2016

OTHER
CONSENT FORMS

Plymouth PUBLIC SCHOOLS
Making dreams come true

1C REGULATED RESEARCH INSTITUTIONAL/INDUSTRIAL SETTING FORM
This form must be completed AFTER experimentation by the adult supervising the student research conducted in a regulated research institution, industrial setting or any other work site other than home, school or field.

2 QUALIFIED SCIENTIST FORM
May be required for research involving human subjects, vertebrate animals, potentially hazardous biological agents, and DEA-controlled Substances. Must be completed and signed before the start of student experimentation.

3 RISK ASSESSMENT FORM
Required for projects using hazardous chemicals, activities or devices and microorganisms exempt from pre-approval. Must be completed before experimentation.

4 HUMAN PARTICIPANTS FORM
Required for all research involving human participants. (IRB approval required before experimentation.)

MSSEF HUMAN INFORMED CONSENT FORM
Required for human participants as determined by the IRB approval, which is required before experimentation. To be completed by Student Researcher in collaboration with the Teacher/Adult Sponsor/Designated Supervisor/Qualified Scientist. Students may use this sample form or may copy ALL elements of it into a new document.

5A VERTEBRATE ANIMAL FORM
Required for all research involving vertebrate animals that is conducted in a school/home/field research site. (SRC approval required before experimentation.)

5B VERTEBRATE ANIMAL FORM
Required for all research involving vertebrate animals that is conducted at a Regulated Research Institution. (IACUC approval required before experimentation.)

6A POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS RISK ASSESSMENT FORM
Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines, and tissue cultures), blood, blood products, and body fluids. SRC/IACUC/IBC approval required before experimentation.

6B HUMAN AND VERTEBRATE ANIMAL TISSUE FORM
Required for research involving fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids. If the research involves living organisms, please ensure that the proper human or animal forms are completed.
All projects using any tissue listed above, must also complete Form 6A.

7 CONTINUATION/RESEARCH PROGRESSION PROJECTS FORM
Required for projects that are a continuation/progression in the same field of study as a previous project.
This form should be accompanied by the previous year's abstract and Research Plan.

Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed AFTER experimentation by the adult supervising the student research conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

This form MUST be displayed with your project; responses must be on the form.

Student's Name(s) _____

Title of Project _____

_____

To be completed by the Supervising Adult in the Setting (NOT the Student(s)) after experimentation:
(Responses must remain on the form as it is required to be displayed at the student's project booth.)

The student(s) conducted research at my work site:

a) ☐ to use the equipment b) ☐ to perform experiment(s)/conduct research

1) Have you reviewed the MSSEF/ISEF rules relevant to this project? ☐ Yes ☐ No

2) Is this research a subset of your work? ☐ Yes ☐ No

3) How did the student get the idea for her/his project?
(e.g. Was the project assigned, picked from a list, an original student idea, etc.)

4) Did the student(s) work on the project as part of a research group? ☐ Yes ☐ No
If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)

5) What specific procedures or equipment did the student(s) actually use for the project?
Please list and describe. (Do not list procedures student **only** observed.)

6) How independent or creative was the student's/students' work?

Student research projects dealing with ***human participants, vertebrate animals or potentially hazardous biological agents*** *require review and approval by an Institutional Regulatory Board (IRB/IACUC/IBC).* **Copy of approval(s) must be attached, if applicable.**

_____ _____ _____
Supervising Adult's Printed Name Signature Title

_____ _____
Institution Date Signed (must be after experimentation)

_____ _____
Address Email/Phone

Qualified Scientist Form (2)

May be required for research involving human subjects, vertebrate animals, potentially hazardous biological agents, and DEA-controlled Substances. Must be completed and signed before the start of student experimentation.

Student's Name(s) _____

Title of Project _____

_____

To be completed by the Qualified Scientist:

Scientist Name: _____

Educational Background: _____ Degree(s): _____

Experience/Training as relates to the student's area of research:

Position: _____ Institution: _____

Address: _____ Email/Phone: _____

1) Have you reviewed the MSSEF Ethics Statement and MSSEF/ISEF rules relevant to this project? ☐ Yes ☐ No

2) Will any of the following be used?
   a) Human participants ☐ Yes ☐ No
   b) Vertebrate animals ☐ Yes ☐ No
   c) Potentially hazardous biological agents
   (microorganisms, rDNA, and/or tissues, including blood and blood products) ☐ Yes ☐ No
   d) DEA-controlled substances ☐ Yes ☐ No

3) Was this study a sub-set of a larger study? ☐ Yes ☐ No

4) Will you directly supervise the student? ☐ Yes ☐ No

   a. If no, who will directly supervise and serve as the Designated Supervisor? _____
   b. Experience/Training of Designated Supervisor (when applicable):

To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the **Research Plan** prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the **Research Plan**. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my **DIRECT** supervision.

_____
Qualified Scientist's Printed Name

_____ _____
Signature Date of Approval

To be completed by the Designated Supervisor when the Qualified Scientist cannot directly supervise.

I certify that I have reviewed the **Research Plan** and have been trained in the techniques to be used by this student, and I will provide **DIRECT** supervision.

_____
Designated Supervisor's Printed Name

_____ _____
Signature Date of Approval

_____ _____
Phone Email

Risk Assessment Form (3)

Required for projects using hazardous chemicals, activities or devices and microorganisms exempt from pre-approval. Must be completed before experimentation.

Student's Name(s) _____

Title of Project _____

To be completed by the Student Researcher in collaboration with Designated Supervisor/Qualified Scientist:
(All questions must be answered; additional page(s) may be attached.)

1. List/identify microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules), and all hazardous chemicals, activities, or devices or that will be used.

2. Identify and assess the risks involved in this project.

3. Describe the safety precautions and procedures that will be used to reduce the risks.

4. Describe the disposal procedures that will be used (when applicable).

5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):
I agree with the risk assessment and safety precautions and procedures described above. I certify that I have review the **Research Plan** and will provide **DIRECT** supervision.

_____ _____ _____
Designated Supervisor's Printed Name Signature Date of Review (mm/dd/yy)
(must be prior to experimentation.)

_____ _____
Position & Institution Phone or email contact information

_____
Experience/Training as relates to the student's area of research

Human Participants Form (4)

Required for all research involving human participants. (IRB approval required before experimentation.)

Student's Name(s) _____ Title of Project _____

Teacher/Adult Sponsor Name _____ Phone/Email _____

Must be completed by Student Researcher(s) in collaboration with the Teacher/Adult Sponsor/Designated Supervisor/Qualified Scientist:

1. ☐ I have submitted my Research Plan which addresses ALL areas indicated in the Human Participants Section of the Research Plan Instructions.
2. ☐ I have attached any surveys or questionnaires I will be using in my project or other documents provided to human participants.
   ☐ Any published instrument(s) used was/were legally obtained.
3. ☐ I have attached an Informed Consent Form. (if applicable)
4. ☐ Yes ☐ No Are you working with a Qualified Scientist/Designated Supervisor? If yes, attach a Form (2) and/or Form (3) as applicable.

BELOW – IRB USE ONLY

Must be completed by Institutional Review Board (IRB) after review of research plan. All questions must be answered for the approval to be valid. (If not approved, return the paperwork to the student with instructions for modifications.)

☐ Approved with Full Committee Review (3 signatures required) and the following conditions: (All 5 must be answered)

1. Risk Level (Check one): ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Designated Supervisor (DS) Required: ☐ Yes ☐ No
4. Written Minor Assent required for minor subjects: ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Parental Permission required for minor subjects: ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
6. Written Informed Consent required for subjects 18 years or older: ☐ Yes ☐ No ☐ Not applicable (No minors in this study)

☐ Approved with Expedited Review (1 signature required). Study involves either of the following:

- ☐ Human participants will only provide feedback on project design/student-designed invention or prototype/etc., no personal data will be collected and there are no health or safety hazards.
- ☐ Student is the only subject of the research and no more than minimal risk is involved.

IRB SIGNATURES (All 3 signatures required) None of these individuals may be the teacher/adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project, that the checkboxes above have been completed to indicate the IRB determinations and that I agree with the decisions above.

Medical or Mental Health Professional: (a psychologist, psychiatrist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)	
Printed Name	Degree/Professional License
Signature	Date of Approval *(must be prior to experimentation.)*
Educator	
Printed Name	Degree/Professional License
Signature	Date of Approval *(must be prior to experimentation.)*
School Administrator	
Printed Name	Degree/Professional License
Signature	Date of Approval *(must be prior to experimentation.)*

MSSEF Human Informed Consent Form

Required for human participants as determined by the IRB approval, which is required before experimentation. To be completed by Student Researcher in collaboration with the Teacher/Adult Sponsor/Designated Supervisor/Qualified Scientist. Students may use this sample form or may copy ALL elements of it into a new document.

Student Researcher(s) _____

Title of Project _____

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

Purpose of the project:

If you participate, you will be asked to:

Time required for participation:

Potential Risks of Study:

Benefits:

How confidentiality will be maintained:

If you have any questions about this study, feel free to contact:

Teacher/Adult Sponsor/QS/DS: _____ Phone/email: _____

Voluntary Participation:

Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent or Minor Assent Date Reviewed & Signed: _____

_____ Signature: _____

Printed Name of Research Subject

Parental/Guardian Permission (if applicable) Date Reviewed & Signed _____

_____ Signature: _____

Parent/Guardian Printed Name Required for all subjects under 18 years

Vertebrate Animal Form (5A)

Required for all research involving vertebrate animals that is conducted in a school/home/field research site. (SRC approval required before experimentation.)

Student's Name(s) _____

Title of Project _____

To be completed by Student Researcher:

1. Common name (or Genus, species) and number of animals used.

2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc.

3. What will happen to the animals after experimentation?

4. Attach a copy of wildlife licenses or approval forms, as applicable.

5. The ISEF/MSSEF Vertebrate Animal Rules require that any death, illness, or unexpected weight loss be investigated and documented by a letter from the qualified scientist, designated supervisor or a veterinarian. If applicable, attach this letter with this form when submitting your paperwork to the SRC **prior to competition**.

To be completed by Regional Scientific Review Committee (SRC) BEFORE experimentation

Level of Supervision Required for agricultural, behavioral or nutritional studies:

- ☐ Designated Supervisor REQUIRED. Please have applicable person sign below.
- ☐ Veterinarian and Designated Supervisor REQUIRED. Please have applicable persons sign below.
- ☐ Veterinarian, Designated Supervisor and Qualified Scientist REQUIRED. Please have applicable persons sign below and have the Qualified Scientist complete Form (2).

The SRC has carefully reviewed this study and finds it is an appropriate study and may be conducted in a non-regulated research site.

Regional SRC Pre-Approval Signature:

SRC Chair Printed Name	Signature	Date of Approval (mm/dd/yy) *(must be prior to experimentation)*
_____	_____	_____

To be completed by Veterinarian:

- ☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation.
- ☐ I certify that I have approved the use and dosages of prescription drugs and/or nutritional supplements.
- ☐ I certify that I will provide veterinary, medical and nursing care in case of illness or emergency.

Printed Name	Email/Phone
_____	_____

Signature	Date of Approval
_____	_____

To be completed by Designated Supervisor or qualified supervisor when applicable:

- ☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation and I accept primary responsibility for the care and handling of the animals in this project.
- ☐ I certify that I will directly supervise the experiment.

Printed Name	Email/Phone
_____	_____

Signature	Date of Approval
_____	_____

Vertebrate Animal Form (5B)

Required for all research involving vertebrate animals that is conducted at a Regulated Research Institution.
(IACUC approval required before experimentation.)

Student's Name(s) _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

1. Species of animals used: _____ Number of animals used: _____

2. Describe, in detail, the role of the student in this project: animal procedures and related equipment that were involved, oversight provided and safety precautions employed. (Attach extra pages if necessary.)

3. Was there any weight loss or death of any animal? If yes, attach a letter obtained from the qualified scientist, designated supervisor or a veterinarian documenting the situation and the results of the investigation.

4. Does the student's project also involve the use of tissues?
   - ☐ No
   - ☐ Yes (Forms 6A and 6B also required)

5. What laboratory training, including dates, was provided to the student?

6. **Attach a copy of the Regulated Research Institution IACUC Approval.** A letter from the Qualified Scientist or Principal Investigator is not sufficient.

Qualified Scientist/Principal Investigator	
Printed Name	
Signature	Date

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA , fresh/frozen tissue (including primary cell lines, human and other primate established cell lines, and tissue cultures), blood, blood products, and body fluids.
SRC/IACUC/IBC approval required before experimentation.

Student's Name(s) _____

Title of Project _____

To be completed by Student Researcher(s) in collaboration with Qualified Scientist/Designated Supervisor:
(All questions are applicable and must be answered; additional page(s) may be attached.)

1) Identify potentially hazardous biological agents to be used in this experiment. **Include the source, quantity and the biosafety level risk group of each microorganism.**

2) Describe the site of experimentation including the level of biological containment.

3) Describe the procedures that will be used to minimize risk. (personal protective equip., hood type, etc.)

4) **What final biosafety level do you recommend for this project given the risk assessment you conducted?**

5) Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

To be completed by Qualified Scientist or Designated Supervisor

1) What training did the student receive for this project?

2) Do you concur with the biosafety information and recommendation provided by the student researcher above?
☐ Yes ☐ No If no, please explain.

3) Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable)

_____	_____	_____
QS/DS Printed Name	Signature	Date of Signature (mm/dd/yy)

To be completed by SRC: (Check all that apply.)

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-1 study, which must be conducted at a BSL-1 or above laboratory.
Date of SRC approval (before experimentation) _____

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-2 study, which must be conducted at a BSL-2 or above laboratory.
Date of SRC approval (before experimentation) _____

☐ This project was conducted at a Research Institution and was reviewed and approved by the appropriate institutional board (e.g. IACUC, IBC) before experimentation at a BSL-1 or BSL-2 laboratory and complies with the ISEF rules. The required institutional forms are attached.
Date of SRC approval (after experimentation) _____

☐ The Research Institution where this study was conducted does not require approval for this type of study. The student has received proper training and the project complies with ISEF rules. Attached is a letter from an institutional representative certifying the above. Date of SRC approval _____

_____	_____
SRC Chair's Printed Name	Signature

Human and Vertebrate Animal Tissue Form (6B)

Required for research involving fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures)**, blood, blood products and body fluids. If the research involves living organisms, please ensure that the proper human or animal forms are completed. All projects using any tissue listed above must also complete Form 6A.**

Student's Name(s) _____

Title of Project _____

To be completed by Student Researcher:

1) What vertebrate animal tissue will be used in this study? Check all that apply.
   - ☐ Fresh or frozen tissue sample
   - ☐ Fresh organ or other body part
   - ☐ Blood
   - ☐ Body fluids
   - ☐ Primary cell/tissue cultures
   - ☐ Human or other primate established cell lines

2) Where will the above tissue(s) be obtained? If using an established cell line include source and catalog number.

3) If the tissue is obtained from a vertebrate animal study conducted at a research institution, attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.

To be completed by the Designated Supervisor or Qualified Scientist:

☐ I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.

AND/OR

☐ I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

_____	_____	_____
Printed Name	Signature	Date of Approval *(Must be prior to experimentation.)*
_____	_____	
Title	Phone/Email	
_____		
Institution		

Continuation/Research Progression Projects Form (7)

Required for projects that are a continuation/progression in the same field of study as a previous project.
This form must be accompanied by the previous year's abstract and Research Plan.

Student's Name(s) _____

To be completed by Student Researcher:
List all components of the current project that make it new and different from previous research. The information must be on the form.

Components	Current Research Project	Previous Research Project
1. Title		2014-2015: 2013-2014: 2012-2013:
2. Changes in Goal/Purpose/ Objective		2014-2015: 2013-2014: 2012-2013:
3. Changes in Methodology		2014-2015: 2013-2014: 2012-2013:
4. Variables Studied		2014-2015: 2013-2014: 2012-2013:
5. Additional Changes		2014-2015: 2013-2014: 2012-2013:

Attached are:

☐ 2014-2015 Abstract and Research Plan ☐ 2013-2014 Abstract ☐ 2012-2013 Abstract

I hereby certify that the above information is correct and that the current year Abstract & Certification and project display board properly reflect work done only in the current year.

Student's Printed Name	Signature	Date of Signature
Student's Printed Name (team member)	Signature	Date of Signature
Student's Printed Name (team member)	Signature	Date of Signature