

ISEF SRC 2019 Workshop
The PHBA Project

DIRECTIONS: For each of the scenarios in Parts I – IV below, explain:

- a. What additional information would you, as an adult sponsor, need before proceeding?
- b. Should the project be approved? Why or why not?
- c. What supervision is needed?
- d. Is the project allowable at home? At a standard high school lab? Why or why not?
- e. What forms, if any, in addition to 1, 1A, and 1B, are needed?
- f. What additional questions/considerations do you have?

Part I:

Alex wanted to study the effect of *Aloe vera* leaves on the yeast *Saccharomyces cerevisiae*. The rate of growth would be measured by the volume of gas that was collected in balloons that covered the flasks in which the yeast was grown.

Part II:

For a follow-up experiment, Alex wanted to use the CRISPR-Cas9 system to insert a gene for the production of the active ingredient in *Aloe vera* into the *Saccharomyces cerevisiae*.

Part III: While doing background research above, Alex learned that the yeast *Candida albicans*, the most common member of human gut flora, is used as a model organism to study cellular growth and differentiation. Therefore, he decided to repeat the experiment in Part II, and compare it to the results in *Saccharomyces cerevisiae*.

Part IV: Alexa read that there have been several reported cases of *Candida auris* infections. She wants to do a project on in which she can modify a growth-regulating gene from this organism.

Extra Credit: As a team project, three students wanted to isolate and identify different types of yeast from soil in their neighborhood.

**ISEF SRC 2019 WORKSHOP
THE ENGINEERING PROJECT**

DIRECTIONS: For each of the scenarios in Parts I – II below, explain.

- a. What additional information would you need before allowing the student to proceed?
- b. What supervision is needed?
- c. What forms/approvals, if any, are needed in addition to Forms 1, 1A, and 1B?
- d. Is this project allowable at home? In school? Why or why not?
- e. What additional questions/considerations do you have?
- f. Should this project be approved?

Part I:

A student wants to do an engineering project involving the development of a device and an app that detects irregular heart beat patterns. His adult sponsor is his mother who is a medical doctor in private practice in the community. The student researcher works on the device and app for 9 months. He tests the device on himself and notices that the readings seem to be consistent with his activity level. The app does not suggest any irregularities in his heart rate patterns. His mother is aware of this testing on himself.

Part II:

Next, the student wants to test the device on 10 of his adolescent friends.

ISEF SRC 2019 Workshop The Pig Project

DIRECTIONS: For each of the scenarios in Parts I – IV below, explain:

- a. What additional information would you, as an adult sponsor, need before proceeding?
- b. Should the project be approved? Why or why not?
- c. What supervision is needed?
- d. Is the project allowable at home/on farm site? Why or why not?
- e. What forms, if any, in addition to 1, 1A, and 1B, are needed?
- f. What additional questions/considerations do you have?

Background:

Callie's family owns a farrow to finish hog operation. Callie and her sister Grace both enjoy showing the pigs they raise at various open hog shows in her area. The girls were going to attend the World Pork Expo held in their state each year but it has been cancelled for June 2019 due to the economic concern posed by potentially bringing the African Swine Fever (ASF) virus to the United States, even though there was negligible risk of this occurring. The African Swine Fever is responsible for serious production and economic loss (not currently in the United States). It is a transboundary animal disease (TAD) that can be spread by live or dead pigs (domestic or wild) and pork products. Transmission can occur via contaminated feed and fomites (non-living objects) such as shoes, clothes, vehicles and equipment due to the high environmental resistance of the ASF virus. There is no approved vaccine against ASF.

Callie's father has told her that when he used to show hogs during the pseudorabies outbreak in the 90's all of the shows were terminal. The pigs had to be loaded onto trailers and taken to the processing facility immediately. No pig could go back to the farm. Callie has decided that she would like to study potential disease transfer from the open shows and county fairs she will be attending this coming summer.

Part I:

Callie's family will clean out trailers as normal before loading. She will swab the trailer in multiple locations pre and post loading in of the pigs. She will also swab each family members boots pre and post loading. Once at the show she will swab shoes pre and post show and she will swab trailer pre and post load. Once home she will swab boots and trailer pre and post cleaning. She will later use prepared agar plates and incubate the plates to analyze.

Part II:

Her teacher has a friend at the local university in the Veterinary Science disease lab who has offered to help Callie with her samples. She would be able to take her swabs there and do the analysis under the supervision of the disease lab staff.

Part III:

Callie later determines she would like to conduct a survey of area hog farmers in her region of the state to determine the level of concern of disease prevention and/or outbreak. She would also like to include reactions to economic impact and the National Pork Producers Council's (NPPC) cancellation of the World Pork Expo.

Extra Credit 1: Callie decides she would like to ask other families that show pigs at these same events if she could swab their boots and trailers.

Part IV:

Callie's sister Grace also wants to research with the pigs she shows. The latest trend is to practice walking your show pigs through tall grass to train them to walk with their heads up. Grace would like to know how this affects the rate of gain and the quality of meat. She first looks at rate of gain before she sends her show pigs and her own farm raised pigs (never left farm) to the processor. From the processor she receives the following data: grade, live weight, dressed (or hanging) weight and final (or take home) weight.

Extra Credit 2: Callie and Grace are both homeschool students how does that affect any of the decisions you have made? What if they are dual enrolled in school for Agricultural Education but the rest of the time they are schooled at home – any difference?

ISEF 2019 Workshop – Vertebrate Animal

Directions: For each scenario in Parts I-III, explain:

1. What additional information would you, as an adult sponsor, need before proceeding?
2. What supervision is needed/recommended?
3. Is the project allowable? Why or why not?
4. Should the project be approved? Why or Why not? By whom?
5. What forms, if any, in addition to 1, 1A, 1B, are needed?
6. What additional questions/considerations do you have?

Part I:

Jane is a diabetic student and has proposed a study looking at “A new method of treatment: Vegetables and their benefit to diabetics.” She plans on testing mice (Wild Type (WT)) with broccoli to see if the blood sugar level is decreased as compared to control mice (6 mice in each group). (No RRI is mentioned)

Group 1: WT mice (6) with broccoli supplement Group 2: WT no broccoli (6 control)

She will feed the “treatment” mice (Group 1 and 3) 1 oz of broccoli per pan, in addition to their standard diet. (3 mice per pan). This will be fed every day for 4 weeks. Blood samples to test blood sugar will be collected: Sample 1 will be taken before broccoli is started and then taken every other day starting on day 8.

Submental blood collection is a non-invasive method of blood collection that does not require sedation to collect a small drop of blood (from the side of cheek/neck area). This is considered less than minimal pain/distress.

Part II:

Jane wants to try the vegetable treatment herself and test her blood glucose levels over the same time period as the mice.

Bonus: She wants her parents to test their blood sugar levels as well to see if it has an effect on them!

Part III:

Jane will be working with Dr. Bill at TBU (The Best University). He works with Non-Obese Diabetic (NOD) mice, so she is going to compare Wild Type (WT) mice and NOD mice with her broccoli treatment to see if the blood sugar level is decreased as compared to control mice (6 mice in each group).

Group 1: WT mice (6) with broccoli supplement Group 2: WT no broccoli (6 control)

Group 3: NOD mice (6) with broccoli supplement Group 4: NOD no broccoli (6 control)

The same procedures will be used as in Part I.

2019 PHBA WORKSHOP – CHEAT SHEET

Part I:

- Saccharomyces cerevisiae* is brewer's/baker's yeast, and is therefore exempt. No additional forms are required. (P. 15, Exempt Studies, 2a)
- The project should be approved.
- This project does not need a qualified scientist or designated supervisor, but an adult sponsor should be present.
- This project is allowed at home, because it is a fermentation project. However, if the yeast is cultured, that may not be done at home, but must be done in a school lab.
- No additional forms are needed.

Part II:

- You would have to know more about the risks involved with using the CRISPR-Cas9 system.
- It may be approved if there is proper supervision.
- A qualified scientist is needed.
- It may be done in a school BSL-2 lab, either at a high school or RRI, but it is no longer exempt because of rDNA.(P. 14, Column 1, B3.)
- Forms 2, 3, and 6A are needed. If the project is done at a Regulated Research Institution, 1C is also needed.

Part III:

- Candida albicans* is usually a commensal, but may be an opportunistic pathogen, particularly in people whose immune system is compromised.
- It may be approved if there is proper supervision.
- A qualified scientist is needed.
- It must be done at a BSL-2 lab, because *C. albicans* is a BSL-1 organism, which may have the possibility of reverting to a BSL-2 because of the rDNA.
- Forms 2, 3, and 6A are needed. If the project is done at a Regulated Research Institution, 1C is also needed.

Part IV:

- This strain of *Candida auris* is a clinically significant multidrug resistant organism (MRDO) with known resistance to antifungal agents. (P. 13, Rule 7.) The student and parent/guardian should be made aware of this major problem before proceeding.
- This **must not** be approved unless the student has obtained a written justification for its usage from a Regulated Research Institution, and there is documented IBC review and approval. (P. 13, Rule 7.)
- A qualified scientist is needed.
- This must be conducted at a BSL-2 or higher lab at a Regulated Research Institution.
- Forms 1C, 2, 3, and 6A are needed.
- Also, think about ethical considerations about the unknown effects of this mutation.

EXTRA CREDIT:

- Although many yeasts are harmless, there may be some that are pathogenic.
- Approval depends on the location, and whether there is proper supervision.
- A qualified scientist is needed.
- Collection of organisms may be done at home, but the container must be sealed and brought to the appropriate lab for further research. (P. 13, Rule 3.) If the students are planning to isolate and identify unknowns, it must be done in a BSL-2 lab. If they are planning to culture the organisms without opening the plate except for decontamination and disposal, they may use a BSL-1 lab. (P.14, A 1, A2.)
- They will need Forms 2, 3, and 6A. If they are working at a Regulated Research Institution, they will also need 1C.

ISEF SRC 2019 WORKSHOP CHEAT SHEET - THE ENGINEERING PROJECT

Part I:

What forms are needed?

Form 2 (Qualified Scientist), to be completed by the mother/adult sponsor/physician.

Is this a conflict of interest?

No. One person may have more than one role in the student's project. In this case it is adult sponsor, parent, and Qualified Scientist. However, any person who is involved in the student's project **must not** be a member of any committee that oversees a project, such as SRC, IRB, IACUC, or IBC. (P. 6, Column 1, **Bold** paragraph)

Note: IRB is not needed if invention testing is done by the student researcher him/herself and/or his/her adult sponsor/parent/QS.

Part II:

Discussion Points:

What will the student do if his device and app detect heart beat irregularities in any of his subjects?

- What are the risks associated with telling his subjects the results of the test?
 - The results could be wrong as it is not a validated test.
 - He could tell a subject his heart beat pattern is fine when in reality it is not.
 - He could cause a subject to have significant stress/worry if he tells the person something is wrong with his heart beat if there is nothing wrong.
 - If he does tell the subjects the results, he is practicing medicine without a license using an unapproved medical device.

- What are the risks associated with not telling the subjects the results of the test?
 - If he does not tell the subjects the results, there are significant ethical concerns (possibly withholding useful and important information)

Can this project be done at home or school?

- No. (P. 9 Column 2 – Human Participant Involvement in Student Designed Inventions, etc.) While it would be tempting to try to get School IRB approval with the physician mother as a QS, this would not be a good idea as the physician could be in trouble for being responsible for the use of a non-FDA approved medical device. If the student wants to test the device with people, the student must go to a regulated research institution and gain IRB approval from an institution that can provide guidance about how to ethically carry out this of medical device testing. (P. 9, Human Participant Risk Assessment – Item 2.)

