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MOSTRATEC
A World of Creativity and Research
International Fair of Science and Tecnology

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RESEARCH REGULATIONS

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MOSTRATEC REGULATIONS

Fundação Liberato, organizer of MOSTRATEC, reinforces its commitment to the health and well-being of all and provides for the regulation and operationalization of administrative and pedagogical activities following the guidelines of the competent bodies.

MOSTRATEC Regulations are based on the Official Regulation of ISEF - International Science and Engineering Fair. MOSTRATEC is autonomous and reserves the RIGHT TO ADOPT MODIFICATIONS IN ACCORDANCE WITH BRAZILIAN LEGISLATION OR TO MATCH TO ITS REALITY.

The objectives established by the Organizing Committee when proposing the Regulations for MOSTRATEC are:

• determine eligibility for competition at MOSTRATEC;

• protect the rights and wellness of the student researcher;

• protect the rights and wellness of the human participant;

• protect the health and wellness of the vertebrate animal subject;

• ensure adherence to state, federal and international regulations related to research;

• ensure use of safe and responsible laboratory practices, of devices or any other hazardous activity offering risk to the student researcher;

• highlight the environmental responsibility of the student researcher (proper discard, reuse and quantity reduction);

• disclose and guide the accomplishment of the mentors' rights and duties;

• disclose and guide the accomplishment of the student researchers' duties with the mentor, with the institutions to which they are connected to, with the environment, with the country in which they are conducting their research, and with the one in which they are exhibiting their study (Brazil).

1 COMMON RULES AND GUIDELINES FOR ALL PROJECTS

1.1 Ethics statement

Scientific fraud and misconduct are not condoned at any level of research or competition, including plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify participation in MOSTRATEC. The Organization Board reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

1.2 Eligibility and limitations

A project may run for participation in MOSTRATEC through two processes:

- affiliated fairs with MOSTRATEC[1]: each affiliated fair accredits the number of projects authorized and agreed in the Affiliation Letter and not more. The code of the fair must be used for online registration;

- MOSTRATEC selection process: projects are submitted directly on the fair website. The SRC (Scientific Review Committee) selects the projects according to the number of vacancies available.

Online Registration is accessed at MOSTRATEC website Edition[2], link Registration[3]. All student researchers that intend to participate in MOSTRATEC must meet the following requirements:

- be enrolled in a high school or pre-college institution of professional/technical education having regular attendance;

- belong to age group of 14, minimum;

- submit only one project (technological or scientific) per student (individual or team projects no more than three members);

- participate with one (01) project (technological or scientific) only;

[1] http://www.mostratec.com.br/en

[2] www.mostratec.com.br/en

[3] http://www.mostratec.com.br/en/current-edition/criteria-for-participation-in-mostratec

- have a mentor (older than 21);
- develop the project study in accordance with MOSTRATEC research rules;
- observe the areas of knowledge established by MOSTRATEC;
- focus on one of the characteristics: investigation and/or innovation;
- submit a project that includes no more than 12 months of continuous research (see 1.5 Continuation of projects, when applicable);
- submit team projects with two or three members only. No member may be substituted during the development of the research to guarantee authorship of the research;
- not conduct projects that are mainly demonstrations, bibliographic research only, informational projects, "explanation" models. Projects with the characteristics here mentioned will not be accepted at MOSTRATEC;
- present only the own portion of the complete study at MOSTRATEC.

1.3 Requirements and regulations

The requirements and the rules are:

a) all students participating in an affiliated fair with MOSTRATEC and all the finalists of MOSTRATEC must adhere to the rules as set in this document;

b) all projects must adhere to the Ethics Statement above;

c) all projects (affiliated fairs or selection process) must adhere to the **requirements** of the affiliated fair(s) in which they compete to qualify for participation in MOSTRATEC or to the requirements of MOSTRATEC by itself. Knowledge of these requirements is the student and Adult mentor´s responsibility;

d) projects must adhere to local, state and federal Brazilian regulations and permitting conditions. In addition, projects conducted outside Brazil must also adhere to the Brazilian laws and to its jurisdiction;

e) the use of non-animal research methods and the use of alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project;

f) introduction of plant species, pathogens, toxic chemicals or substances that may cause hazard to people involved in the project and to MOSTRATEC's environment is prohibited;

g) Exhibitions at MOSTRATEC must adhere to the Display and Safety Requirements[4] and to the Code of Conduct and Releases[5].

1.4 Approval and documentation

Before experimentation begins, a local or regional Institutional Review Board (IRB) must review and approve all projects involving human participants, vertebrate animals, and potentially hazardous biological agents. It is strongly advised that each Educational Institution creates its own Institutional Review Board (IRB).

Each student must complete the research paper and the Review Form-1, proofread the project with the **Mentor** and fill in the Abstract, as specified on the website.

A Qualified Scientist is required for all studies involving potentially hazardous biological agents BSL-2 (Biosafety Level 2) and substances controlled by the Army, especially those restricted substances in the Brazilian and/or International laws, as well as for many human participant studies and many vertebrate animal studies.

The research paper must be approved prior to the start of the experimentation. Any changes proposed on the initial Plan, the same must be submitted again to the Institutional Review Board (IRB) for approval.

Projects which are continuous of a previous year's work and which require IRB approval must undergo the review process with the current year proposal prior to experimentation/ data collection for the current year.

Any continuation of project must document that the additional research is new and different from the previous year. (see Continuation Projects Form (7))[6].

If research was conducted in a regulated research institution, industrial setting or any other work site other than home, school or field, the Regulated Research Institutional/Industrial Setting Form (1C) must be completed and be available at the booth at MOSTRATEC.

Each student or team must submit a page abstract summarizing the current year's work. In the abstract, the author(s) must describe research conducted by the student. THE ABSTRACT MUST BE CLEAR, WITH FUNDAMENTAL DATA THAT PROMOTE UNDERSTANDING OF THE PROJECT SUBMITTED TO MOSTRATEC. ABSTRACTS

[4] http://www.mostratec.com.br/en/current-edition/develop-your-project/research-rules

[5] http://www.mostratec.com.br/en/current-edition/develop-your-project/forms

[6] http://www.mostratec.com.br/en/current-edition/develop-your-project/forms

WHICH DO NOT HAVE MEANINGFUL INFORMATION AND/OR DO NOT PROMOTE UNDERSTANDING MAY FAIL TO QUALIFY AT MOSTRATEC. The Abstract and the Research Paper must be completed on the Online Registration Form.

All necessary forms must be inserted in the Online Registration Form observing the deadline.

All deadlines established in the calendar must be strictly met.

1.5 Continuation of projects

As in academic research or professional life, research projects can be conducted based on prior works. A project can be considered a continuation project if it presents a strong scientific commitment, that is, it shows innovation compared to the research of the previous year. At MOSTRATEC, students will be evaluated based on the research carried on during the 12 months prior to the project submission.

If the current year's project submission (2023) could not have been conducted without the outcome of a past year's research project (2022), then it is considered a continuation for MOSTRATEC. These projects must document that the additional research is a substantive expansion from prior work (e.g. testing a new variable or new line of investigation). Repetition of previous experimentation with the same methodology and research question, even being an increased sample size does not deepen the research, and is therefore not an example of an acceptable continuation.

The display board must reflect the current year's work only. The title of the project exhibited must mention continuation. (Example: Construction of a Wheelchair of Lower Cost II).

Longitudinal studies are permitted as an acceptable continuation under the following conditions:

• the study is a multi-year study testing or documenting the same variables in which time is a critical variable. (Example: effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time);

• each consecutive year demonstrates time-based change;

• display board is based on collective past definitive data and compared to the current year data set. No raw data from previous years may be displayed.

• all continuation of projects must be reviewed and approved each period of maximum 12 months and the forms must again be completed.

NOTE: To compete at MOSTRATEC, documentation must include the Continuation of Project Form (7), the previous year's Abstract and Research Paper. Documentation must be clearly labeled showing the research period (ex: 2022 -2023) and submitted to the SRC.

1.6 Team projects

Team projects:

a) may compete and are judged at MOSTRATEC scientific research category undergoing the same rules of an individual project;

b) may have two or three members and may not have had more than three members at any level of research work. Teams cannot substitute members in a given research year. Conversion from individual to team project, or vice versa, is prohibited during a research year;

c) are encouraged to appoint a team leader to coordinate the work and act as a spokesperson. However, each member of the team should be able to serve as a spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members;

d) must submit the Review Form-1 for each member, participating or not in the fair.

e) team members must jointly submit the Review Form-1, the Research Paper, the Rules of Conduct and Release, the Abstract and other required forms;

f) must write the full names of all team members on all forms.

2 ROLES AND RESPONSIBILITIES OF STUDENTS AND ADULTS

2.1 Student(s) researcher(s)

The student researcher is responsible for all aspects of the research project including enlisting the aid of any required supervisory adults (mentor, Qualified Scientist, etc), obtaining necessary approvals (IRB and SRC), following MOSTRATEC Rules and Guidelines, besides conducting the research work.

Scientific fraud and misconduct are not condoned at any level of research competition. This includes 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. MOSTRATEC reserves the right to revoke recognition of a project found to have been fraudulent.

2.2 Mentor

A mentor must:

a) be 21 years old;

b) must be graduated (may be a teacher, parent, professor, and/or other professional scientist in whose lab the student is working);

c) have a solid background in science and should have close contact with the student during the course of the project. The Adult mentor is responsible for working with the student to evaluate any possible risks involved in order to ensure health and safety of the student conducting the research and the humans and/or animals involved in the study;

d) be familiar with the regulations that govern potentially dangerous research as they apply to a specific student project. These may include chemical and equipment usage, experimental techniques, research involving human and/or vertebrate animals, and cell cultures, microorganisms, or animal tissues. Regulations must be discussed with the student when completing the Research Paper - some experiments involve procedures or materials that are regulated by laws. If not thoroughly familiar with the regulations, the Adult mentor should help the student enlist the aid of a Qualified Scientist;

e) be responsible for ensuring the student's research is eligible to participate in MOSTRATEC.

2.3 The qualified scientist

A Qualified Scientist should have earned a scientific professional degree related to the student's area of research. Professionals with a PhD or master's degree are recommended, but the SRC may accept or not professionals with proven experience in the student's area of research. The SRC decides if documentation evidencing the degree and/or professional experience should be required.

The Qualified Scientist must be thoroughly familiar with local, state, and federal regulations that govern the student's area of research.

The Qualified Scientist and the Mentor may be the same person, if that person is qualified as described in the previous item. A student may work with a Qualified Scientist in a city, state or country that is not where the student resides. In this case, the student must work

locally with a Designated Supervisor (see item 2.4 below) who has been trained in the techniques to be applied by the student in his research.

2.4 The designated supervisor

The Designated Supervisor is an adult who is directly responsible for overseeing student´s experimentation. The Designated Supervisor does not need to have an advanced degree, but must be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Mentor may act as the Designated Supervisor.

