Responsible Innovation of AI and the Life Sciences

Industry Connections Activity Initiation Document (ICAID)

Version: 1.0, 13 November 2020

IC20-027-01 Approved by IESS SMDC 18 December 2020

Instructions

- Instructions on how to fill out this form are shown in red. It is recommended to leave the instructions in the final document and simply add the requested information where indicated.
- Shaded Text indicates a placeholder that should be replaced with information specific to this ICAID, and the shading removed.
- Completed forms, in Word format, or any questions should be sent to the IEEE Standards Association (IEEE SA) Industry Connections Committee (ICCom) Administrator at the following address: industryconnections@ieee.org.
- The version number above, along with the date, may be used by the submitter to distinguish successive updates of this document. A separate, unique Industry Connections (IC) Activity Number will be assigned when the document is submitted to the ICCom Administrator.

1. Contact

Provide the name and contact information of the primary contact person for this IC activity. Affiliation is any entity that provides the person financial or other substantive support, for which the person may feel an obligation. If necessary, a second/alternate contact person's information may also be provided.

Name: Filippa Lentzos/Kobi Leins/Nancy Connell/Anja Kaspersen
Email Address:
filippa.lentzos@kcl.ac.uk/kleins@unimelb.edu.au/nancyconnell@jhu.edu/anthka@icloud.com
Employers: King`s College London/Melbourne University/John Hopkins
Affiliations: Individuals*

*BIOs for all primary contacts hyperlinked above

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

2. Participation and Voting Model

Specify whether this activity will be entity-based (participants are entities, which may have multiple representatives, one-entity-one-vote), or individual-based (participants represent themselves, one-person-one-vote).

Specify: "Entity-Based" or "Individual-Based".

Individual Based.

3. Purpose

3.1 Motivation and Goal

The goal of this Industry Connections Program is to strengthen IEEE Standards Association work on biosecurity and safety aligning and supporting with IEEE`s mission of "Advancing Technology for Humanity".

Nowhere is the potential of Artificial Intelligence (AI) and autonomous intelligent systems (AIS) more apparent than in human health and human biology, where increasingly sophisticated computational data modelling methods have led to dramatic improvements in our ability to precisely diagnose and treat disease, to estimate risks, and to deliver care. Genetic information is increasingly being used in AI algorithms to guide treatment selection and even whether treatment is provided at all. The transformative impact of these technologies and the commodification of our biological and genomic data will have significant impact on the future biological continuum and geopolitical order.

AI and AIS have also expedited public health responses to biosecurity. Advances in computational sciences and bioengineering present a set of entrenched challenges to global security, international standards, guidelines and treaties, and national frameworks, in particular, those geared towards preventing the proliferation of biological risks such as the accidental or deliberate release of pathogens or the deliberate targeting of certain groups of people or even individuals. The colossal challenges of converging technologies will require bold ideas to re-envision future biosecurity and biosafety innovation. Biosecurity is a term encompassing a broad range of policies, practices and regulatory frameworks, from overseeing biosafety, through dual use research of concern, to biological weapons programmes. Moreover, new forms of surveillance fueled by personal and biological data, prompted by a global health crisis such as the COVID-19 pandemic, can also enable unprecedented social and biological control.

Indeed, five years ago, a group of 18 scientists, engineers and ethicists, including the 2020 winner of the Nobel Prize, warned that CRISPR, a revolutionary new tool to cut and splice DNA, should be used cautiously when attempting to correct human genetic diseases, and strongly discouraged any attempts at making deliberate changes to the human genome. Conversely, the same year, more than 1000 experts, scientists and researchers warned about the dangers of autonomous weapon systems, drawing inspiration from biologists' stand against the militarization of their science. However, the uncomfortable reality of both these noble initiatives is that such weapons will likely not be purpose-built but rather derived from repurposing existing, commercial industry-driven technologies.

3.2 Related Work

The proposal for a dedicated IC for biosecurity and AI provides tangible, practical and actionable tools and resources, as well as knowledge-building for biotechnologists, life scientists and A/IS Creators to help guide the development and deployment of AI-based technologies in the life sciences. There have not yet been specific consortia or associations in this area directly focused on the development of official standards or working with the standards ecosystem. Although some of the ISO standards under negotiation will apply, none are specifically contemplating AI and the life sciences.

The lack of a regular technical and scientific dialogue and collaborative platform impact on the ability to comprehensively and collectively review and appropriately address the risks arising from the speed in complexity and breadth of applications in life sciences, genomic technologies and bioinformatics. A lack of shared scientific and technical standards as well as the lack of a common vernacular to define the qualities of these transformative technologies and potentially bio-invasive surveillance tools, raise multiple concerns, and require urgent attention. The proliferation of data-reliant health technologies, the fast-growing biotechnology community and the ubiquity of health data will likely contribute to the onset of new biometric-based revenue streams and the onset of a new digital age. Moreover, the lack of global and shared industry standards in key domains of the life sciences with deep and profound impact on international security not only hinders the interoperability of such technologies but also raises a separate set of concerns which might complicate regulatory compliance of opportunities and assessments.

This activity will identify key priority areas requiring improved engagement and work from the standards community.

Related and relevant work include:

- IEEE Explore: Malaysia: Bioethics as a biosecurity measure for monitoring genetic engineering activities against the threat of bioterrorism. Marina Abdul Majid. 2012.
- IEEE Explore: Experiences with Extreme Programming in Telehealth: Developing and Implementing a Biosecurity Health Care Application. A Fruhlin, K.Tyser, G.J. de Vreede
- IEEE Explore: A comprehensive threat management framework for a crop biosecurity national architecture. R.L. King, DH Poston, L.Wasson, W.Givens
- IEEE Journal of Biomedical and Health Informatics
- IEEE. A New Horizon within reach for personal health data security and patient safety with block chain. Maria Palombini. 2017

There are also related IC efforts, which will be instrumental to collaborate with to bring this work forward. These include:

- IEEE Brain and Brain-Machine Interfacing/Brain Computer Interface Initiatives
- IEEE AI/AIS

3.3 Previously Published Material
Provide a list of any known previously published material intended for inclusion in the proposed deliverables of this activity.

List the previously published material, if any.

Kobi Leins, 'Regulation of the Use of Nanotechnology in Armed Conflict', (May 2017) IEEE Society on Social Implications of Technology, 46-47
Robin Coupland & **Kobi Leins**, 'Science and Prohibited Weapons', (24 June 2005) Science Magazine Simon Coghlan & **Kobi Leins**, "Living Robots": Ethical Questions about Xenobots (2020) The American Journal of Bioethics
Simon Coghlan & **Kobi Leins**, 'Not bot, not beast': Scientists create first ever living, programmable organism (2020) *The Conversation*

Simon Coghlan & **Kobi Leins**, "Living Robots": Ethical Questions about Xenobots (2020) *The American Journal of Bioethics*

Robin Coupland & **Kobi Leins**, 'Science and Prohibited Weapons', (24 June 2005) *Science Magazine*

Filippa Lentzos (2019) Re-thinking biological arms control for the 21st Century *Fletcher Security Review* Vol.6(1): 33.

Filippa, Lentzos (2020) BioPower and Precision Surveillance, Lockdown Texts Springer

Filippa Lentzos (2020) How to Protect the world from ultra-targeted biological weapons, Atomic Bulletin, (Forthcoming, December 2020).

Filippa Lentzos, Laboratories in the cloud, Atomic Bulletin (July 2019).

Filippa Lentzos, Michael Goodman, and James Wilson, Health Security intelligence: Engaging Across Disciplines and Sectors, Intelligence and National Security 35 (2020) 4

Filippa Lentzos & Guy Reeves Scientists are working vaccines that spread like a disease. What could possibly go wrong?, Atomic Bulletin (September 2020).

Kelsey Lane Warmbrod, James Revill and **Nancy Connell**. UNIDIR 2020. Advances in Science and Technology in the Life Sciences. Implications for Biosecurity and Arms Control.

Richardson, LC, **Nancy D Connell**, SM Lewis, Pauwels E, Murch RS. 2019. Cybersecurity: a call for cooperation in a new threat landscape. Front Bioeng Biotechnol. Jun 6;7:99.

Bowman K, Husbands JL, Feakes D, McGrath PF, **Connell Nancy**, Morgan K. Assessing the Risks and Benefits of Advances in Science and Technology: Exploring the Potential of Qualitative Frameworks (2020). J Health Security Health Secur. May/Jun;18(3):186-194

Anja Kaspersen. 2015. The dark side of the Fourth Industrial Revolution – and how to avoid it. World Economic Forum.

Anja Kaspersen. 2016. 3 technologies that will transform warfare. World Economic Forum.

3.4 Potential Markets Served

Indicate the main beneficiaries of this work, and what the potential impact might be.

AI enhanced or informed biotechnologies will affect multiple markets, including:

o   **Personalised consumer electronics**
o   **Assistive technologies, including prosthetics and communication devices**
o   **Pharmacology and care delivery technologies**
o   **Clinical diagnoses and therapies**
o   **Defensive and offensive Industrial and military applications**
o   **Biometric technologies**
o   **Insurance**
o   **Immunological research**
o   **Agricultural domain**
o   **Genetic engineering**
o   **Research and development labs**
o   **Cyber biosecurity**

3.5 How will the activity benefit the IEEE?

The IEEE SA is in a unique position to facilitate and change the approach to how we develop, pursue and deliver on health for all – beyond standards – is key to advance technology for the benefit of humanity.

This Initiative will position IEEE as a go-to platform for global biosecurity and bioinformatics. It will help IEEE to realise its core vision and move "Beyond Standards" at a critical time for humanity to mitigate unanticipated harm. This project will engender a community-centric co-design practice to formulate ideas on building and sustaining interoperable and trustworthy outcomes (examples: standards, policies, design principles, and creative approaches) for the use of AI and AIS in life sciences, and address increasingly fractured bioinformatics policies and standards amidst unprecedented amount of 'bio data flows'.

In the coming decade, managing the fast and broad technological advances now under way will require new governance structures that draw on individuals and groups with cross-sectoral expertise—from business and academia to politics and defense—to identify emerging security risks and make recommendations for dealing with them, and enable and empower these communities to speak directly with each other to manage and minimize the potential harms and risks of AI and AIS and the life sciences.

4. Estimated Timeframe
Indicate approximately how long you expect this activity to operate to achieve its proposed results (e.g., time to completion of all deliverables).

Expected Completion Date11/2022

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICCom and the responsible committee of the IEEE SA Board of Governors. Should an extension be required, please notify the ICCom Administrator prior to the two-year mark.

5. Proposed Deliverables
Outline the anticipated deliverables and output from this IC activity, such as documents (e.g., white papers, reports), proposals for standards, conferences and workshops, databases, computer code, etc., and indicate the expected timeframe for each.

The deliverables for this IC activity are expected to include:
1. A map of AI based technologies in the biological and health science fields relevant to biosecurity and overview of relevant actors, including in adjacent domains
2. An integrated overview of normative frameworks and related standards activities
3. Identification of gaps in the existing frameworks, norms and standards and a plan to address these gaps
4. Special sessions and workshops focused on the process of developing new standards for responsible innovation of AI and the Life Sciences
5. Thought piece(s) for IEEE
6. Webinar/podcast with co-chairs and key experts

5.1 Open Source Software Development
Indicate whether this IC Activity will develop or incorporate open source software in the deliverables. All contributions of open source software for use in Industry Connections activities shall be accompanied by an approved IEEE Contributor License Agreement (CLA) appropriate for the open source license under which the Work Product will be made available. CLAs, once accepted, are irrevocable.

Will the activity develop or incorporate open source software (either normatively or informatively) in the deliverables?:

Yes, open source software will be used in the deliverables to research, analyze and map related technologies, trends, developments, standards and guidelines.

6. <u>Funding Requirements</u>

Outline any contracted services or other expenses that are currently anticipated, beyond the basic support services provided to all IC activities. Indicate how those funds are expected to be obtained (e.g., through participant fees, sponsorships, government or other grants, etc.). Activities needing substantial funding may require additional reviews and approvals beyond ICCom.

The activity anticipates that there will be funding needed to support selected activities and will develop a budget/funding plan aligned with needs as they are defined by activity members.

7. <u>Management and Procedures</u>

7.1 <u>Activity Oversight Committee</u>

Indicate whether an IEEE committee of some form (e.g., a Standards committee) has agreed to oversee this activity and its procedures.

Has an IEEE committee agreed to oversee this activity? Yes/No

No

If yes, indicate the IEEE committee's name and its chair's contact information.

IEEE Committee Name: Committee Name
Chair's Name: Full Name
Chair's Email Address: who@where

Additional IEEE committee information, if any. Please indicate if you are including a letter of support from the IEEE Committee that will oversee this activity.

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

7.2 <u>Activity Management</u>

If no Activity Oversight Committee has been identified in 7.1 above, indicate how this activity will manage itself on a day-to-day basis (e.g., executive committee, officers, etc.).

The initiative will establish a global, diverse and multi-disciplinary executive committee and advisory board. The IEEE SA Healthcare and Life Sciences Practice will provide an institutional anchoring to ensure that the long term benefits of this initiative is captured and curated. The IEEE SA will also provide necessary project management support in line with standard practice.

7.3 <u>Procedures</u>

[DO NOT MODIFY OR DELETE: ICAID template approved by the IESS SMDC on 8 October 2020]

Indicate what documented procedures will be used to guide the operations of this activity; either (a) modified baseline *Industry Connections Activity Policies and Procedures,* (b) Standards Committee policies and procedures accepted by the IEEE SA Standards

Board, or (c) Working Group policies and procedures accepted by the Working Group's Standards Committee. If option (a) is chosen, then ICCom review and approval of the P&P is required. If option (b) or (c) is chosen, then ICCom approval of the use of the P&P is required.

Specify the policies and procedures document to be used. Attach a copy of chosen policies and procedures.

Modified baseline Industry Connections Activity Policies and Procedures.

8. Participants

8.1 Stakeholder Communities

Indicate the stakeholder communities (the types of companies or other entities, or the different groups of individuals) that are expected to be interested in this IC activity, and will be invited to participate.

Specify types of entities or groups of individuals.

- The IEEE Global Initiative on Ethics of Autonomous and Intelligence Systems
- IEEE P7000 Working Group Members
- United Nations
- World Health Organization
- World Economic Forum
- International Committee of the Red Cross
- Medical Practitioners and Associations
- Corporate groups and representatives.
- Select biotech communities and organisations such as BIO, EuropaBio, IFPMA, PhRMA, International Gene Synthesis Consortium
- Interpol
- IAP and National Academies of Sciences
- Universities
- IGEM
- Research Labs
- Governments

8.2 Expected Number of Participants

Indicate the approximate number of entities (if entity-based) or individuals (if individual-based) expected to be actively involved in this activity.

Number of entities or number of individuals.

By the time, the IC concludes its initial work, 120 - 150 multidomain experts. Minimum 30-40 individuals within twelve months of first Executive Committee meeting.

8.3 Initial Participants

Provide a number of the entities or individuals that will be participating from the outset. It is recommended there be at least three initial participants for an entity-based activity, or five initial participants (each with a different affiliation) for an individual-based activity.

Use the following table for an entity-based activity:

Entity	Primary Contact	Additional Representatives
Entity Name	Contact Name	Name

Use the following table for an individual-based activity:

Individual	Employer	Affiliation
Name		
Filippa Lentzos	Kings College London	Senior Research Fellow
Kobi Leins	Melbourne University	Senior Researcher
Anja Kaspersen	Carnegie Council	Senior Fellow
Nancy Connell	John Hopkins	Professor
Wendell Wallach	Yale University	Senior Researcher