

APPROVED

Ethics Advisory Board
of the BioPhoT Platform

[Date] Protocol No. [number]

Long-term State Research Program

"Research platform for innovative products in biomedicine and photonics"
(BioPhoT)**Ethics Advisory Board****CHARTER****I. GENERAL PROVISIONS**

1. The Ethics Advisory Board Charter (the Charter) serves to define the mission, composition, responsibilities, and operational guidelines of the Ethics Advisory Board (the EAB) of the Long-term State Research Program "Research platform for innovative products in biomedicine and photonics" (BioPhoT) (the Platform).
2. The EAB shall operate in strict adherence to all applicable national and international laws, as well as uphold the highest ethical standards.

II. PURPOSE AND SCOPE**MISSION STATEMENT**

3. The EAB is established by the Platform's Ethics and Conflicts of Interest Working Group to serve as an external and independent body established to provide expert guidance, advice and oversight on the issues of ethics, conflict of interest and inclusion arising during the implementation of the Platform. The primary purpose of the EAB is to ensure that all activities within the Platform adhere to the highest ethical and inclusion standards, thereby enhancing the integrity of the Platform's outcomes and maintaining public trust.

SCOPE OF AUTHORITY

4. The EAB has an advisory role. It provides opinions, advice, and recommendations on issues related to ethics, conflict of interest, and inclusion. It has authority to perform the following tasks:

4.1. By providing feedback and recommendations the EAB contributes to the development and refinement of the Platform's ethics and inclusion strategy and guidelines, ensuring they are comprehensive and comply with the current ethical standards and applicable international, EU, and national laws.

4.2. In its consultative role, the EAB supports the Platform regarding its alignment with ethical standards and relevant regulations. To ensure it the EAB provides annual recommendation reports by reviewing the Platform's annual ethics and inclusion report, identifying key ethical considerations that includes proposed corrective actions when appropriate.

4.3. The EAB offers independent advice to those involved in the implementation of the Platform on ethical, conflict of interest, and inclusion issues identified during the Platform's lifecycle.

III. COMPOSITION, ROLES, AND TERMS

5. In accordance with applicable regulatory requirements, members of the EAB are selected through a transparent evaluation process. Candidates must possess a doctoral degree in a relevant field, have 5–10 years of professional experience in ethics, public health, or diversity and inclusion, and demonstrate expertise in bioethical principles, inclusive practices, and policy-making within health or academic settings.

6. The EAB consists of three members, each playing a specific, complementing role in the EAB. Consequently, the EAB is composed of one member with expertise in research ethics; one with expertise in the management of conflict of interest; and one with expertise in the matters of diversity and inclusion. All members have been selected for their high level of expertise and experience in their respective domains, ensuring the Platform's capacity to effectively address ethical challenges and uphold high ethical standards.

7. The EAB Chair is elected by a majority vote of the EAB members from among themselves.

8. The term of office of the EAB and its Chair is twelve months.



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9. Upon the conclusion of the Chair's term or in the event that the Chair is unable to fulfil their duties, the EAB shall convene a meeting to elect the next Chair from among its members. This meeting should be organized as soon as possible to ensure continued effective functioning of the EAB.

IV. RESPONSIBILITIES

MEMBERS

10. The EAB members within their service period are expected to:

11.1. Affirm that they have read, reviewed and accepted the terms outlined in this Charter, and agree to fulfil their responsibilities in accordance with its provisions. Written feedback is to be submitted to the Head of the Platform's Ethics and Conflicts of Interest Working Group.

11.2. Participate in the inaugural (kick-off) meeting (virtually), during which the Chair of the EAB will be elected.

11.3. Review the Ethics and Inclusion Strategy and Guidelines documents, developed by the Platform's Ethics and Conflicts of Interest Working Group, and submit a consensus-based consolidated recommendation report to the Head of the Platform's Ethics and Conflicts of Interest Working Group.

11.4. Review the Platform's annual Ethics and Inclusion Report, prepared by the Platform's Ethics and Conflicts of Interest Working Group, and provide their assessments and recommendations for improvement. A consensus-based consolidated report summarizing these evaluations shall be submitted to the Head of the Platform's Ethics and Conflicts of Interest Working Group. Additionally, the members of the EAB are to organize up to three virtual meetings to present their findings and discuss issues with the partners of the Platform's Consortium.

11.5. Provide expert opinion (within the scope of and according to their expertise) on relevant issues and challenges, including conflict reports and ethics complaints, in the implementation of the Platform, submitted to them by the Head of the Platform's Ethics and Conflicts of Interest Working Group. If applicable the members are expected to collaborate in preparing their opinion and request a consultation meeting for clarification and more in-depth discussion of the issue. The final opinion in a written is to be submitted to the Head of the Platform's Ethics and Conflicts of Interest Working Group within one month of the receipt of an issue report.



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CHAIR

12. The Chair of the EAB is expected to:

12.1. Facilitate and organise the work of the EAB by monitoring compliance and ensuring timely follow-up, setting the EAB meeting agendas, organizing and leading the EAB's meetings.

12.2. Ensure effective communication within the EAB and between the EAB and the Platform, ensuring timely and accurate information exchange to support the EAB's functions.

12.3. Consolidate the EAB opinions, assessments, suggestions, recommendations into consensus-based documents and submit them to the Head of the Platform's Ethics and Conflicts of Interest Working Group. In cases where dissenting opinions exist, the Chair shall ensure that these perspectives are accurately and respectfully represented in the final documentation submitted to the Platform's Ethics and Conflicts of Interest Working Group.

V. OPERATIONAL FRAMEWORK

MEETINGS

13. The EAB will convene at least once a year, with additional meetings as needed to perform their duties, and will report its findings to the Head of the Platform's Ethics and Conflicts of Interest Working Group until October 31, 2026.

14. The EAB shall convene remotely using secure video conferencing platforms that comply with applicable data protection laws, including the General Data Protection Regulation (GDPR), to ensure confidentiality and the protection of personal data.

15. The meetings of the EAB shall be conducted in closed sessions. Attendance is limited to the EAB members and individuals expressly invited by the Chair to address specific agenda items. Invited participants may attend only the parts of the meeting relevant to their invitation. All attendees, invited participants included, are required to maintain strict confidentiality regarding all discussions and materials presented during the meeting.

16. Minutes of the EAB meetings shall be taken, capturing the most essential information on key discussions and action items. A member responsible for taking the minutes shall be designated prior to or at the commencement of each meeting. After the meeting draft minutes should be distributed to all members for review. Once reviewed and approved, the minutes shall be signed by the Chair and

submitted to the Head of the Platform's Ethics and Conflicts of Interest Working Group for official record-keeping.

RECOMMENDATIONS, ADVISORY OPINIONS, DECISIONS

17. A meeting of the EAB is considered quorate when all three members are present. Decisions, advisory opinions, and recommendations are adopted through an open vote, requiring the participation of all members. A proposal is deemed approved if at least two members vote in favour. In circumstances where a member recuses themselves from deliberation due to a conflict of interest or other valid reasons, the remaining two members may proceed, and their unanimous agreement shall constitute the EAB's official position.

18. The EAB shall strive to reach consensus in developing its recommendations and formulating advisory opinions. However, members who disagree with the majority have the right to have their dissenting opinions formally recorded. In instances where consensus cannot be achieved, the Chair shall ensure that both majority and minority perspectives are accurately and respectfully represented in the document

19. The EAB members shall disclose any potential conflicts of interest. If a member of the EAB has a conflict of interest, they shall inform the other members thereof and shall not participate in discussions or express an opinion on inquiries or action items.

20. The Chair of the EAB is responsible for maintaining all records related to the EAB's activities, including meeting minutes, advisory opinions, and official correspondence. Upon the conclusion of their term or in the event they are unable to continue in their role, the Chair shall promptly transfer all records to the Head of the Platform's Ethics and Conflicts of Interest Working Group to ensure continuity and proper record-keeping.

COMMUNICATION

21. Internal communication within the EAB shall be carried via secure emails and video conferencing platforms. While ensuring communication and information exchange primarily is the responsibility of the Chair, all members of the EAB have the responsibility of duly, regular and transparent communication. If situation permits the Chair shall send out meeting agendas and all the relevant documents to all members of the EAB at least three business days prior to scheduled meetings allowing for adequate time for review and preparation. Members of the EAB are expected to acknowledge receipt of communications and respond to inquiries or action items within three business days promoting efficient workflow continuity.



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22. In the event of communication disputes or misunderstandings, the EAB members are encouraged to address issues promptly through dialogue, facilitated by the Chair if necessary.

23. External communication between the EAB and the Platform shall be carried via secure emails and video conferencing platforms. The Chair of the EAB and the Head of the Platform's Ethics and Conflicts of Interest Working Group serve as the primary liaisons between the EAB and the Platform. If the Chair is unable to fulfil this role, other EAB members shall assume responsibility for maintaining effective communication with the Platform. The liaisons are expected to acknowledge receipt of communications and respond to inquiries or action items within three business days. The Head of the Platform's Ethics and Conflicts of Interest Working Group is responsible for providing feedback on how the EAB's opinions, advice, and recommendations will be put into practice in the implementation of the Platform.

VI. FINAL PROVISIONS

24. The Charter shall be approved by all members of the EAB. Once approved, the Charter shall be signed by the Chair and submitted to the Head of the Platform's Ethics and Conflicts of Interest Working Group for official record-keeping.

25. This Charter shall be reviewed to ensure its continued relevance and effectiveness. Amendments require approval by all members of the EAB.

Chair _____
Name, Surname

THIS DOCUMENT IS ELECTRONICALLY SIGNED WITH A SECURE ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP