Safety Form Final Delivery

Following iGEM's rules and policies

1. Are you planning to do any of the following activities, which are prohibited in the competition? Check all that apply.

If yes, STOP. Contact the Safety and Security Committee for advice by at safety [AT] igem [DOT] org.

- [ ] Using organisms from Risk Group 3 or 4
- [ ] Using parts from an organism in Risk Group 4
- [ ] Releasing or deploying a genetically modified organism outside the lab
- [ ] Testing your product on humans (including yourselves)
- [x] No, we are not planning to do any prohibited activities

2. Please read over iGEM's White List. Will your team use any organisms or parts not on the whitelist, or do any activities not on the whitelist? Check all that apply.

BEFORE you begin any work not covered by the white list, your team must submit a Check In Form to the iGEM Safety and Security Committee.

- [ ] Yes, we are using organisms not on the White List
- [ ] Yes, we are using parts not on the White List
- [x] Yes, we are doing any activities not on the White List
- [ ] No, all our work is covered by the White List

3. Are you planning to do any of the following activities that require advance permission from iGEM? Check all that apply.

According to iGEM's safety policies, certain kinds of work require your team to obtain advance permission from iGEM. Please submit a Check In Form (and, if applicable, an Animal Use Form) to gain permission before starting work.

- [ ] Working with animals or samples from animals (in iGEM, "animals" are vertebrates, like rats or fish, and higher-order invertebrates, like octopus and bees) (Animal use policy)
- [ ] Bringing a product of a genetically modified organism outside the lab (Release beyond containment policy)
- [x] Conducting laboratory experiments using human samples, such as blood, DNA, other bodily specimens, and health or psychological outcomes (Human experimentation policy)
- [ ] Using parts or organisms obtained from anywhere other than a trusted commercial or institutional supplier (Environmental samples policy)
- [ ] Biasing the inheritance frequency of a genetic marker in an organism's progeny, i.e. creating a gene drive (Gene drives policy)
- [ ] Increasing risks from antimicrobial resistance, such as by using novel resistance factors (Antimicrobial resistance policy)
- [ ] No, we are not doing any of the kinds of work outlined above

4. Are you collecting any data about people, such as their opinions, quotations, medical history, gender, behavior, attitudes, or concerns?

For good reasons, many countries require formal approval for Human Subjects Research, as well as consent procedures for participants. You may need formal permission from a Research Ethics Committee, Institutional Research Board, or equivalent. Remember compliance with relevant laws and regulations is a requirement for participation in iGEM.

- [x] Yes, and we have obtained formal / institutional approval for our work (or will obtain it before starting data collection)
- [ ] Yes, and we have confirmed that relevant laws, regulations, and institutional rules do not require us to get formal approval
- [ ] Yes, but we're unsure if we need formal approval (please read the human subjects research policy)
- [ ] No, we are not doing surveys, interviews, or other human subjects research

About your lab

5. Please upload a photo or two of your lab showing the relevant safety features.

Files can be uploaded at uploads.igem.org. If your project does not involve lab work and thus your team has no plans to access lab space, please note this.

Links to lab photos

https://static.igem.wiki/teams/4464/wiki/photos-of-lab.pdf

6. What is the biosafety level of your work space?

If you are working in a biosafety cabinet it may be a biosafety level 2 space (then select Level 2), but biosafety cabinets are sometimes also used in a biosafety level 1 laboratory to provide a sterile work space (then select Level 1). If in any doubt, please discuss this with a biosafety professional or your instructors, supervisors or lab techs to make sure you understand how the equipment you use helps to manage risks. See also the guidance on risk groups.

- ○ Not applicable as we have no lab component
- ◉ Level 1 – standard microbiological lab
- ○ Level 2 – moderate containment
- ○ Level 3 – high containment
- ○ Level 4 – **extremely high containment**
- ○ We have several different lab spaces with different biosafety Levels. Please describe:

Please describe your different lab spaces

7. Which work areas will you use / are you using to handle biological materials? Check all that apply.

Please check all the containment provisions you are using.

- [ ] No lab work (e.g. software project)
- [ ] Open bench
- [x] Biosafety cabinet *(Note: there are important differences between biosafety cabinets and laminar flow hoods / clean benches. iGEM encourages the use of biosafety cabinets but discourages the use of laminar flow hoods or clean benches. This Factsheet from the University of Michigan helps explain the differences.)*
- [ ] Specialist greenhouse
- [ ] Specialist animal house
- [ ] Specialist insect facility
- [ ] Chemical fume hood *(Note: this is designed to manage risks from hazardous chemicals. It is different from a biological safety cabinet designed to manage risks from hazardous biological agents and a clean bench or laminar flow hood designed to prevent contamination.)*
- [ ] Unknown

Please describe why your work areas are unknown

About your project

8. Describe the goal of your project: what is your engineered organism (or other synthetic biology product, system, or tool) supposed to do?

Even though your project might change, please describe the main project idea you are working on right now, including specific technical details. See the example answers for help.

We will build a multiplex Lateral Flow Assay with aptamers to detect three biomarkers using blood as the sample to analyze chronic inflammation levels during aging, better called: inflammaging. The proof of concept will be done with C-reactive protein in blood samples. The blood samples will be used in the characterization protocols and in the standardization process to create a calibration curve; these samples will be just blood serum with high levels of CRP and they will be donated by the National Institute of Cardiology in Mexico City.

9. Which whole organisms, including viruses and cell lines, will you engineer in your project? Check all that apply.

These would be the organism(s) in which you are planning to put your parts or which you are modifying in your project.

- [ ] Escherichia coli *(give all strains you are using, e.g. "DH5-alpha, BL21")*

Please list strains

- [ ] Saccharomyces cerevisiae (Yeast)
- [ ] Lactobacillus spp.
- [ ] Bacillus subtilis
- [ ] Others *(give genus, species, and strain, e.g. "Vibrio natriegens ATCC14048", "Adeno-Associated dependoparvovirus B (AAV 5)")*

Please list other organisms

- [x] Not engineering any organisms *(please comment)*

Please comment on not engineering organisms

10. Will you use any other organisms in your project?

For example, without engineering an organism directly, you might plan to extract RNA or DNA from the organism, or test your product on it.

List organisms, including genus, species, and strain

We are not using organisms in our project.

11. As part of your project, are you planning to make / have made new parts or substantively changed existing parts in the Registry?

- (●) Yes
- ( ) No, our project will only use genetic parts that are already in the registry

12. Could any of your parts be hazardous on their own and/or in the context of your project?

- [ ] Parts that are hazardous on their own *(e.g. a protein toxin, an enzyme that synthesizes a dangerous chemical)*
- [ ] Parts that have a hazardous function in their parent organism, but that might not be hazardous when used in your project *(e.g. a virulence factor that helps a virus get into cells)*
- [ ] Parts with no hazardous function in their parent organism, but that might be hazardous when used in your project *(e.g. quorum-sensing circuit that triggers release of an insecticide)*
- [ ] Other hazards
- [x] None of our parts could be hazardous

If you identified any hazards above, describe them here. It may also be helpful to identify how you will acquire a part (e.g. PCR isolation, gene synthesis company).

13. What experiments will you do with your organisms and parts?

Please explain briefly. We are particularly keen to understand the boundaries or scope of your project. You should include the names of species / cell lines / strains. You should include experiments involving parts taken from other organisms, even if they are being synthesized rather than isolated from nature – you need not include any parts already in the registry.

In our Lateral Flow Assay we will use aptamers as the detection system for our biomarker using a sandwich form. In order to validate our test several experiments must be done and we will divided it in different stages, for the characterization of the aptamers we will do the Electrophoretic Mobility Shift Assay - EMSA (for the affinity of the aptamers with CRP), to test the modifications of our aptamers (thiol and biotin) we will make a DNA electrophoresis gel to see the interaction between the thiol modification and AuNPs, and an assay with alginate pearls to test the binding of the biotin-streptavidin interaction.

14. What kinds of chemicals are you using in your project?

- [ ] Heavy metals
- [ ] Carcinogens
- [ ] Mutagens
- [ ] Highly flammable chemicals
- [ ] Acids and corrosive chemicals
- [ ] Other controlled chemicals *(e.g. explosives, psychoactives)*
- [x] Other hazardous chemicals
- [ ] Not using any hazardous chemicals

If you selected any of the hazardous kinds of chemicals above, please list the specific chemicals you are using.

Polyacrylamide gels

Identifying project risks

15. What hazards are presented by the organisms, parts, chemicals, or experiments you described in Part 2? Check all that apply.

*This question is about possible hazards present **during the iGEM competition** and/or **while you are working in your lab space**. We know you will likely be taking actions to minimize the risk that any of these hazards result in harm to your team, your colleagues, or your community.*

- [x] Human health or safety hazards *(e.g. from pathogens, hazardous chemicals)*
- [ ] Environmental hazards *(e.g. from organisms that get out the lab, such as potentially invasive species)*
- [ ] Dual-use hazards *(e.g. from misuse of knowledge you create)*
- [ ] Other hazards to team members or colleagues in the laboratory
- [ ] Other hazards beyond the laboratory
- [ ] No hazards

Please list the of specific hazards that caused you to check off the categories above. Describe in detail what aspect of your project presents each hazard.

Only during the formation of the polyacrylamide gels; people that will perform it need to have safety measures and protocols.

16. For each of the hazards you identified in the previous question, please give 1-3 sentences describing how harm could occur.

*For most hazards, this will involve **accidental exposure** to a biological or chemical agent or **accidental release** of an agent, but we invite you to be creative and comprehensive in your answers.*

Continuous exposure during the formation of polyacrylamide gels, if it is inhale or touched it might cause dermatitis, headache, dizziness, or in special cases neuropathy.

Anticipating future risks

17. Imagine that, in the future, your project was fully developed into a real product that real people could use. How would people use it? Check all that apply.

Note: we understand that a real world use of your project might require doing experiments that would not be allowed during the competition, like releasing modified organisms into the environment.

- [ ] Our project is foundational / we do not have a specific real-world application in mind *(e.g. library of standardized promoters, system for communication between cells)*
- [ ] Only digital or non-biological products *(e.g. software to model directed evolution experiments, ethical and policy recommendations)*
- [ ] Only in the lab *(e.g. reporter strain for measuring the strength of promoters)*
- [ ] In a factory or other industrial manufacturing context *(e.g. cells that make a flavor chemical for food, cells that make biofuel)*
- [x] In a consumer product that ordinary people buy *(e.g. cells that clean your clothes, bread made with engineered yeast)*
- [ ] In agriculture / on a farm *(e.g. cells that guard against pests, engineered rice plants, cells that promote growth of crop plants)*
- [x] In a small enclosed device *(e.g. a bio-sensing strip with cells that detect arsenic, a paper-based cell-free diagnostic)*

Please describe how your project would be used in the real world.

We will build a Lateral Flow Assay that will work as a point of care device and people will be able to measure their inflammaging levels at home or in a doctor's office/clinic.

18. If you were permitted, would the continued development of your project require release beyond containment?

A definition of release beyond containment may be found in the relevant safety policy.

- ○ Yes, open release in the environment *(e.g. environmental bioremediation)*
- ○ Yes, release into a human or animal body *(e.g. living therapeutic)*
- ○ Yes, semi-contained release *(e.g. cell-based biosensor in a small device)*
- ○ Yes, release to a non-laboratory contained environment *(e.g. wastewater treatment plant)*
- ○ Yes, release of a product of synthetic biology, but not any living organisms *(e.g. biosynthetic fragrance, cell-free diagnostic)*
- ◉ No, the future development of my project would not require release beyond containment

If yes, please briefly (1-3 sentences) describe what experiments, tests, or final uses would need to take place outside of laboratory containment. Include any institutional approval processes or national regulations that you are aware you would need to comply with.

19. Have people on your team had a conversation (within your team or with someone outside the team) about how any of the bad outcomes below might relate to your project? Check all that apply.

- [x] Harm to human health and safety *(e.g. from pathogens, altered immune function)*
- [ ] Harm to agricultural animals, crops, or domesticated animals *(e.g., from pathogens, ecological disturbances)*
- [ ] Harm to materials, equipment, and infrastructure *(e.g. from degrading important materials)*
- [x] Harm to the environment, including wild plants and animals *(e.g. from horizontal gene transfer, out-competing non-engineered organisms)*
- [ ] Reducing global, national or health security *(e.g. from disabling medical countermeasures, making it easier to do harm with biology)*
- [x] Creating or reinforcing of social inequities *(e.g. from engineering a technology that disproportionately benefits an already-advantaged group)*
- [ ] Breaking norms about engineering biology *(e.g. from engineering an organism that is considered unethical to engineer)*

20. Considering the future use(s) and conversations from the previous questions, do you think your project could potentially lead to any of the bad outcomes listed below? Check all the appropriate boxes and expand in the comments section.

The possibility of a bad outcome does not mean your project is bad; virtually all modern biotechnology presents some risk. Being a responsible synthetic biologist requires you to think about how to manage risks to ensure your project has a positive impact as it enters the real world.

- [ ] Harm to human health and safety *(e.g. from pathogens, altered immune function)*
- [ ] Harm to agricultural animals, crops, or domesticated animals *(e.g., from pathogens, ecological disturbances)*
- [ ] Harm to materials, equipment, and infrastructure *(e.g. from degrading important materials)*
- [ ] Harm to the environment, including wild plants and animals *(e.g. from horizontal gene transfer, out-competing non-engineered organisms)*
- [ ] Reducing global, national or health security *(e.g. from disabling medical countermeasures, making it easier to do harm with biology)*
- [x] Creating or reinforcing of social inequities *(e.g. from engineering a technology that disproportionately benefits an already-advantaged group)*
- [ ] Breaking norms about engineering biology *(e.g. from engineering an organism that is considered unethical to engineer)*
- [ ] Other

If other, please describe

21. How might the bad outcomes that you identified in the previous question come to pass? Check all that apply.

- [ ] Accidental exposure to a hazardous organism or chemical
- [ ] Accidental release of an engineered organism or part into the environment
- [ ] Combining the results of the project with other technologies
- [ ] Deliberate misuse by someone intending to cause harm
- [x] Other unintended consequences

If other, please describe

If the device we build is not accessible to everyone in the country, then it could create a social inequity, allowing only the people that can afford the test to have this preventive device.

- [ ] No bad outcomes identified

22. If your project were fully developed, could any of your engineered organisms or parts spread autonomously in the environment?

Organisms or parts might enter the environment intentionally (e.g. in field trials) or accidentally.

- ( ) Yes, autonomous environmental spread of one or more of our organisms or parts is possible

Describe how this could happen

- (•) No, our engineered organisms or parts are unable to spread in the environment

Describe why they are unable to spread

The only parts that we will use are aptamers and they will be freeze-dried at the beginning of the test, so they won't have any activity until they are rehydrated. And at the end of the test, the device will be disposed in a biological-hazard's waste bag to avoid contamination with general trash.

- ( ) No, we use biocontainment strategies (e.g. kill switches, auxotrophy) to prevent spread (please briefly note these strategies and why you chose them)

Describe these strategies and why you chose them

Managing risks

23. Who are the experts, other than your supervisor(s), supporting you in managing risks? If you discover a hazard or risk in your project, who would you go to for help?

You might plan to seek help from institutional biosafety officers or others that have expertise with the experimental techniques, organisms, or parts involved in your project.

Our main advisors (Dr. Jose Mario Gonzalez Meljem, Dr Carlos Diaz Tufinio and Dr. Alvaro de Obeso), the leaders of the laboratory at our institution, the researchers of the National Institute of Geriatrics (Dra. Nadia A. Rivero Segura and Dr. Juan Carlos Gomez Verjan), a researcher from UNAM institution that works with biosensors (Dra. Tatiana Flordelisio Coll) and an iGEM mentor (Michael Magaraci).

24. What safety and security rules or guidance cover your work?

In your country / region, what are the laws and regulations that govern biosafety or biosecurity in research laboratories? At your institution, what are the guidelines for laboratory biosafety and biosecurity? Please provide a link to these resources, or briefly describe them if you cannot find a link.

To manage in a correct form all the substances, organisms, residues and genetic material according to our country laws, we would have to take into consideration the Reglamento de la Ley General de Salud en Materia de Investigacion para la Salud (DOF: 2 abr 2014. http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf), and the Reglamento de la Ley de Bioseguridad de Organismos Geneticamente Modificados (DOF: 2 de abril de 2009. http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf); all of them published by the Secretaria de Gobernacion in the Diario Oficial de la Federacion.
This is the link for our institution website to use properly the labs and all the measurements needed to taken into account when entering the lab: https://sites.google.com/tec.mx/laboratoriosdeingeniera/laboratorios-de-ingenier%C3%ADa/ibqbio

25. Will your project need extra support or review to manage the risks you have identified above?

By "extra", we mean support or review beyond what happens for every life sciences project at your institution.

- ○ Yes, at the iGEM project stage *(e.g. from the iGEM safety and safety committee, bioethics advisors, institutional biosafety officers)*
- ○ Yes, if our project were to be developed further for a real-world use after the iGEM project stage *(e.g. regulatory review, assistance designing field trials)*
- ◉ No, the project does not need additional support or review.

26. Have your team members received any safety and/or security training?

For the purposes of iGEM, safety and security training covers the procedures and practices used to manage risks from accidents or deliberate misuse of your projects.

- ○ Yes, we have already received safety and/or security training.
- ◉ We plan to receive safety and/or security training in the future.

Please specify approximately when

We will have basic security training in the summer before we enter the lab to perform our experiments.

- ○ We will not have safety or security training. *(Please explain in detail how team members will become aware of and learn how to manage risks in the absence of training. If training is not relevant because there is no lab component to your project, please note this.)*

Please explain how you will learn to manage risks

27. Please select the topics that you learned about (or will learn about) in your safety and security training.

- [x] Lab access and rules *(e.g. appropriate clothing, eating and drinking)*
- [ ] Responsible individuals (e.g. lab or departmental specialist or institutional biosafety officer)
- [x] Differences between biosafety levels
- [x] Biosafety equipment (e.g. biosafety cabinets)
- [ ] Good microbial technique
- [x] Disinfection and sterilization
- [x] Emergency procedures
- [x] Rules for transporting samples between labs or shipping between institutions
- [ ] Physical biosecurity *(e.g. tracking materials, access controls)*
- [ ] Personnel biosecurity *(e.g. watching for unusual behaviour)*
- [ ] Data biosecurity / cyberbiosecurity *(e.g. managing database access)*
- [ ] Dual-use research and/or experiments of concern
- [x] Chemical, fire and electrical safety
- [ ] We will not have safety and security training

28. What laboratory biosafety and biosecurity measures are you using to manage the risks in your project?

This could include actions your team decided on or actions required by your advisors or institution. Select as many as are relevant.

- [x] Accident reporting *(system to record any lab accidents)*
- [x] Personal Protective Equipment / PPE *(wearing lab coats, gloves, eye protection, etc.)*
- [x] Inventory controls *(tracking who has what physical materials and where the materials are)*
- [x] Physical access controls *(controlling who can access your lab or storage spaces)*
- [ ] Data access controls *(controlling who can access computers or databases)*
- [ ] Lone Worker or Out of Hours policy *(procedures for working alone or at times when normal support is unavailable)*
- [ ] Medical surveillance *(finding out if you get sick because of an organism or chemical you used)*
- [x] Waste management system *(such as decontaminating waste before it leaves your institution)*
- [ ] Additional containment *(such as working at a higher biosafety level)*
- [ ] Other risk management tools

If other, please describe your measures

29. What other actions have you taken to manage the risks in your project?

This could include voluntary actions or actions required by your advisors or institution.

- [ ] Project-specific safety or security training *(e.g. training on handling certain organisms)*
- [x] Participating in a safety workshop hosted by iGEM *(e.g. the Values and Risks workshop)*
- [x] Other consulting with iGEM about managing risks *(e.g. submitting a check-in form, emailing a committee)*
- [x] Consulting with other experts about managing risks *(e.g. an institutional biosafety officer)*
- [x] Consulting with stakeholders about managing risks
- [ ] Evaluating countermeasures against your organism, parts, or other products *(e.g. efficacy of therapeutics, detection in case of environmental release)*
- [x] Crafting a responsible communication plan *(e.g. redacting specific information, highlighting the biosafety measures used)*
- [ ] Modifying your experimental design or methodology *(e.g. using an attenuated strain, employing biocontainment measures)*
- [ ] Deciding not to do an activity *(e.g. deciding against animal use experiments, avoiding infection experiments with a plant native to your country)*
- [ ] Other risk management action

Please briefly describe how the risk management actions you checked above apply to your project.

Taking workshops in iGEM will help us assure the safety in our lab protocols, as well the mentorship from iGEM people. Consulting with experts and stakeholders will help us in the feedback of our protocol techniques and the managing of blood samples. And finally, the communication plan will aid us in transmitting safety measures to the whole team when working in the lab.

30. Overall, how will the actions you've taken, expert support, rules, training, and other procedures and practices you described help you to manage the risks in your project?

Please provide a detailed answer. You might include more information on:

- The rules and guidance you identified
- The training you have had
- The equipment and spaces you had or will have access to
- Waste treatment / inactivation procedures
- Other procedures and protocols you will follow

Please give details of how these will help you to manage the risks you have identified.

The rules and guidance we will have from mentors, iGEM workshops, stakeholders and advisors will help us determine the safety measures we will need to take during our lab practices. Moreover, all the protocols, planification and experiments that we will be doing, previously must be reviewed by them. The training we will have will help us to determine the potential risks during our lab protocols and the impact the test might have in the environment and society. It is important to know the space and equipment we will have

access to during the lab experiments, as we need to know the evacuation process, what to do in case of a chemical spill, and other health measurements. In the waste treatment of our device it is important to consider a biological hazardous waste bag in order to contain the test away from other types of trash. Finally, we will take into account the safety sheet forms of every reagent used in the lab, in order to know the right disposal or safety measures when using them.

Sign-Off

31. Is there anything else you would like us to know?

This might be about risks associated with your project, how you are managing them, or your compliance with iGEM's safety and security rules and policies; above improvements you would like to see to our safety and security efforts; about anything that has not been sufficiently clear, or where additional guidance would be useful; and anything else you think would be relevant.

As we might be using blood samples in our project, we submitted the Check-in form on the iGEM website, and it was successfully approved by the Safety Committee.

PI Sign Off | Due September 16, 23:59 EDT (September 17, 03:59 UTC)

Only logged-in **PIs** or **Instructors** can sign off the final version of this form.

Please read the form and confirm that all its information is correct.

By checking the **I agree** box, you are agreeing that the Project Safety Form**accurately describes the activities of your team** and that they have complied with**all relevant laws, rules and regulations** at the institutional, national and/or regional level.

We are using the **I agree** box in lieu of a signature.

☑ **I agree** (form must be un-submitted to check)

Submitted on 2022-09-15