If a student is experimenting with vertebrates and live animals, or if their behavior, or their habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

3 RESEARCH REGULATORY COMMITTEES

3.1 The Institutional Review Board (IRB)

An Institutional review Board (IRB) is an ethics committee which, according to the federal law (resolução nº 466 de 12 de dezembro de 2012 do Conselho Nacional de Saúde), must evaluate potential physical and/or psychological risk of research involving humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

If necessary, the local SRC or the SRC of the Affiliated Fair with MOSTRATEC can serve as an IRB as long as it has the required membership**.** An IRB must consist of a minimum of three members:

- an educator;
- a school administrator (preferably principal or vice principal);
- an individual who is knowledgeable about and capable of evaluating the physical and/or the psychological risk involved in a given study (this may be a medical doctor, nurse, psychologist, licensed social worker or licensed clinical professional counselor.

Additional expertise: if an expertise is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of the expert.

It is highly recommended that no Mentor, parent or other relative of the researcher, Qualified Scientist or Designated Supervisor of the projects of an institution may serve on the IRB reviewing those projects. Additional members are recommended to avoid conflicts of interest and to increase the expertise of the committee.

The Mentor and the local IRB are responsible for ensuring that the project is appropriate for a high school/ technical student and adheres to MOSTRATEC rules.

An IRB is responsible for assessing risk and documenting the determination of risk level on Form 4 (Human Subjects and Informed Consent Form)**.** However, a SRC in reviewing projects just prior to a fair and judging human participants were placed in risk, may override the IRB decision and the project may fail to qualify for competition. It is advised that the IRB consult with local or affiliated fair SRC and/or with MOSTRATEC SRC in questionable cases.

3.2 The scientific review committee of the affiliated fair

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, forms, research papers and for compliance with the rules and applicable laws and regulations at each level of science fair competition.

Most proposed research projects involving vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved BEFORE experimentation. Local or regional SRC prior review is not required for human studies previously reviewed and approved by a local or regional IRB properly constituted.

ALL projects, including those previously reviewed and approved by an IRB must be reviewed and approved by the SRC after experimentation and before competition in an affiliated fair with MOSTRATEC.

Projects which were conducted at a Regulated Research Institution (not home, high school or field) and which were reviewed and approved by the proper IRB before experimentation, must also be approved by MOSTRATEC Affiliated Fair SRC.

An Affiliated Fair SRC must include:

- a minimum of three persons;
- a biomedical scientist (earned doctoral or master degree);
- an educator;
- at least one additional member.

Note: An additional expertise may be required for many projects. If the SRC needs an expert as one of its members and one is not in the immediate area, all documented contact with an external expert must be submitted. If animal research is involved, at least one member must be familiar with proper animal care procedures. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied.

A Scientific Review Committee (SRC) examines projects for the following aspects:

- evidence of literature search and appropriate attribution;
- evidence of proper supervision;
- use of accepted and appropriate research techniques;
- completed forms, signatures and dates showing maximum of one year duration of research and appropriate pre-approval dates (where required);
- evidence of search for alternatives to animal use;
- humane treatment of animals, when applicable;
- compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents;
- documentation of substantial expansion for continuation of projects;
- compliance with MOSTRATEC ethics statement.

3.3 MOSTRATEC Scientific Review Committee - SRC

All projects are reviewed by the MOSTRATEC Scientific Review Committee, prior competition, analyzing: ABSTRACTS, research papers (they should be clearly and well written), and all documentation required to guarantee adherence to MOSTRATEC regulations.

The MOSTRATEC SRC is the final arbiter to qualify students to participate in the fair and may request additional information.

The MOSTRATEC SRC, like any other Affiliated Fair SRC, is a group of adults knowledgeable about research regulations.

In addition to the review of all projects participating in MOSTRATEC, the committee members answer questions students and teachers may have about the rules throughout the year. The MOSTRATEC SRC can be contacted by email[7].

IMPORTANT: All projects participating in MOSTRATEC must adhere to the rules and regulations established in this document. If non-compliance with the rules is evidenced the project may fail to qualify.

4 RESEARCH WITH HUMANS

Student researchers must adhere to The Resolução do Conselho Nacional de Saúde (CNS) 466/12 (Brazilian guidelines and regulatory research standards involving human participants), and the international rules for each category of investigation and each type of research, in addition, observing the principles that issued this Resolution. Student researchers must adhere to sectorial requirements and specific regulations to protect human participants and the student researcher during research development.

When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB) and informed consent from the research participant.

4.1 Terms and definitions (Resolution CNS 466/12)

a) Research - a formal and systematic process aiming at production, advancement of knowledge and/or at getting answers to problems using scientific methodology;

b) Research involving human participants - investigation which involves individually or collectively, directly or indirectly, totally or partially human participants including management information and materials;

c) Research Protocol - document including research description in its fundamental aspects, information related to the research subject, researchers qualification, and to all responsible parties. For MOSTRATEC, the Research Protocol is a set of documents: research paper, Human Participants Form (4), Risk Assessment Form (3), Qualified Scientist Form (2)

