HUMAN SUBJECTS FORM (4)

This form is required for all research involving humans. Institutional Review Board (IRB) approval is required before experimentation.

Project title:
Student(s)´s name(s):

Mentor's name: phone/email:

To be completed by the Student Researcher(s) in collaboration with the mentor / Designated Supervisor/ Qualified Scientist. Mark:

1. I have submitted my Research Plan which adheres to all the procedures in the Research Rules involving humans: objectives, how to minimize risks and stress (if existing), benefits, confidentiality, procedures to obtain consent, etc.
( ) Yes ( ) No

2. I have attached any surveys or questionnaires I will be using in my research.
( ) Yes ( ) No

3. I have attached an informed consent form, wich I will use if required.
( ) Yes ( ) No

4. Are you working in collaboration with a Qualified Scientist?
( ) Yes (Form 2 must be attached)
Name: _____
Degree: _____
Address:_____ Telephone: _____ E-mail: _____
Experience in the Project research area: _____
( ) No

TO BE COMPLETED BY THE INSTITUTIONAL REVIEW BOARD (IRB) AFTER THE RESEARCH PLAN REVIEW

( ) The research project has **NO**T been **APPROVED** yet. It has to undergo changes.

( ) The research project **is APPROVED** according the following conditions:
1. Risk level: ( ) There is no risk ( ) Minimal risk ( ) More than minimal risk
2. Qualified Scientist is required: ( ) Yes ( ) No
3. Participation Assent needed for minors: ( ) Yes ( ) No ( ) Not applicable (there are no minors in this study)
4. Parental/Guardian Informed Consent for minors:
5. ( ) Yes ( ) No ( ) Not applicable (there are no minors in this study)
6. Written Informed Consent for participants aged 18 or more:
( ) Yes ( ) No ( ) Not applicable (there are no participants aged 18 or more)

IRB SIGNATURES: (all three signatures are required)
Those must not be the Mentor, Designed Supervisor, Qualified Scientist or someone related to the student (parent, etc.) signatures, in order to avoid conflicts of interest.

I attest that I have reviewed the student(s)´s project and ratify the information above.

Medical or Mental Health Professional (a psychologist, psychiatrist, medical doctor, licensed social work assistant, registered nurse)	
Name	Degree
Signature	Approval date

School Administrator	
Name	Degree
Signature	Approval date

EXAMPLE OF INFORMED CONSENT FORM

Instructions for the student researcher: a consent form must be developed in collaboration with the Mentor, Designed Supervisor or Qualified Scientist.

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

- When written documents are needed, the researcher keeps the original, signed form.
- The students may use this form or may copy **ALL** the items in a new document.

I ASK YOUR VOLUNTARY HELP IN MY RESEARCH PROJECT. PLEASE, READ THE FOLLOWING INFORMATION AND, IF YOU WANT TO PARTICIPATE, I KINDLY ASK YOU TO SIGN YOUR NAME AT THE END OF THE FORM.

Project objective:
If you participate, you will have to:
Necessary time to participate:
Risks:
Benefits:
How will confidentiality be maintained?

Participation in this research is TOTALLY VOLUNTARY. If you decide not to participate, there will be no consequences. Be aware that, if you decide to participate, you can leave the research at any time, and there will be no need to explain your decision.

If you have any questions about the research, you can contact the mentor of the research:
Mentor's name:
Telephone number/e-mail:

Signing this document, I attest that I have read and understood the information above and I am giving freely consent/agreement to participate or permission to my child's participation.

Consent of an adult or minor agreement
Name of the participant in the research:
Date:
Signature:

Parental/Guardian permission (if applicable)
Father's/mother's name:
Date:
Signature: