DELIVERABLE 11.5

GEN – REQUIREMENT NO. 5

WORK PACKAGE NUMBER: 11

WORK PACKAGE TITLE: ETHICS REQUIREMENTS

ETHICS

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Lead beneficiary	BIU
Lead Author(s)	Jos Dumortier and Liesa Boghaert
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Coordinator	Prof. Gur Yaari	Bar Ilan University	28.12.19	GY
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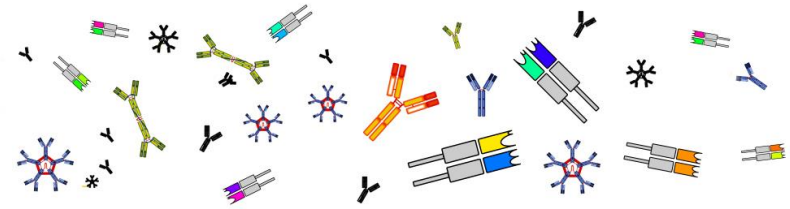
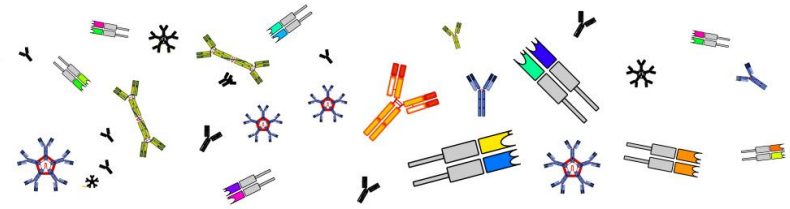


Table of Contents

This project is funded by the European Union's H2020 Research and Innovation Programme under Grant Agreement No. 825821 and Canadian Institutes of Health Research (CIHR)



Executive Summary

This deliverable incorporates the ethics requirement GEN- Requirement No. 5. It describes how the iReceptor Plus Ethics Board (EB) was established, who is member to the EB, what the tasks of this EB are and how the Board will operate.

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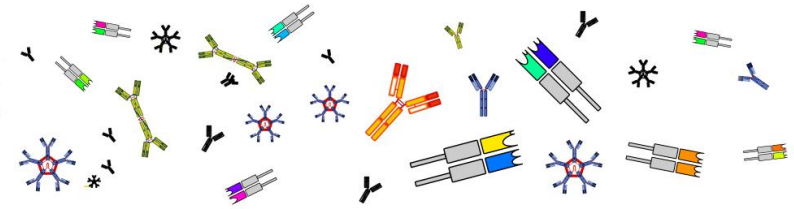

Introduction

As a part of Work Package 11 'Ethics Requirements', Deliverable 11.5 is aimed at demonstrating that an Ethics Board (EB) was established for iReceptor Plus, which includes the relevant independent expertise to monitor the ethical concerns in the project. This Ethics Board will issue periodic reports, that may be submitted as well.

1. The Ethics Board

This section contains details on the constitution of the EB, its role and independence.

1.1 Members and constitution

The iReceptor Plus project has designated an Ethics Board consisting of independent experts to monitor and provide guidance on ethical issues raised throughout the project implementation.

The EB consists of 3 experts: Dr. Aisling De Paor, Ms. Heidi Beate Bentzen and Prof. Dr. Yann Joly.

In what follows, their expertise and professional experience is described.

Dr. Aisling De Paor, is a researcher and lecturer at the School of Law and Government of Dublin City University, Ireland, where she teaches the subjects 'Medical Law and Bioethics' and 'Genetics, Law and Society'. Dr. De Paor's research focuses on medical law and bioethics, genetic discrimination and the law, genetic privacy and data protection and science, new technologies and the law more generally.

She was previously a part-time Lecturer in Law at National University of Ireland (NUI), Galway (2009- 2014), lecturing modules including Health Law and Policy, and Genetics, Disability and the Law. She is a former Irish Research Council Scholar and former Ph.D. candidate at the Centre for Disability Law and Policy at NUI Galway. In 2013 Aisling defended her Ph.D., entitled 'Advancing Science and Controlling the Misuse of Genetic Information in Employment and Insurance – Towards an Effective European Union Regulatory Framework.' Aisling graduated from NUI, Galway with a B.C.L. in 2005, and graduated from University College Cork with LL.M. in 2006. She is a qualified Solicitor and trained in a large commercial law firm in Dublin (from 2006 to 2009), having specialised in Employment Law and Commercial Litigation for the majority of her traineeship. She has also worked as a Research Assistant at the Centre for Disability Law and

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Policy (2009-2010). Aisling is an honorary fellow and affiliated researcher with the Burton Blatt Institute, Syracuse University, New York. She regularly collaborates with this Institute and was a visiting scholar there in October 2012 and May 2014.

