training, capacity-building support, and comprehensive information about the general operation of the CMS and the website. It is expected that after the training, the staff of the Committee will have sufficient skills to run the website without constraints.

The training should be envisaged for ~~27~~ persons.

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3.5.2. Training materials and approaches

- All materials, including user manuals, presentations, videos, etc., should be provided to trainees before the training.
- The training should be conducted in Armenian language.
- The training format can vary depending on the actual need assessed by the Supplier before the fully operational live status. The training methods may, without limitation, include presentations for the trainees, intensive classroom activities during which manuals and other technical literature will be handed over, briefings and orientation classes, seminars and on-site workshops.

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3.6. Testing of the products

System testing and acceptance plan shall include testing scenarios.

Website must be beta tested to MEC's satisfaction before final launch.

The Supplier should share the link of website in testing mode after the development phase and before launch of the website.

UAT of the product should be conducted by the members of the Committee To conduct the UAT, the Supplier should develop functional requirement checklists.

In the case of revealed discrepancy between functional requirements specifications and UAT testing, the Supplier should record the revealed bugs and appropriately fix them.

3.7. Source codes and intellectual property

The Supplier, within fifteen (15) days of, conveys to CoE the Source Code of the website and the CMS and all relevant documents.

During the warranty period, the Supplier should supply to CoE, within fifteen (15) days of any changes in the production release, the Source Code and related documents that are complete, accurate and up to date corresponding to the current production release.

The Source Code shall contain all information in human-readable form necessary to enable a reasonably skilled programmer or analyst to maintain and/or enhance the website and the CMS. The Source Code and related documentation shall contain all listings of programmers' comments, data, and process models, logic manuals, and flowcharts.

The Supplier should convey to CoE a permanent, irrevocable license for the use of the website and CMS. This license should entitle MEC to modify, extend, duplicate, and prepare derivative software or materials for use. MEC should become the exclusive holder of all the corresponding economic rights of the provided product.

3.8. Support and Warranty

3.8.1. Technical Support

After the official handover of the website and the e-gov platform to MEC, the Supplier should provide **36 months** of technical support. Within this support, upgrades and releases should be submitted to correct the errors and bugs.

In case of detecting incompliance in the website and in the CMS, those should be eliminated by the Supplier and at the Supplier's expense. The Supplier will take into account that during this time period MEC may request changes in the website for **up to 15 (fifteen) percent of the total scope of works**.

3.8.2. Warranty

The supplier should provide warranty services that will cover any defects or malfunctions that are observed by MEC during operation of the website and the CMS. All works completed under warranty services will not be included in 15 (fifteen) percent of the total scope of works.

Warranty terms need to be considered during the servicing periods and include errors which are software defects that cause incorrect functions of the website or the CMS. The types of errors described including but not limited to:

- The system is not accessible.
- The system performance is too slow, which is not connected with the internet speed.
- The response is not processing logical requests resulting in performance issues, not connected with the database operations.
- Not all entered data is saved in the system or saved correctly.

- Reports/documents/webpages do not display the expected results; and
- The system generates messages of unsolvable problems and shows errors to the users.

4. Critical considerations

4.1. Assumptions

The following assumptions should be taken into consideration

- Members of MEC will provide information and explanations required for setting up the website, as well as all business process and flows
- All MEC members have workplaces equipped with computer connected to the Internet
- The Government will provide the Supplier with the e-gov platform for configuration and incorporation of business processes mapped during the project.
- The Supplier should provide hosting of the website with the CMS throughout the whole period of Support services

4.2. Constraints

The Supplier should take into account that throughout the implementation of the project they can encounter several constraints and risks, some of which are the following.

- The current regulations mandate communication exclusively through email. To implement the digital service, changes to these regulations will be necessary.

5. Requirements traceability matrix

Requirement ID	Requirement description	Required/optional
WEB01	The website should follow the principles of universal design	R
WEB02	The website should be compliant with WCAG principles	R
WEB03	The website should get the compliance approval from the Ministry of High tech industries	R

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WEB04	Website viewing and interaction should adapt to the screen size layout on desktops, tablets, and mobile devices.	R
WEB05	Users should be able to search for content on the website using keywords and filters to find relevant information quickly.	R
WEB06	Implementation of SSL certificate	R
WEB07	The website should allow users to subscribe to news and announcements by providing an e-mail address.	R
WEB08	The website should be able to integrate with analytics packages like Google Analytics	R
CMS01	Creating content, editing(with rich text editor), and publishing in all modes, including text, video, pictures, etc. by non-IT-literate users.	R
CMS02	Creating multilanguage content	R
CMS03	Download and upload features should be supported.	R
CMS04	Display of content in selected order should be supported.	R
CMS05	Drag, drop, cut, and paste options should be easily supported.	R
CMS06	Content preview before publishing is supported.	R
DGS01	Opportunity to submit structured complaints to the Committee is ensured	R
DGS02	The business processes of the Committee are mapped	R
DGS03	Notifications to the beneficiary about the need for resubmission of the form, provision of additional evidence, and communicating the final resolution through the same platform	R
TR01	The staff is trained to use the product and is provided with all necessary materials	R

HB01	Host the product in Armenia compliant to existing regulations	R
HB02	Ensure Backup is compliant with requirements set out in the ToR	
HB03	Ensure all security measures set out in ToR are in place	R
SWS01	Support and Warranty services are provided for a period of 36 months.	R

6. Schedule

Below is the estimated schedule for implementation of the project.

[illegible]