iGEM Ethical Guideline

for Human Practices

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Promoting well-being

At its essence, synthetic biology aims to engineer new biological systems to promote the advancement and well-being of people while minimizing risks. As such, each iGEM project should start with:

a. A clear goal statement that identifies the problem or opportunity improvement, the current state of the research, alternatives and potential stakeholders.
b. A risk-benefit analysis of the project based initially on literature, at the midpoint and at the end of the research project (some key features include cost, containment, stakeholders).

Transparency

iGEM Toronto and the BioBrick Foundation were created on the basis of open science. As such, iGEM teams have a commitment to disclose information to the fullest extent possible. Disclosure of information happens at two levels: (i) between researchers (including iGEM teams) and (ii) with the public.

Transparency between researchers:

Good documentation is key to open science. The current gold standard is currently the Good Laboratory Practices (GLP) that provides guidance on non-clinical research in various countries including Canada, the US and the EU. While GLP may be too demanding for iGEM teams, some steps can be taken to make our work more reproducible. This can be achieved in the following ways:

a. Open Methods: Notebooks on iGEM wikis should be organized and searchable. In order to advance research in synthetic biology, it should be easy to access and reproduce lab protocols and code.
b. Detailed Methods: This requires careful note-taking of procedures as well as observations during its execution (even if it is what you expect). These protocols should be living documents that are updated as improvements are made throughout the summer.
c. Equipment: Document the equipment used including the model, make and any personal notes you may have. This includes safety equipment.
d. Safety: Document safety protocols, disposal techniques and help develop resources that promote a safety culture in the lab.

Transparency with the public:

iGEM teams should make an active effort to contact stakeholders identified in the first steps and gain meaningful feedback from them. Many iGEM teams have done this through surveys, interviews and conferences.

Due care

The concept of due care is centered around acting cautiously and providing mechanisms for future reassessment in the light of future advances and cultural opinions. In designing their human practices, iGEM teams should make efforts to go beyond the development and manufacturing of new technologies. Equal considerations should be given to developing ways to track the progress and effectiveness of the device after its distribution to market. Below are a few examples could integrate this idea:

a. For diagnostics, it may be useful to consider potential sources of error and variability in the test population and how the accuracy and precision could be monitored against orthogonal tests after distribution.
b. For the energy track, it may be useful to consider how the efficiency and potential environmental impacts of the technology could be monitored.
c. For food and nutrition, it may be useful to consider FDA regulations which would impact the toxicological monitoring of genetically modified food products after it reaches market.
d. For the therapeutic track, it may be useful to consider how clinical trials and post-market monitoring would be designed particularly with therapeutics that involve gene therapy or altering the gut microbiome. Computationally modeling interactions in humans and designing fail safe mechanisms would help in that regards.
e. For environment, it may be useful to design mechanisms for containment, monitoring and dealing with accidental release into the environment including potential kill switches.
f. For manufacturing, it may be useful to design how each step of the process would be monitored through quality control. Distribution and post-market monitoring should also be analyzed from a legal and scientific perspective.
g. For foundational advances and new applications, it may be useful to develop scenarios in which the application is to be used and consider ethical guideline for future research and market release.

Responsible science

Responsible science requires a commitment to quality experimental design and analysis, appropriate review and correction of misleading data or analysis. As such, we recommend that iGEM teams perform and document multiple levels of review throughout their project.

a. Firstly, iGEM teams should seek feedback from their principal investigators in designing and analyzing experiments.
b. Secondly, regional iGEM teams should collaborate through boards that meet periodically to review and critically analyze each other's results. In particular for public engagement projects, it may be useful to have members of the iGEM human practices committee support regional iGEM boards. These periodic meetings would be documented and a collaborative report could be written.

c. Finally, iGEM teams should be encouraged to document short-comings of their genetic systems and potential confounding variables that may have affected their assays. This would help future research to build upon past projects to produce robust research.

Respect for persons

In considering the ethical and socio-economic impact of a new technology, consequences to different demographics and stakeholders should be taken into account. In particular, teams should have a commitment to individual decision abuse and protection of vulnerable populations. This can be achieved by:

a. Engaging populations that usually do not have a voice in public outreach activities.
b. Identifying vulnerable groups involved in the development, manufacture, distribution, consumption and disposal of products.

Fairness

New technologies developed by iGEM teams often have a high initial cost and risk for implementation. As such, there should be special considerations for the accessibility of the product and equitable distribution of the burdens and benefits involved. This is particularly relevant for iGEM teams working with energy or therapeutics where the product may be publicly funded. Teams should consider mechanisms for preventing potential abuse or socio-economic disparity.

Transnational Cooperation

The implementation of research performed by iGEM teams often involves multinational cooperation. Whether the product is meant to be distributed on the international market or involves health, environmental and energy legislations, iGEM teams should make an effort to consider and analyze regulatory and legislative context of their project on an international stage. Patent law and public policy, in particular, should be key considerations in human practices. Transnational cooperation can also be achieved through collaborations between iGEM teams on a global stage. However, current initiatives fulfill this requirement adequately.

Useful resources:

1. Imperial College 2016 PBL + STIR protocol
2. iGEMer' Guide to the future (Synenergene)
3. Responsible Research and Innovation Tools (RRI)
4. Human Genome Editing: Science, Ethics and Governance
5. Genetically Engineered Crops: Experiences and Prospects
6. Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values
7. Workshop on Gene Editing to Modify Animal Genomes for Research: Sci- entific and Ethical Considerations (Institute for Animal Laboratory Research [ILAR] Roundtable)
8. Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System
9. Communicating Science Effectively: A Research Agenda
10. Public Participation in Environmental Assessment and Decision Making
11. Understanding Risk: Informing Decisions in a Democratic Society