

3rd Flr., Bonifacio Bldg., DepEd Complex, U. L. Complex, Meralco Avenue, Pasig City Telephone No.: (02) 633-7242, 632-7746 and 636-5172

Checklist for Adult Sponsor (1) This completed form is required for ALL projects.

To be completed by the Adult Sponsor in collabora Student's Name(s):	
Project Title:	
1) I have reviewed the Intel ISEF Rules and Guide	
2)	• ,
3)	ving and requires prior approval by an SRC, IRB, IACUC or IBC:
☐ Humans	Potentially Hazardous Biological Agents
☐ Vertebrate Animals	☐ Microorganisms ☐ rDNA ☐ Tissues
	E Flictoorganishis E FBTWY E Fissues
5) ltems to be completed for ALL PROJECTS	
☐ Adult Sponsor Checklist (1)	☐ Research Plan
☐ Student Checklist (1A)	☐ Approval Form (1B)
_	al Setting Form (1C) (when applicable after completed experiment)
Continuation Form (7) (when applicable)	
,	es the use of one or more of the following (check all that
apply):	orthogol Davids and CIDD) and full track of the order)
`	utional Review Board (IRB); see full text of the rules.)
☐ Human Participants Form (4) or appropria	
☐ Sample of Informed Consent Form (when applied	
Qualified Scientist Form (2) (when applicaVertebrate Animals (Requires prior approval,	
`	s conducted in a school/home/field research site (SRC prior
approval required.)	
 Vertebrate Animal Form (5B)—for project: Animal Care and Use Committee (IACUC) a 	s conducted at a Regulated Research Institution. (Institutional approval required prior experimentation.)
 Qualified Scientist Form (2) (Required for when applicable) 	all vertebrate animal projects at a regulated research site or
Potentially Hazardous Biological Agents (Recommittee (IBC), see full text of the rules.)	equires prior approval by SRC, IACUC or Institutional Biosafety
☐ Potentially Hazardous Biological Agents R	isk Assessment Form (6A)
involves the use of fresh or frozen tissue,	m (6B)—to be completed in addition to Form 6A when project , primary cell cultures, blood, blood products and body fluids.
Qualified Scientist Form (2) (when applica	·
	rojects involving protists, archae and similar microorganisms sting, fuel production or other non-culturing experiments (6A,
• • •	es (No prior approval required, see full text of the rules.)
☐ Risk Assessment Form (3)	(No prior approvarrequired, see ruit text or the rules.)
` ,	projects involving DEA-controlled substances or when
Adult Cooper's Drieted News	Date of Davids
Adult Sponsor's Printed Name Signature	Date of Review
Phone	Email





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Student Checklist (1A) This form is required for ALL projects.

1)	a. Student/Team Leader:	Grade:
	Email:	Phone:
	b. Team Member: c. T	eam Member:
2)	Title of Project:	
3)	School:	School Phone:
	School Address:	
4)	Adult Sponsor:	— Phone/Email: ————————————————————————————————————
5)	Is this a continuation from a previous year? If Yes:	☐ Yes ☐ No
	 a) Attach the previous year's Abstract and b) Explain how this project is new and different from project. 	
6)	This year's laboratory experiment/data collection: (mo	ust be stated (mm/dd/yy)
	Start Date:	- End Date: ————
7)	Where will you conduct your experimentation? (check a ☐ Research Institution ☐ School ☐ Field	all that apply) ☐ Home ☐ Other:
•	List name and address of all non-school work site(s): me:	
Ad	dress:	
Ph	one:	
9)	Complete a Research Plan following the Research Pl	an instructions and attach to this form.
10	An abstract is required for all projects after experin	nentation.