Ms. Heidi Beate Bentzen, is a doctoral research fellow at the University of Oslo, Norway. Ms. Bentzen holds an LLM/Master of Laws degree and shares her time between The Centre for Medical Ethics at the Faculty of Medicine and The Norwegian Research Center for Computers and Law at the Faculty of Law, both at the university of Oslo. She collaborates with The Norwegian Cancer Genomics Consortium. Bentzen is also an Academic Affiliate at HeLEX Centre for Health, Law and Emerging Technologies at the University of Oxford. She is a member of the United Nations Special Rapporteur on the Right to Privacy's Task Force on privacy and the protection of health data (MediTAS) and was part of drafting the global Recommendation on the protection and use of health-related data. Bentzen is a member of the Norwegian Directorate of Health's Bio Reference Group, which is an expert advisory board for the Norwegian authorities in biotechnology related matters. She contributes to the drafting of a GDPR Code of Conduct for health research in the EU, an initiative spearheaded by the European biobank network BBMRI-ERIC. She is a Board Member of the Norwegian Association for Computers and Law, and Bioethics Advisor for the European Huntington's Disease Network. Bentzen co-chaired the law and ethics working group in the European network for researchers working on ELSI aspects of genomics, COST Action IS1303. She is a member of COST Action CA17130 on implementation of psychiatric genetic counseling, testing, and training in Europe.

Ms. Bentzen's PhD project pertains to the legal regulation of personalized medicine in the EU/EEA. This includes the regulation of genetic testing, and the processing of human biological samples and DNA data, including reuse and data sharing both within and outside the EU/EEA. Bentzen also researches reuse of health data through the Nordic, interdisciplinary, empirical project Governance of health data in cyberspace, led by the University of Oxford, with the University of Oslo, Uppsala University and the University of Iceland as partners.

Ms. Bentzen's academic interests focus on biotechnology law, privacy and data protection law, health law, bioethics, life science, personalized medicine, precision medicine and artificial intelligence. Bentzen is an ad hoc reviewer for several international scientific journals.

Prof. Dr. Yann Joly, is a Lawyer Emeritus from the Quebec Bar and the Research Director of the Centre of Genomics and Policies (CGP). He is an Associate Professor at the Faculty of Medicine, Department of Human Genetics cross-appointed at the Bioethics Unit, at McGill University, in Montreal, Canada. He is a Research Fellow at the Fonds de recherche du Québec- Santé (FRQS) and an Associate Researcher at the Centre de recherche en droit public at Université de Montréal.

Prof. Dr. Joly is also the Chair of the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC) and of the UNESCO and Human Variome Project (HVP) Standards Group. He

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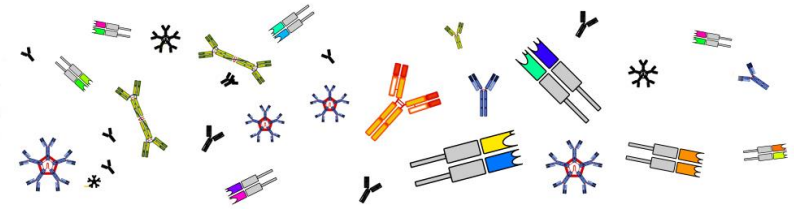

is the Data Access Officer of the International Cancer Genome Consortium (ICGC) and a member of the Human Genome Organization (HUGO) Committee on Ethics, Law and Society (CELS).

His research interests lie at the interface of the fields of intellectual property, health law (biotechnology and other emerging health technologies) and bioethics. Prof. Dr. Joly has published his findings in over a hundred peer-reviewed articles featured in top legal, ethical and scientific journals. He served as a legal advisor on multiple research ethics committees in the public and private sectors. He also sits on editorial committees and acts as a reviewer for a wide range of publications in his field. In 2012, he received the Quebec Bar Award of Merit (Innovation) for his work on the right to privacy in the biomedical field.

1.2 Role and function

The role of the EB is to provide professional external independent advice and input on the activities planned in iReceptor Plus. The European Commission (EC) highlights the role of Ethics Advisors as it states: "the role of Ethics Advisors (EAs) and Ethics Advisory Boards (EABs) should be seen as the EC fulfilling its obligations to help avoid public uneasiness towards science and to mitigate concerns where they exist."[1] Therefore, the EB must maintain an overview of the activities and progress of iReceptor Plus.

The essential task of the EB is to do whatever is necessary to diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards and ensures that the researchers, the Commission and the general public are not exposed, by the work of the project, to activities that would be considered to be ethically unacceptable. More precisely, the EB must intervene actively where necessary and to the extent possible in a preventive manner.

The EB will apply the following principles in their work:

- appropriate participation
- procedural justice
- responsible stewardship
- accountability
- transparency
- effectiveness
- coherence

[1] See p. 1, „Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects" (2012), available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf.

