Synthetic Biology iGEM ethics assessment form for research project

This form is designed to encourage the contemplation and assessment of all ethical issues involved within your iGEM project. The form is split into five sections addressing various aspects of ethical implications a synthetic biology project could have. The concept of this is similar to a risk assessment form and adopts a pseudo quantitative analytical approach. The main assessment component is in tabular form, below are instructions for completing these tables with each column explained.

Identify- State here the ethical hazards in question and the target audience that it could potentially affect and elaborate in as much detail as possible what implications they could result in

Control- State here the controls e.g. elimination, substitution, engineering controls and personal protective equipment which will be used to minimise the risks from the ethical hazards. Continue on a separate sheet if necessary.

Inform- State here the information (relevant policy/code of practice/local rules or local, local rules), instruction & training that will be provided to the researchers and if necessary the public on the hazards and control measures.

Review- State whether this ethical hazard needs review after a certain time. Remember to review this assessment at least annually and more often if there is a material change to the work which may affect this risk assessment.

Risk – Scale of 1-5

Ethical impact – Scale of 1-5

Risk (1-5) x ethical impact (1-5)

Severity - The product of impact and risk- depending on this score, review whether action is needed for the ethical concern in question. See table below- Key: Green= ethical severity minimum, Yellow= ethical severity could be lowered, Orange= ethical severity needs assessing, Red= Immediate action needs to be taken towards the ethical severity of this concern.

x	1	2	3	4	5
1					
2					
3					
4					
5					

1) Economic implications

Synthetic biology has the potential to create an abundance of new industries and jobs, however in the process of doing so can cause current industries, companies and/or jobs to become redundant. This can result in a sharp increase in unemployment which can be made worse by the fact that these people may have a very specific skill set and thus need retraining.

Identify – Could your research cause job loss? Could it cause a current industry to be made redundant? Is the funding source kosher?
Control - Not particularly that relevant for this section; however consider possible solutions or preventative procedures that one could implement
Inform – Not particularly that relevant for this section
Review - This could be quite important, could need to review after the research has been conducted to check on the economic impact

Identify	Control	Inform	Review	Risk (score 1-5)	Ethical impact (score 1-5)	Severity (risk x ethical impact)
There are no ethical impacts of our project that could affect the economy that we can identify	N/A	N/A	N/A	N/A	N/A	N/A

2) Legal implications

Patent law is an extremely crucial part of scientific research and development. It is important to assess whether you are illegally using other people's work/products and consider when it is appropriate to ask for permission. It is also important to consider the implications of potentially patenting your final research, for example patenting a vaccine could result in it saving a lot less lives. This section can also be used to consider dealing with illegal substances such as drugs as part of one's research.

Identify – Are you defying current patent laws? Have you carried out research into the legality of your product? Could your research result in a need for new laws/regulation? Are you using any illegal substances as part of your research?
Control – Do you permission? How can you be careful with illegal substances?
Inform – Do you need to inform someone who owns the intellectual property
Review - This could be quite important, could need to review after the research has been conducted to check if a patent is needed

Identify	**Control**	**Inform**	**Review**	**Risk (score 1-5)**	**Ethical impact (score 1-5)**	**Severity (risk x ethical impact)**
No research has been carried out into the legality of the Micro-Beagle	We have permission to use all the parts from the registry in our Device	The Device will be owned by iGEM		1	1	1

3) Bioterrorism risks

Bioterrorism is a new area of terrorism that could become a big problem if Synthetic Biology and other Biological Science research is used in the wrong way. Your device may have the potential to be made weaponizable and this is something that worries the public. This section deals with the potential of your device being harmful and what would happen if it were to be used for something other than its original purpose.

Identify – Could your device be weaponizable? Could your device have harmful effects? Can you identify any way that your device could be used in a negative way?
Control - How will you make sure that your device can't be used in a harmful manner? What precautions could you put in place to make sure that it can't be used in that way?
Inform – How will you protect your device to make sure that it will not become weaponizable?
Review - This could be quite important, could need to review after the research has been conducted to think about whether the device could be used for other, harmful, purposes. What is the plan to make sure the device does not fall into the wrong hands?

Identify	**Control**	**Inform**	**Review**	**Risk (score 1-5)**	**Ethical impact (score 1-5)**	**Severity (risk x ethical impact)**

4) Accidental release

A major worry of the public is that harmful bacteria, with modified genes, may be accidentally released into the environment if lab procedures are careless. However accidental release of genetically modified organisms is more likely to occur during their use in the field. The worry is that GMO's could pass on their modified genes to wildtype organisms and create new lines of that particular species.

Identify- What problems could occur from your device being accidentally released?

Control- What measures need to be put in place to make sure that accidental release is minimised? What measures can you take to make accidental release doesn't cause harm if it does occur?

Inform- How will you publicize that the organism is safe to use?

Review- After the project has been undertaken, did accidental release occur? When using the device in its field, what aspects have you considered to make it safe in case it is accidently released?

Identify	**Control**	**Inform**	**Review**	**Risk (score 1-5)**	**Ethical impact (score 1-5)**	**Severity (risk x ethical impact)**
If the device was accidentally released, the bacteria could pass on their added genes to other harmful strains of bacteria.	A kill switch could be added to the device so that any bacteria containing the engineered genes can be easily killed.	The public should be able to see that the kill switch will enable quick and easy control over the modified bacteria		3	4	12
Antibiotic resistance genes could be passed onto virulent strains of bacteria from the Micro-Beagle	Again a kill switch can be added. The modified bacteria are only being planned to use in a test sample so the bacteria should be contained and release should be minimal.	*As above*		3	4	12

5) Testing

Some people share the view that testing on animals and humans is unethical and wrong. Your biodevice has to be tested in some way, but what experiments could you do that don't involve testing on animals or humans. Some people believe that testing on humans is a little less unethical than testing on animals as humans have to give their consent to be tested upon, whereas animals have no choice and are often breed for that sole purpose.

Identify- Identify any issues there is with testing the device. Is there any stage in your project that it will be necessary to test your device using animals or humans?

Control- Is there any other ways that it is possible to do such experiments and gaining the data not using either animals or humans? What other experiments could you run that are more ethical?

Inform- How will you reassure the public that your testing method is safe and ethical?

Review- Review the implications of all the methods used during the project. Were any experiments unethical? What could you have done better in terms of the ethics during the experimental stages of the project?

Identify	**Control**	**Inform**	**Review**	**Risk (score 1-5)**	**Ethical impact (score 1-5)**	**Severity (risk x ethical impact)**

6) Damage to the environment/ecosystem

Many Synthetic Biology research projects plan to introduce genetically modified organisms into the environment. Some devices aim to improve the quality of the environment but in doing so is there some risk that they could change the balance in an essential ecosystem? Another aspect that falls into this category is that during the research stages of the project, a lot of lab equipment is used and there is a possibility of wastage of reagents and equipment if they are not used in a proper manner. This could cause environmental damage in the form of; unnecessary use of plastics or unsafe disposure of reagents. This section is intended to make you consider any wider environmental implications your device could cause when it is used in its intended field.

Identify- Will your device or research cause any damage to the environment? If so, specify e.g. which species, which ecosystem, what environment?

Control- How can you minimise the damage caused to the environment during your research? How can you minimise the amount of damage your device causes to the environment?

Inform- How can you inform people that you have considered the impact you are causing to the environment whilst carrying out your environment? How can you reassure the public that your device will cause minimum damage to the environment and ecosystems?

Review- After you have undertaken the research project, review the methods you undertook to make sure the impact on the environment was minimal. Review the methods you undertook to make sure the impact your device has on ecosystems when it is used in the field.

Identify	**Control**	**Inform**	**Review**	**Risk (score 1-5)**	**Ethical impact (score 1-5)**	**Severity (risk x ethical impact)**
If the bacteria got out into the environment they could cause an upset in the balance in the ecosystem	The bacteria will be used in samples and not released into the environment so won't have the chance to change anything within ecosystems or the environment.	The device wont cause any damage as it is being used in a controlled sample media, it doesn't interact with the environment in any way		2	5	10