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Research Plan Instructions

A complete research plan is required and must accompany Checklist for Student (1A)

Provide a typed research plan and attach to Student Checklist (1A). Please include your name on each page. The research plan for ALL projects is to include the following:

- A. Question or Problem being addressed
- B. Goals/Expected Outcomes/Hypotheses
- **C. Description in detail of method or procedures** (The following are important and key items that should be included when formulating ANY AND ALL research plans.)
 - Procedures: Detail all procedures and experimental design to be used for data collection
 - Data Analysis: Describe the procedures you will use to analyze the data that answer research question or hypothesis
- **D. Bibliography:** List at least five (5) major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.
 - o Choose one style and use it consistently to reference the literature used in the research plan
 - o Guidelines can be found in the Student Handbook

Items 1-4 below are subject-specific guidelines for additional items to be included in your research plan as applicable:

- 1. Human participants research:
 - Participants. Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify
 any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
 - Recruitment. Where will you find your participants? How will they be invited to participate?
 - **Methods.** What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
 - Risk Assessment
 - Risks. What are the risks or potential discomforts (physical, psychological, time involved, social, legal etc) to participants? How will you minimize the risks?
 - o **Benefits.** List any benefits to society or each participant.
 - **Protection of Privacy.** Will any identifiable information (e.g., names, telephone numbers, birthdates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?
 - Informed Consent Process. Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

2. Vertebrate animal research:

- Briefly discuss potential ALTERNATIVES to vertebrate animal use and present a detailed justification for use of vertebrate animals
- Explain potential impact or contribution this research may have
- Detail all procedures to be used
 - Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experimentation
 - Detailed chemical concentrations and drug dosages
- Detail animal numbers, species, strain, sex, age, source, etc.
 - o Include justification of the numbers planned for the research
- Describe housing and oversight of daily care
- Discuss disposition of the animals at the termination of the study

3. Potentially Hazardous Biological Agents:

- Describe Biosafety Level Assessment process and resultant BSL determination
- Give source of agent, source of specific cell line, etc.
- Detail safety precautions
- Discuss methods of disposal

4. Hazardous Chemicals, Activities & Devices:

- Describe Risk Assessment process and results
- Detail chemical concentrations and drug dosages
- Describe safety precautions and procedures to minimize risk
- Discuss methods of disposal





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Approval Form (1B)

A completed form is required for each student, including all team members.

1) To Be Completed by Student and Parent

- a) Student Acknowledgment:
 - I understand the risks and possible dangers to me of the proposed research plan.
 - I have read the Intel ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.
 - I have read and will abide by the following Ethics statement

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and the Intel ISEF. Student's Printed Name Signature Date Acknowledged (Must be prior to experimentation.) b) Parent/Guardian Approval: I have read and understand the risks and possible dangers involved in the Research **Plan**. I consent to my child participating in this research. Parent/Guardian's Printed Name Signature Date of Approval (Must be prior to experimentation.) 2) To be completed by the Fair SRC (Required for projects requiring prior SRC/IRB APPROVAL. Sign 2a or 2b as appropriate.) a) Required for projects that need prior SRC/IRB Required for research conducted at all Regulated approval BEFORE experimentation Research Institutions with no prior fair SRC/IRB (humans, vertebrates or potentially hazardous approval. OR biological agents) This project was conducted at a regulated research institution (not home or high school, etc.), was The SRC/IRB has carefully studied this project's Research Plan and all the required forms are included. reviewed and approved by the proper institutional My signature indicates approval of the Research Plan board before experimentation and complies with the before the student begins experimentation. Intel ISEF Rules. Attach (1C) and required institutional approvals (e.g. IACUC, IRB) SRC/IRB Chair's Printed Name SRC Chair's Printed Name Signature Date of Approval Signature Date of Approval (Must be prior to experimentation.) 3) Final Intel ISEF Affiliated Fair SRC Approval (Required for ALL Projects)

SRC Approval After Experimentation and Street I certify that this project adheres to the appropriate the street of		
Regional SRC Chair's Printed Name	Signature	Date of Approval
State/National SRC Chair's Printed Name (where applicable)	Signature	Date of Approval



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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.

Stı	ident's Name(s)	
Tit	e of Project	
	be completed by the Supervising Adult in the Setting (NOT the Stuesponses must remain on the form as it is required to be displayed at student	
Th	e student(s) conducted research at my work site:	
а	\square to use the equipment b) \square to perform experiment(s)/conduct re	esearch
1)	Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐	l No
2)	How did the student get the idea for her/his project? Was it a subset of your (e.g. Was the project assigned, picked from a list, an original student idea, etc.	
3)	Did the student(s) work on the project as a part of a research group? If yes, how large was the group and what kind of research group was it (student).	l Yes □ No dents, group of adult researchers, etc.)
4)	What specific procedures or equipment did the student(s) actually use for the Please list and describe. (Do not list procedures student only observed.)	ne project?
5)	How independent or creative was the student's/students' work?	
	Student research projects dealing with human subjects, vertebrate animals agents require review and approval by an institutional regulatory board (IRE must be attached, if applicable.	
	Supervising Adult's Printed Name Signature	Title
	Institution	Date Signed (must be after experimentaiton)
	Address	Email/Phone





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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.

Stı	rudent's Name(s)			
Tit	tle of Project			
То	be completed by the Qualified Scientist:			
Sci	ientist Name:			
	ducational Background: Department of the student's area of research:	egree(s):		
Po:	osition: Institution:			
Ad	ddress: Email/Phone:			
1)	Have you reviewed the Intel ISEF rules relevant to this project?	□ У	es	□ No
2)	 Will any of the following be used? a) Human subjects b) Vertebrate animals c) Potentially hazardous biological agents (microorganisms, rDNA a including blood and blood products) d) DEA-controlled substances 	☐ Y ☐ Y nd tissues, ☐ Y	es	□ No □ No □ No □ No
3)	Will you directly supervise the student? a) If no, who will directly supervise and serve as the Designated Sub) Experience/Training of the Designated Supervisor:	□ Y pervisor?		□ No
4)	Describe the safety precautions and training necessary for this proje	ct:		

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 Na	ame
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



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Risk Assessment Form (3)
Required for projects using hazardous chemicals, activities or devices.
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.)	
 List/identify the hazardous chemicals, activities, devices or microorganisms exempt from pre-approva Potentially Hazardous Biological Agent rules) that will be used. 	(see
2. Identify and assess the risks involved.	
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 reviewed the Research Plan and will provide direct supervision.	e):
Designated Supervisor's Printed Name Signature Date of Review	
Position & Institution Phone or email contact information	
Experience/Training as relates to the student's area of research	





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Human Participants Form (4)
Required for all research involving human participants not conducted at a Registered Research Inst. (IRB approval required before experimentation.)

Student's Name(s)		Title of F	Title of Project		
		y Student Researcher(s) in co		Phone/Email dult Sponsor/Designated Supervisor/Qua	alified
1. 🗆	I have submit Plan Instructi		Idresses ALL areas indica	ated in the Human Participants Section of t	:he Research
2. 🗆		ed any surveys or questionnairo shed instrument(s) used was /v		roject.	
3. 🗆	I have attach	ed an informed consent that I w	vould use if required by t	the IRB.	
4. □	Yes □ No	Are you working with a Qua	lified Scientist?		
		Name:		Degree:	
		Email Address/Phone Numb	oer:		
		Experience/Training as it re	elates to this project:		
Res Che	Research Plan meck one of the Research proconcerns an Research proconcerns and Research process and Research proconcerns and Research process and Research proconcerns and Research process and Research proconcerns and Research process and Research pro	ust address all areas indicate following: pject requires revisions and i d/or requested revisions. pject is Approved with the f el (check one): d Scientist (QS) Required: No Parental Permission required No Informed Consent required f No Informed Consent required f No Is signatures required) N Is scientist or related to (e.g.,	ed on the Human Particle on the Human Particle is NOT approved at the following conditions be in Minimal Risk Yes inor participants: Not applicable of the participant Not applicable of participants 18 years Not applicable of these individual mother, father of the	No minors in this study)	structions. ating sk study)
Medi	ical or Mental	Health Professional (a psyc	hologist, psychiatrist, me	dical doctor, licensed social worker,	ı
	e d clinical profe d Name	ssional counselor, physician's as:	sistant, or registered nurs	Degree/Professional License	l
Signat	Signature Date of Approval			I	
Scho	ol Administra	tor			ı
Printe	d Name			Degree/Professional License	I
Signature Date of Approval			i		
Educa	ator				ı
Printe	d Name			Degree/Professional License	ı
 Signat	Signature Date of Approval			Date of Approval	ı





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Human Informed Consent Form

Instructions to the Student Researcher(s): An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist.

This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form or may copy ALL elements of it into a new document.

If the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.

Student Researcher(s):		
Title of Project:		
I am asking for your voluntary participation in mahout the project. If you would like to participat		
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 fre	e to contact:	
Adult Sponsor: Pho	one/email:	
Voluntary Participation: Participation in this study is completely voluntary. I consequences. Please be aware that if you decide to decide not to answer any specific question.		
By signing this form I am attesting that I have read consent/assent to participate or permission for my		ation above and I freely give my
Adult Informed Consent or Minor Assent Printed Name of Research Participant:	Date Reviewed & Signed: Signature:	
Parental/Guardian Permission (if applicable)	Date Reviewed & Signed:	
Parent/Guardian Printed Name:	Signature:	



Student's Name(s)_____

Republic of the Philippines DEPARTMENT OF EDUCATION BUREAU OF SECONDARY EDUCATION



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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.)

itle of Project			
To be completed by St	udent Researcher:		
. Common name (or Gen	us, species) and number of anim	als used.	
	ne housing and husbandry to be pudding, type of food, frequency of		
cage, environment, bed	dulig, type of food, frequency of	Tiood and water, now ofter	i ariiiriai is observed, etc.
R What will hannen to th	e animals after experimentation	7	
. What will happen to th	e driimais arter experimentation		
1 Attach a copy of wildlif	fe licenses or approval forms, as	annlicable	
	e neerises of approval forms, as	аррисавіс.	
•	ntific Review Committee (SRC) BE	•	
	equired for agricultural, behav		S:
_	isor REQUIRED. Please have applicable p	-	
_	esignated Supervisor REQUIRED. Please		
☐ Veterinarian, Desigr Qualified Scientist c	nated Supervisor and Qualified Scientist complete Form (2).	t REQUIRED. Please have applicab	le persons sign below and have the
The SRC has carefully review SRC Pre-Approval Signat	red this study and finds it is an appropri	ate study that may be conducted	in a non-regulated research site.
Sic Fre-Approval Signat	uie.		
SRC Chair Printed Name	Signature		Date of Approval
To be completed by V	eterinarian:		esignated Supervisor or
	reviewed this research and animal	qualified supervisor v	
husbandry with the experimentation.	student before the start of		eviewed this research and animal student before the start of
☐ I certify that I have a	approved the use and dosages of	experimentation and	I accept primary responsibility for the the animals in this project.
	nd/or nutritional supplements.		ectly supervise the experiment.
I certify that I will pr	rovide veterinary medical and nursing s or emergency.		,,
Printed Name	Email/Phone	Printed Name	Email/Phone
Signature	Date of Approval	Signature	Date of Approval
			1.1





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Vertebrate Animal Form (5B)

Required for all research involving vertebrate animals that is conducted in 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 I		
1. Species of animals used:	Number of a	nimals used: ————
2. a. Pain designation for the IACUC protocol:		
b. Pain designation for student's project:		
Describe, in detail, the role of the student in this project: involved with, oversight provided and safety precautions		
 4. Does the student's project also involve the use of tissue No Yes, Be sure to complete Forms 6A and 6B 	s?	
5. What laboratory training, including dates, was provided t	o the student?	
6. Attach a copy of the Regulated Research Institution I. Principal Investigator is not sufficient.	ACUC Approval. A letter from the	e Qualified Scientist or
Certification or Documentation of Student Researcher Train	ing	
List Certificate Number or Attach Documentation		Date(s) of Training
Qualified Scientist/Principal Investigator Printed Name	Signature	Date
IACUC Chair/Coordinator Printed Name	Signature	Date





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Potentially Hazardous Biological Agents Risk Assessment Form (6A)
Required for research involving microorganisms, rDNA, fresh/frozen tissue, blood and body fluids.
SRC/IACUC/IBC approval required before experimentation.

Stu	dent's Name(s)
Title	e of Project
	e completed by Student Researcher(s) in collaboration with Qualified Scientist/Designated Supervisor: questions are applicable and must be answered; additional page(s) may be attached.)
	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.
1. 2.	be completed by Qualified Scientist or Designated Supervisor What training will the student receive for this project? Do you concur with the biosafety information and recommendation provided by the student researcher above? Yes Do No If no, please explain. 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
То	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 Intel 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 Intel ISEF rules. Attached is a letter from an institutional representative certifying the above. Date of SRC approval





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Human and Vertebrate Animal Tissue Form (6B)

Required for projects using fresh/frozen tissue, primary cell 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 Stude 1) What tissue(s), organ(s), or	ent Researcher(s): part(s) will be used, or vertebrate animals?	
2) Where will the above tissue	e, organ, or part be obtained (identify each s	separately):
vertebrate study from which	m a source within a research institution, plact th the tissue was obtained. Attach a copy o le of the study, the IACUC approval number	f the IACUC certification with the name of the
☐ I verify that the student w or qualified personnel from purpose other than the stu AND/OR☐ I certify that the blood, blo	Qualified Scientist or Designated Sup vill work solely with organs, tissues, cultures or continuous the in the laboratory; and that if vertebrate animals of udent's research. and products, tissues or body fluids in this project of the forth in Occupational Safety and Health Act, 2	tells that will be supplied to him/her by myself were euthanized they were euthanized for a set will be handled in accordance with the
Printed Name	Signature	Date Signed (Must be prior to experimentation.)
Title		Phone/Email
Institution		



Student's Name(s)

To be completed by Student Researcher:

Republic of the Philippines DEPARTMENT OF EDUCATION **BUREAU OF SECONDARY EDUCATION**



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Continuation Projects Form (7)
Required for projects that are a continuation in the same field of study as a previous project. This form must be accompanied by the previous year's abstract and Research Plan.

Components	Current Research	Previous Research
components	Project	Project
1. Title		2010–2011
		2009-2010
2. Change in goal/purpose	:/	2010-2011
objective		2009-2010
3. Changes in methodology	,	2010-2011
		2009-2010
4. Variables studied		2010-2011
		2009-2010
5. Additional changes		2010-2011
changes		2009-2010
ttached are: 1 2010–2011 Ab	ostract and Research Plan	□ 2009–2010 Abstract and Research Plan
	that the above information is correct and the operly reflect work done only in the curren	hat the current year Abstract & Certification and project tyear.
Student's Printed	d Name(s) Signature	Date of Signature





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	OFFICIAL ABSTRACT and CERTIFICATION		Category Pick one only-	
		r	nark an "X" in oox at right	
		<i>p</i>	Animal Sciences	
			Behavioral and Social Science	
		E	Biochemistry	
			Cellular & Molecular Biology	
		C	Chemistry	
		C	Computer Science	
		E	arth Science	
			ing: Electrical & 1echanical	
			ng: Materials & Bioengineering	
			nergy & ransportation	
			nvironmental Ianagement	
			invironmental sciences	
			lathematical sciences	
			ledicine and lealth	
1	As a part of this research project, the student directly handled, manipulated, or interacte	٠.d	1icrobiology	
١.	As a part of this research project, the student directly handled, manipulated, or interacte with (check ALL that apply):		Plant Sciences Physics and	
	human subjects potentially hazardous biological agents		Astronomy	
	vertebrate animals microorganisms nDNA tissue			
2.	This abstract describes only procedures performed by me/us, reflects my/our own independent research, and represents one year's Work only] No		
3.	I/we worked or used equipment in a regulated research institution or industrial setting:] No		
4.	This project is a continuation of previous research.			
5.	My display board includes non-published photographs/visual Yes No depictions of humans (other than myself):			
6.	I/we hereby certify that the abstract and responses to the See No above statements are correct and properly reflect my/our own work.	\		,
	is stamp or embossed seal attests that this project is in compliance with all federal d state laws and regulations and that all appropriate reviews and approvals have been			

obtained including the final clearance by the Scientific Review Committee.