2019 “ANSWERS / RESPONSES” to Pig Project Workshop

Part I: Swab of trailer and boots - PHBA

- a. Sample collection and storage methods. Plate onsite? Environmental/contamination concerns.
- b. The project should be approved.
- c. DS required. May want to have a QS. (Either should complete a Fm 2)
- d. Project is not allowed at home. Unknown microorganisms – can be swabbed on plates in school BSL1 lab as long as they are in plastic/non-breakable petri dishes and are sealed and left sealed (cannot be opened); must be properly disposed (autoclave or disinfection under the supervision of a designated supervisor) (P. 15, A1)
- e. Form 6A is required. This is NOT a vertebrate animal project – this is a PHBA project. No Form 5A required.

Part II: VetMed Disease Lab – Regulated Research Institution (RRI)

- a. Disease lab may or may not approve to have a high school student work with them.
- b. The project should be approved.
- c. A qualified scientist is needed.
- d. Under proper supervision of the university lab in a BSL2 the plates could be opened. (p. 15, A2)
- e. Forms 1C, 2, 6A are needed.

Part III: Additional Survey – Human Subject

- a. Survey methods, review of survey, keeping anonymity. (P. 9, #3)
- b. After student submits an updated research plan, this project/addition should be approved.
- c. Need a school IRB; they may decide a qualified scientist is needed (probably not for this type of survey). (P. 8, #2A)
- d. Project may be done from school or home.
- e. Form 4 and Human Informed Consent Form are needed. QS or written informed consent may or may not be needed – to be determined after review of research plan and survey by the IRB. (p. 8, #4.) IRB may waive written informed consent. (P. 9, IRB Waiver #2)

EXTRA CREDIT 1: Additional Families

- a. Think about consent and collection methods. Does not need to be anonymous.
- b. After student submits an updated research plan, this project/addition should be approved.
- c. Need a school IRB; they may decide a qualified scientist is needed (probably not for this type of survey).
- d. Project may be done from school or home.
- e. Form 4 and Human Informed Consent Form are needed. QS or written informed consent may or may not be needed – to be determined after review of research plan by the IRB. (See references above.)

Part IV: Show Pig Training – Vertebrate Animal

- a. This would be considered standard agricultural practice. Part of raising pigs is taking them to shows to show off genetics and sell or promote your farm’s genetics.
- b. The project should be approved.
- c. Veterinarian or a QS who is knowledgeable about swine husbandry and care. (Either should complete a Form 2). DS to oversee proper animal care. A responsible adult needs to have oversight of the animals and their care. (P. 12, Section A)
- d. Project may be done at home. (P. 12, A, first paragraph #3)
- e. Forms 2, 5A are needed. Form 5B is not needed as all the data will be coming from processor. If the student were to look at meat samples herself – example for fat content/marbling data she would need the Form 5B.
- f. Under standard agricultural practices the student is allowed to raise the animal and have it processed to look at carcass data. (P. 12, A#7.) Note: The student in this scenario would also be able to sell and/or eat the meat processed.

EXTRA CREDIT 2: Homeschool

- a. Part I – swabs can be taken at home/environment if properly collected; plating/incubating must be done in a BSL1 lab. In a homeschool situation a school may allow the student access to a science lab if they have a supervising teacher at the school. Through a homeschool coop/group there may be access through one of the families/parents to utilize a BSL1 lab in the community.
- b. Part II – no issues.
- c. Part III – will need to have an IRB; if part of a homeschool group there may be an administrator of this group that can serve as the administrator or may use a Homeschool Assistantship Program supervisor (this would be through the school). If necessary, the local or ISEF-affiliated SRC can serve as an IRB as long as it has the required membership (P.5, IRB section, 2nd paragraph)
- d. Extra Credit 1 – same as Part III.
- e. Part IV – is allowable at home/field.
- f. Extra Credit 2 – dual enrolled in AgEd – all would be acceptable as stated in the original explanations.

2019 “ANSWERS / RESPONSES” to Vertebrate Animal Workshop

Part I: Diabetic MICE – HOME/SCHOOL

1. What additional information would you, as an adult sponsor, need before proceeding?
 - a. Housing: Home, school?
 - b. Health and welfare of the animal, monitoring. Daily weights, Body Condition Scoring to assure animal is in good condition.
 - c. School: Who is taking care of the animals on weekends/holidays? This must be considered and addressed.
 - d. Are you using males and females? Will you keep separate to avoid litters?
 - e. Disposition – Who is going to keep these 12 mice?
2. What supervision is needed/recommended?
 - a. Veterinarian or a QS who is knowledgeable about Mouse husbandry and care, and hopefully blood collection methods. (Either should complete a Fm 2)
 - b. DS to oversee proper animal care. A responsible adult needs to have oversight of the animals and their care
 - c. Training on Submental method of blood collection, this will most likely come from a QS at an RRI.
3. Is the project allowable?
 - a. Supplemental diet, so OK at either home or school (P. 12, A1)
 - b. Blood collection: If trained properly, this method is a non-invasive and noninvasive method that do not affect the animals' wellbeing, so OK at home/school. Would want assurance that there is proper training and oversight.
 - c. Would also want assurance that there will be continued observation of animal health.
 - d. School: Who is taking care of animals on weekends/holidays? This must be considered and addressed?
4. Should the project be approved and by whom?
 - a. Who reviews? Local/Regional SRC – Before
 - b. Yes, approvable at home/school.
5. What forms, if any, in addition to 1, 1A, 1B, are needed?
 - a. Fm2 QS – if trained for Submental method, Form 5A, Forms 6A & 6B – blood!
6. What additional questions/considerations do you have?
 - a. What if they want to have the Vet euthanize the animals for tissue collection?
NO. (Not at home/school/field (rule A.6.) – ok at an RRI.

Part II: Added Humans

1. What additional information would you, as an adult sponsor, need before proceeding? a. Jane (Self): IRB Needed (PHBA P. 16 C. 10.c)
2. b. BONUS (Parents): IRB needed. As adults the IRB can decide they do not need

written consent. (Up to IRB). If others are tested, not adults, then yes, you'd expect

the IRB to want signed informed consents and parental permission. (PHBA P. 15 C 8; Human Participants P. 8, #2.)

c. Who is taking blood samples? Jane or the person? Or a nurse/QS? This will need to be clear in the research plan. Jane cannot be taking blood samples from humans unless directly (supervised by a QS. Better to have QS do the sampling if the participant is not doing the finger prick themselves.

3. What supervision is needed/recommended?
 - a. Nurse or Medical professional if others are involved in the blood sugar testing.
4. Is the project allowable? Yes
5. Should the project be approved? If good oversight
6. What forms, if any, in addition to 1, 1A, 1B, are needed? Form 4, possible Form 2 QS (Nurse/Medical?) 6A, 6B.

Part III: At RRI with NOD mice

1. What additional information would you, as an adult sponsor, need before proceeding?
 1. Is this part of Dr. Bill's study? It must be clear what is his portion and what is her portion?
 2. Who will euthanize and take tissues? (P. 13, B2.)
 3. What happens to the mice? Are they left for the QS research, or are they euthanized and the tissues examined?
 1. By whom? (Never the student.)
 2. If this is the student's study, is this allowed? (Yes, if at RRI, but not at school/home/field (Rule A. 6.)
2. What supervision is needed? Recommended?
 1. QS – Yes. Needs training and oversight.
3. Is the project allowable? YES.
4. Should the project be approved? (P. 13, B 2)
 1. It's always good to have local/regional SRC approval, but it MUST have IACUC approval from the RRI. It also needs Form 1C, with attached IACUC letter of approval (showing that the project was approved at the time the student's project was conducted.)
5. What forms, if any, in addition to 1, 1A, and 1B are needed?
 1. Form 2 for Dr. Bill, Form 1C for the RRI, Form 5B (RRI), Forms 6A, 6B.