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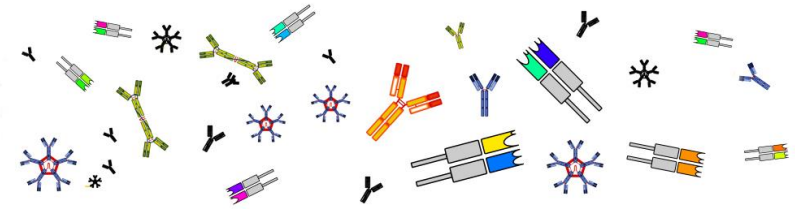

The concrete work and form of integration of the EB within the project iReceptor Plus in terms of participation and contribution of the EB in meetings and work packages is described in sections 2.2 “Participation and contribution”.

The EB should recall that the reports it produces and the advice it offers must be pragmatic/workable, clearly explained and justified (with reference to the principles, criteria, approached being applied, and the sources of this guidance), and be understandable by the partners so that appropriate actions can be taken.

The EB should aim to give consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EB provides a transparent overview on its discussion to the project management, detailing why no consensus-based advice was possible.

1.3 Independence

The members of the EB are independent experts and do not belong to any of the partner organisations in the consortium.

2. Work Programme

This section describes how the EB shall operate in practice.

2.1 Internal organisation

The members of the EB should coordinate their actions internally before providing opinions and recommendations to the consortium or to members of the consortium. To do so the EB shall identify ethical challenges based on their expertise and define principles, criteria or guidance to address ethical challenges.

2.1.1 Meetings of the Ethics Board

The EB will meet a maximum of three times, at the invitation of the Project Coordinator.

In addition to the EB members, Timelex (as the legal counsel), Bar Ilan University (as the Project Coordinator) and SFU (as the Scientific Manager) may be invited to attend the meetings of the Ethics Board as a guest to either guide and support the EB by providing details on the project activities or to ensure consistency with parts of the work of WP3.

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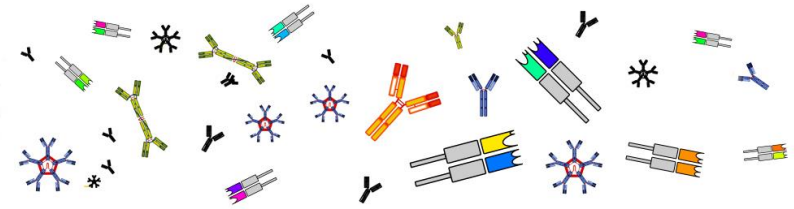

A proposal for a basic agenda of EB meetings is the following:

- Confirmation of attendance
- Discussion on recent activities and project progress
    - Identification of relevant ethical challenges
    - Development of recommendations/approaches to handle ethical challenges
- Any other business

2.1.2 Communication

For transparency reasons and in order to ensure that everybody is informed in an adequate way the consortium decided to implement mailing lists for all bodies and work packages within the project iReceptor Plus, including for the Ethics Advisory Board.

2.1.3 Documentation

Minutes of the EB meetings, incorporating at least the following fields, may be taken in the iReceptor Plus template:

- Attendance
- Results and recommendations
- Decisions taken
- Next step (actions required and by whom)
- Other notes
- Next meeting

2.2 Participation and contribution

2.2.1 Meetings with the Consortium

The EB shall address the consortium as a whole with their recommendations and advice. Therefore, the attendance of selected sessions organised in the context of relevant GA meetings by the EB may be recommendable. To that extent, the Project Coordinator can invite EB members to the meetings of GA sessions, either remotely or by physical attendance, or he can invite the EB members to meet the day before or after the GA.

The EB members can access and supervise all work packages of iReceptor Plus to ensure keeping an overview of activities connected to ethical issues.

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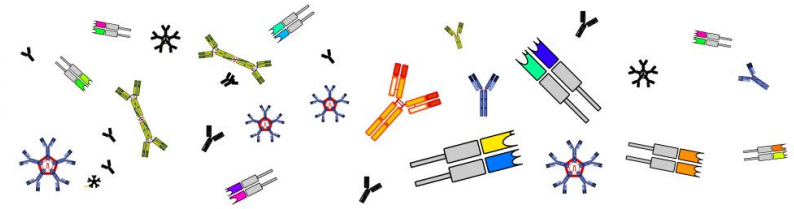

2.2.2 Communication

The EB members are included in a general mailing list which consists of all consortium partners of the iReceptor Plus project. This way, they will be informed about general activities, GA meetings and minutes and the overall project progress. The EB members can by request be included in the mailing lists of the work packages as well. This way, they will be informed about detailed activities, meetings and the progress of the respective work package.

EB members will also be given access to the project's repository in order to access all minutes from meetings within the project iReceptor Plus and other documents such as deliverables.

2.2.3 Review activities

During project implementation, the EB may review and comment on selected deliverables as the concrete outcomes of the project.

2.2.4 Reporting

The EB will need to report on its work done at regular intervals. These report of the Ethics Board are submitted to the European Commission.

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