[7] crc.mostratec@liberato.com.br

when applicable, and any other documents which may be required by the Ethics Committee (SRC and/or IRB);

d) Responsible for the research: person in charge of coordinating the research and of preserving body integrity and welfare of the subjects involved. For MOSTRATEC, a research responsible may be the STUDENT RESEARCHERS or the MENTORS;

e) Research Institution: a regulated public or private organization in which scientific research is conducted;

f) Research Risk: possibility of physical, psychical, moral, intellectual, social, cultural or spiritual damage to the human participant in any research stages;

g) Damage associated with or resulting from research: immediate or delayed injury to the individual or collective and proved as being directly or indirectly caused by the research study;

h) Research Subject: a participant being researched individual or collectively, as a volunteer. Any type of reward is prohibited;

i) Informed Consent: consent of the research subject and /or his legal representative, free from defects (simulation, fraud or error), dependence, subordination or subpoena, after fully and detailed explanation about the nature of the research, its purposes, methods, anticipated benefits, potential risks, and nuisance that the consent may cause;

j) Ethics Research Committee: interdisciplinary and independent collegiate, “legal obligation”, of advisory character, deliberative and educational, created to defend the interests of the research subjects in their integrity and dignity, and to contribute for research development observing ethical standards. MOSTRATEC considers the IRBs and SRCs as ETHICS COMMITTEES;

k) Vulnerability: related the state of people or groups, which for any reason or motive, have their capacity of self-determination reduced, mainly referred to voluntary consent and clarification.

4.2 Studies exempt from consent

Studies exempt from consent are those which dispense pre-approval of an Institutional Review Committee and the human participant document. They are:

4.2.1 Risk exempt projects

MOSTRATEC and Affiliated Fairs consider projects based on examination of an investigation, of a program, of a concept, etc, examples of risk exempt projects, conducted by the student where the feedback received is a direct reference to the product, where there is no personal data collection, and the testing does not pose ANY RISK, that is, RESEARCH MUST BE DECLARED AS EXEMPT FROM RISK BY THE MENTOR AND STUDENT RESEARCHERS.

4.2.2 Data/record review studies

Studies (e.g., sports and crime statistics) in which data obtained are a set of pre-existing data, and are publicly available and/or published , and do not involve any interaction with humans or collection of any kind of human participant data for the purpose of the student's research project.

4.2.3 Behavioral observations of unrestricted public settings

Observations conducted in settings as shopping malls or public parks, in which the following items may be applied:

a) the researcher has no interaction with the individuals being observed;

b) the researcher does not manipulate the environment in any way;

c) the researcher does not record any personally identifiable data.

4.2.4 Data in an anonymous format

Projects in which the student receives data in a de-identified/anonymous format and complies with both of the following conditions:

- the professional providing the data certifies in writing that the data have been appropriately de-identified and are in compliance with the CNS 466/12, and with all federal and international privacy laws;

- the MENTOR MUST ensure that the data were appropriately de-identified by review of the written documentation.

4.3 Rules

4.3.1 Human participants in science projects

The use of humans is allowed under the conditions and rules based upon the Resolution CNS 466/12. These projects require pre-approval of an ETHICS COMMITTEE or of an IRB, and may also require the documentation of written informed consent. Examples of projects that are considered human participant research requiring IRB pre-approval include:

a) subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure);

b) psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)

c) studies in which the researcher is the subject of the research.

d) behavioral observations:

- where the student researcher interacts with the observed individual(s) or where the researcher modified the environment (e.g., posts a sign, places an object);

- that occur in non-public or restricted settings (e.g., day care center, doctor's office);

- that involve the recording of personally identifiable information;

e) data/record review projects involving identifiable/ not anonymous data (e.g., name, date of birth, phone number and/or other identifying variables).

4.3.2 Research data collection with human participants

The student researcher must complete ALL details related to the item Humans in the research paper instructions which are available at MOSTRATEC website[8], assess and minimize physical, psychological hazards and privacy of the individuals involved in the research (see items 4.3.4 and 4.3.5.1).

The study research must be in accordance with the Resolution CNS 466/12, and with the national and international laws related to privacy when applied to the project (e.g., project involves medical data).

All projects involving human participants including any revisions MUST BE REVIEWED AND APPROVED BY AN IRB, PRIOR THE STUDENT STARTS THE COLLECTION AND/OR INTERACTION WITH THE SUBJECT OF THE RESEARCH. The

[8] http://www.mostratec.com.br/en/current-edition/conduct-your-project/research-plan

IRB must assess risk and document it in Form (4). After initial approval, the student researcher who has any change proposal in the research paper must repeat the approval process and get re-approval prior experimentation and/or data collection.

Research conducted by a student at a federally Regulated Research Institution (e.g., university, medical center, government laboratory, correctional institution) must be reviewed and approved by that institution's Ethics Committee where the research was conducted. A copy of the IRB initial approval for the entire project (which must include research procedures/measures the student is using). An official letter from the mentor is not a sufficient documentation to prove IRB review and approval.

The human participants in the research should give voluntary consent/permission (in some cases a parental consent is required) before participating in the study. Minor participants (under 18) and/or individuals who are not able to give their own consent (e.g., individuals with mental developed disabilities) give their permission through parental/responsible consent. The IRB defines if the consent is verbal or written, depending on the level of risk which involves the research.

A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a medical professional. This medical professional must be named in the research protocol approved by the IRB. STUDENTS ARE PROHIBITED FROM ADMINISTERING MEDICATION AND/OR PERFORMING INVASIVE MEDICAL PROCEDURES. The IRB must also confirm that the student is not violating the medical practice act of the state or country in which he/she is conducting the research.

Student researchers must NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) WITHOUT THE WRITTEN CONSENT OF THE PARTICIPANTS.

Studies that involve the collection of data via use of the internet (e.g. email, web-based surveys) are allowed, but researchers should be aware that they can face challenges in collecting anonymous data, obtaining informed consent, and ensuring that participants are of the appropriate age to give informed consent. (See item 4.3.4 - RISK ASSESSMENT FOR HUMAN PARTICIPANTS)

After experimentation and before the competition at MOSTRATEC, the MOSTRATEC SRC reviews and approves previously approved projects to ensure that students followed the approved research paper and the rules established in this document.

4.3.3 Cases in which The IRB exempts researchers from written consent

The IRB exempts researchers from the written consent/assent and/or parental permission if the research involves only minimal risk, anonymous data collection, and if it is one of the following:

a) research involving normal educational practices or specific characteristics;

b) research on individual or group behavior or on characteristics of individuals where the researcher does not manipulate the participants´ behavior and the study does not involve more than minimal risk;

c) surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress;

d) studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

4.3.3.1 Especial cases

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is STRONGLY RECOMMENDED that documentation of written informed consent/assent/parental permission be obtained. If the project involves not more than minimal risk and those with more than minimal risk are allowed under the following guidelines (item 4.3.4).

4.3.4 Human participant risk assessment

“No more than minimal risk exists” when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.

“More than minimal risk” exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is

typically encountered in everyday life. These studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

4.3.4.1 Examples of greater than minimal physical risk

a) exercise other than ordinarily encountered in everyday life;
b) ingestion, tasting, smelling, or application of a substance;
c) exposure to any potentially hazardous material.

4.3.4.2 Examples of greater than minimal psychological risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include:

a) answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety;

b) answering questions that could result in feelings of depression, anxiety, or low self-esteem;

c) viewing violent or distressing video images.

4.3.5 Privacy concerns

The student researcher, the Mentor and the IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4.3.5.1 Risk groups

If the research study includes participants from any of the following groups, the IRB and student researcher must consider whether the nature of the study requires special protections or accommodation:

a) any member of a group that is naturally at-risk (e.g. pregnant women, develop mentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.);

b) special groups that are protected by federal regulations or guidelines (e.g. children/ minors, prisoners, pregnant women, students with disabilities).

4.4 Required forms

a) Research Paper;
b) Review Form- 1;
c) Regulated Research Institutional/Industrial Setting Form - 1C, when applicable;
d) Qualified Scientist Form - 2;
e) Risk Assessment Form -3;
f) Human Subject Form - 4.

5 VERTEBRATE ANIMALS

Animal use in educational/research activities is allowed only in:

- universities;
- secondary school institutions of professional/technical education in the area of biomedicine.

In addition, these Institutions that may conduct vertebrate animal research studies must have obtained a registration at CONCEA (Conselho Nacional de Controle de Experimentação Animal) or at an equivalent office in the country where the research is being conducted. When a research is conducted at an institution regulated by CONCEA, it will have its documentation signed by the respective IACUC (Institutional Animal Care and Use Committee).

A MOSTRATEC strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals can not be avoided, students must adhere to the Brazilian Federal Law Nbr 11.794/2008 or to an equivalent law for students from other countries.

All projects involving vertebrate animals must adhere to the International Laws and Rules, depending on the nature of the study and the research setting.

A project is considered a tissue study and not a vertebrate animal study if tissue is obtained from an animal that was euthanized for a purpose other than the student’s project.

(Documentation is required of the IACUC to prove the origin of the tissues to be studied). In tissue studies, a student may observe the vertebrate study, but may not manipulate or have any direct involvement in the vertebrate animal experimental procedures.

5.1 Rules for all vertebrate animal studies

The use of vertebrate animals in science projects is allowed under the Federal Law Nbr 11.794/2008. For the purposes of this Law the following definitions apply:

a) *Filo Chordata*: animals that have as unique features, at least in the embryonic stage, the presence of notochord, branchial slits in pharynx and dorsal nerve tube only;

b) *Subfilo Vertebrata:* chordates that have unique features like a large brain enclosed in the skull and spine.

5.1.1 Experiments

Experiments are procedures performed on live animals with the goal of elucidating physiological and pathological phenomena using specific and predetermined techniques.

5.1.2 Alternatives to the use of vertebrate animals

Alternatives to the use of vertebrate animals for research must be explored and discussed in the research paper. Alternatives include the following “Four R’s”:

a) replace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible and/or computer simulations where possible

b) reduce the number of animals without compromising statistical validity;

c) refine the experimental protocol to minimize pain or distress to the animals;

d) respect animals and their contribution to research.

5.1.3 Review of research work on vertebrates

All vertebrate animal studies must be reviewed and approved before experimentation begins and must be preapproved by an IACUC.

All vertebrate animal studies adhering to Law Nbr 11.794/2008 must have the following items on their research paper:

- justification for the use of animals , including the reason for the choice of species, source and number of animals. Describe any alternatives which were considered to substitute the use of the animal and why they were unacceptable. Describe the impact and major contribution that this research may have in the fields of medicine and biology;

- description of the way animals are used in the study. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, sex, age, weight, source and number of animals proposed for use.

5.1.4 Observation of animal behavior and exemption from a Qualified Scientist review

Studies involving behavioral observations of animals are exempt from Qualified Scientist review if:

- there is no interaction with the animals being observed;

- there is no manipulation of the animal environment in any way;

- the study applies to the Federal Law Nbr 11.794/2008 (or an equivalent) besides being in accordance with all the agricultural, fish farming, game and wildlife regulations.

5.1.5 Restriction of animal research

Research projects causing more than momentary or slight pain or distress are prohibited. If there is illness or unexpected weight loss, this must be investigated and a veterinarian must be consulted to oversee any indicated medical care. This investigation must be documented by the Qualified Scientist, Designated Supervisor or veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.

NO VERTEBRATE ANIMAL DEATHS IN ANY GROUP OR SUBGROUP ARE ALLOWED. If a study is approved by an IACUC, all animals must be monitored for signs of distress and significant weight loss. The maximum permissible weight loss or growth retardation (compared to controls) of any experiment or control animal is 15%.

5.1.6 Prohibition of vertebrate animal research

Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:

a) induced toxicity studies with known toxic substances that could impair health or end life, including, but not limited to, alcohol, acid rain, pesticides, or heavy metals;

b) behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness;

c) studies of pain;

d) hunting experiment of vertebrates;

e) predator-prey experiment.

5.1.7 Animal research oversight

A Qualified Scientist or Designated Supervisor must oversee directly any research involving vertebrate animals.

After the initial IRB approval, a student who may have any proposal of change in the Project research paper must repeat the approval process before resuming the laboratory experimentation and/or data collection.

5.2 Additional rules for projects conducted at home/ school/ field (non-regulated settings)

Some vertebrate animal studies may be conducted at a home, school, farm, ranch, in the field, etc. According to the Federal Law Nbr 11.794/2008, the following practices are not considered as experiments:

a) prophylaxis and veterinary treatment of the animal in need of them;

b) banding, tattooing, tagging or applying another method with the purpose of identifying the animal, since it causes only momentary pain or distress or slight damage;

c) experimental interventions not related to agricultural practices.

5.2.1 Review and approval of projects in non-regulated institutions

Projects conducted at non-regulated institutions must be reviewed and approved by an IRB in which one member is either a veterinarian and/or a biologist.

These projects must adhere to BOTH of the following guidelines:

a) the research involves only agricultural, behavioral, observational or supplemental nutritional studies on animals;

b) the research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

Studies meeting the general guidelines but not meeting the above criteria for research conducted at home, school or field must be conducted at a Regulated Research Institution (see item 5.3).

5.2.2 Treatment and care

Animals must be treated kindly and cared for properly. The animal must be housed in a clean and ventilated, comfortable environment appropriate for the species. They must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned frequently. Proper care must be provided at all times, including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and welfare by a Designated Supervisor to oversee the daily husbandry of the animals.

5.2.3 Requirement of a veterinarian's certification and the research paper

The IRB must verify if a veterinarian's certification is necessary, prior approval study, to assure that the research paper observes adequate animal husbandry. If applicable, this certification is required prior experimentation and must be documented on the Vertebrate Animal Form -5.

A veterinarian must certify experiments that involve supplement nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.

5.2.4 Occurrence of an illness or emergency

If an illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian. A student researcher must stop experimentation if there is unexpected weight loss or death in the experimental subjects. The experiment can

only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors. If death is the result of the experimental procedure, the study must be terminated, and will not qualify to participate in MOSTRATEC.

The final disposition of the animals must be described on Vertebrate Animal Form -5. Euthanasia for tissue removal and/or pathological analysis is not permitted.

5.3 Additional rules for projects conducted at a regulated research institution

All studies not meeting the criteria in item 5.2, but are allowed under MOSTRATEC rules must be conducted in a Regulated Research Institution, according to the Federal Law Nbr 11.794/2008, and owning a registration at CONCEA. For projects conducted outside Brazil, a Regulated Research Institution would be a comparable institution adhering country laws governing care and use of vertebrate animals.

5.3.1 Projects approved under IACUC

The IACUC or a comparable animal oversight committee must approve all student research projects prior experimentation. MOSTRATEC SRC must also oversee the research project to certify that the same is adhering to MOSTRATEC rules.

ANIMAL RESEARCH STUDIES INVOLVING EUTHANASIA ARE NOT ALLOWED.

Table 1: Studies involving vertebrate animals and pain levels.

PAIN LEVELS	DEFINITION	RULES
Level A	Live animals that are painlessly manipulated. Animals may undergo euthanasia performed only by trained professionals at Regulated Research Institutions in order to obtain tissues, cells, etc…	Allowed with restriction and under prior IRB approval.
Level B	Live animals undergoing momentary pain or distress stimulus, but not suffering euthanasia, resulting in short-term response. Examples include but not	Allowed.

	restricted to: injections, blood tests, standards of animal husbandry practices.	
Level C	Live animals suffering significant manipulation, surgery under anesthesia. Animals will be euthanized without recovering consciousness at the end of the procedure.	Allowed only at a Regulated Institution, kind treatment and with certifications.
Level D	Live animals manipulated while under the effect of anesthesia and may recover and/or animals developing signs of visible pain, distress, spontaneous or resulting physiological changes. Examples: survival to surgery procedure of any type and studies including tumor development. ALL STUDIES DESCRIBED ABOVE MUST INCLUDE A PAIN AND/OR DISTRESS RELIEF TREATMENT.	Restricted procedures of pain level D are allowed under proper certification. The project study must adhere to all regulations established by the Brazilian and International laws. BIG PART OF LEVEL D STUDIES ARE CONSIDERED INAPPROPRIATE FOR STUDIES OF HIGH SCHOOL STUDENTS (PRE-COLLEGE). IT IS HIGHLY RECOMMENDED CONSULTING THE SRC BEFORE STARTING EXPERIMENT.
Level E	Live animals experiencing significant or severe pain and/or distress (discomfort) without the benefit of anesthetics, tranquilizers or painkillers.	Prohibited.

Source: MOSTRATEC 2013 SRC.

5.4 Required forms

a) Research Paper;

b) Review Form -1;

c) Regulated Research Institutional/Industrial Setting Form - 1C;

d) Qualified Scientist Form -2, if applicable;

e) Vertebrate Animal Form - 5.

6 POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

Research using microorganisms (including bacteria, viruses, viroids, prions, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal tissues, blood, or body fluids may involve potentially hazardous biological agents. Students are permitted to do some research projects with potentially hazardous biological agents meeting the conditions and rules described below and regulated by federal and international biosafety guidelines.

6.1 Risk assessment

Information in this section must be used to complete Potentially Hazardous Biological Agents Research Form -6A.

Risk assessment defines the potential hazard, injury or sickness which plants, animals and humans may undergo when biological substances are used. The final result of a risk assessment is a biosafety level definition which will establish laboratory facilities, equipment, necessary training and supervision.

Risk assessment involves the definition of a group risk for biological substances, based on the following criteria:

a) studies involving known microorganisms must begin with an initial assignment of the microorganism considering biosafety level risk group based on information available through literature search;

b) the study of unknown microorganisms and the use of fresh tissues relies on the expertise of the supervising adult(s);

c) establishment of levels of biological containment available for the student researcher to conduct the experiment. (See item 6.1.2);

d) assessment of the experience and expertise of the adult(s) supervising the student;

e) assignment of a biosafety level for the study based on risk group of biological agent, level of biological containment available and the expertise of the Qualified Scientist or Designated Supervisor who will be supervising the project.

If the study is conducted in a Non-regulated Institution (example: school), the biosafety level must be defined by the local or by the affiliated SRC.

If the research is conducted at a Regulated Research Institution, the biosafety level must be assigned by an Institutional Biosafety Committee (IBC) or equivalent approval body. If no approval body exists at the Regulated Research Institution, a letter or document from the Regulated Research Institution that the research does not require review is required. The local or affiliated fair SRC must review the project and assign a biosafety level. THIS REVIEW MUST BE PRIOR EXPERIMENTATION.

6.1.1 Classification of Biological Agents Risk Groups

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes. For this purpose, the BSL must be observed:

a) BSL-1 risk group: contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 (BSL-1) containment. Examples of BSL-1 organisms are: *Agrobacterium radiobacter, Aspergillus niger, Bacillus thuringiensis, Escherichia Coli K12, Lactobacillus acidophilus, Micrococcus leuteus, Neurospora crassa, Pseudomonas fluorescens, Serratia marcescens.*

b) BSL-2 risk group: contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require BSL-2 containment. Examples of BSL-2 organisms are: *Mycobacterium, Streptococcus pneumonia, Salmonella choleraesuis.*

c) **BSL-3 AND BSL-4: ORGANISMS OR AGENTS WITH BSL-3 AND BSL-4 ARE PROHIBITED.**

6.1.2 Levels of Biological Containment

There are four levels of biological containment (Biosafety level 1-4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques described below:

a) BSL-1 containment: normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in a fume hood. Standard microbiological practices are used when working in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats are required and gloves recommended. The laboratory work must be supervised by an individual with general training in microbiology or a related science.

b) BSL-2 containment: designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats, gloves and face protection are required. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

c) ORGANISMS AND AGENTS OF BSL- 3 AND BSL-4 CONTAINMENT: PROHIBITED GROUPS!

6.2 Regulation

When using potentially hazardous biological agents, the student and all the adults involved in a research project are responsible for conducting and documenting the potential level of hazard, damage or distress that plants, animals and humans may undergo on Potentially Hazardous Biological Agents Research Form - 6A. (See item 6.1)

6.2.1 Projects involving microorganisms, DNA technologies, human and animal tissues

All projects involving microorganisms, recombinant DNA technologies and human or animal tissues, blood or body fluids must adhere to the rules below AND, depending on the study, to the additional rules in the previous items in this chapter.

6.2.2 Projects exempt from the IRB review

The following types of studies are exempt from prior IRB review and require no additional forms:

a) studies involving *Sacharomises Cereviseae* and brewer's yeast, except when used with rDNA studies;

b) studies involving Lactobacillus, Bacillus thugensis, nitrogen-fixing, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a Petri dish environment);

c) water or soil not concentrated in conductive means for growth of biological agents;

d) mold growth on food items if the experiment is terminated at the first evidence of mold;

e) mushrooms and *amoebozoa* (mold and slime).

6.2.3 Projects exempt from IRB review, but with Risk Assessment Form - 3

The following types of studies are exempt from prior IRB review, but require a Risk Assessment Form - 3:

a) studies involving *protists, archaea* and similar microorganisms;

b) research using manure for composting, fuel production, or other non-culturing experiments;

c) commercially-available color change coliform water test kits. These kits must remain sealed and must be properly disposed;

b) studies involving decomposition of vertebrate organisms (such as in forensic projects);

c) studies of microbial fuel cells.

6.2.4 Permission to use potentially hazardous biological agents

The use of potentially hazardous microorganisms ARE NOT RECOMMENDED. Research involving microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids, is allowable as follows:

a) the Institutional Review Board, the Institutional Biosafety Committee or The Institutional Animal Care and Use Committee must approve research study before the experiment starts. The initial risk assessment determined by the student researcher and adults that oversee the project must be confirmed by the MOSTRATEC Scientific Review Committee;

b) experimentation involving the culturing of potentially hazardous biological agents, even Biosafety Level 1 (BSL-1) organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the MOSTRATEC Research Rules or by the IRB of the institution where the research is being conducted;

c) research determined to be at Biosafety Level 1 (BSL-1) can be conducted in a basicBSL-1 laboratory or higher. The research must be supervised by a trained Designate Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.

6.2.5 Research determined to be a Biosafety Level 2 (BSL-2)

Research determined to be a Biosafety Level-2 (BSL-2) must be conducted in a laboratory rated BSL-2 where microorganisms of risk level 2 are manipulated. It is applicable to clinical or hospital laboratories of primary level diagnosis. The use of primary (biological safety cabinet and personal protective equipment) and secondary (laboratory design and organization) physical berries besides the adoption of good practices is necessary which usually demands the use of a Regulated Research Institution. The research study must be reviewed and approved by the Institutional Biosafety Committee (IBC) or submit a letter or a document of the Regulated Research Institution declaring that the review is unnecessary. The research must be reviewed by a Qualified Scientist.

6.2.6 Especial cases related to biosafety

RESEARCH STUDIES DETERMINED TO BE OF BIOSAFETY LEVEL-3 OR 4 (BSL-3 OR -4) ARE PROHIBITED.

Laboratory studies culturing known MRSA (Methicillin resistant Staphylococcus aureus), VRE (Vancomycin resistant enterococci) and KPC (Klebsiella pneumonia) must be conducted in a BSL-2 laboratory in a Regulated Research Institution with documented IBC

Committee review and approval. Students are prohibited to cultivate CRE (*Carbapenem-Resistant Enterobacteriaceae*).

Other relevant cases related to biosafety:

a) studies that genetically engineer bacteria with multiple antibiotic resistances are prohibited;

b) extreme caution must be exercised when selecting and sub-culturing antibiotic resistant organisms. Studies using such organisms require at least BSL-2 containment;

c) naturally-occurring plant pathogens may be studied at home, but may not be introduced into a home/garden environment;

d) the culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study;

e) all potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or BSL 2 organisms: autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable;

f) any proposed changes in the research paper by the student after initial approval by the local IRB or by the MOSTRATEC SRC must again be submitted for review and approval before changes are made and before experimentation resumes.

6.3 Additional rules for projects involving unknown microorganism

Studies involving unknown microorganisms ARE NOT RECOMMENDED. These researches present a challenge because the presence, concentration and pathogenicity of possible agents are unknown by science. In science fair projects, these studies typically involve the collection and culturing of microorganisms from the environment (e.g. soil, household surfaces, skin.)

6.3.1 Research involving Biosafety Level 1 (BSL-1)

Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:

a) organism is cultured in a plastic Petri dish (or other standard non-breakable container) and sealed;

b) experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies);

c) the sealed Petri dish is disposed of via autoclaving or disinfection under the supervision of the Designated Supervisor;

d) if a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.

6.4 Additional rules for projects involving recombinant dna (r-dna) technologies

Studies involving recombinant DNA technologies (r-DNA) in which microorganisms have been genetically modified require close review to assess the risk level assignment. Some r-DNA studies can be safely conducted in a BSL-1 high school laboratory with prior review by a knowledgeable IRB:

a) all r-DNA technology studies involving BSL-1 organisms and BSL-1 host vector systems must be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or Designated Supervisor and must be approved by the IRB prior to experimentation. Examples include cloning of DNA in E. coli K12, S. cerevesiae, and B. subtilis host-vector systems;

b) commercially available r-DNA kits using BSL-1 organisms may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation;

c) an r-DNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility;

d) all rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the Institutional Biosafety Committee (IBC) prior to experimentation;

e) propagation of recombinants containing DNA coding for oncogenes or other human, plant or animal toxins (including viruses) is PROHIBITED.

6.5 Additional rules for projects involving tissues and body fluids, including blood and blood products

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper RISK ASSESSMENT is required.

6.5.1 Tissues treated as potentially non-harmful

The following types of tissue do not require treatment as potentially hazardous biological agents:

a) plant tissues;

b) plant and non-primate established cell lines and tissue culture collections. The source and/or catalog number of the cultures must be identified in the research paper;

c) fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses;

d) hair;

e) teeth that have been sterilized to kill any blood-borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended;

f) fossilized tissue or archeological specimens;

g) prepared fixed tissue.

6.5.2 Collections considered as Biosafety Level-1 (BSL-1) and Biosafety level-2 (BSL-2)

Research involving human and/or non-human primate established cell lines and tissue culture collections must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/or catalog number of the cultures must be identified in the research paper.

If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.

6.5.2.1 Biosafety Level-1 (BSL-1) tissue studies

Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids (not including blood or blood products from a non-infectious source

with little likelihood of microorganisms present). Biosafety level 1 studies must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor. (See item 6.3.1)

6.5.2.2 Biosafety level-2 (BSL-2) tissue studies

Biosafety Level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or -2. These studies must be conducted in a Regulated Research Institution in a BSL-2 laboratory under the supervision of a Qualified Scientist. The following studies are considered BSL-2:

a) all studies involving human or animal blood, or its products, should be considered a Biosafety Level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. All blood must be handled in accordance with standards and guidelines set forth in the OSHA (Occupational Safety and Health Administration. Any tissue or instruments with the potential of containing blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation;

b) human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2.

6.5.3 Additional issues about biosafety

Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or -4 is prohibited.

Studies of human body fluids, where the sample can be identified with a specific person, must have a previous IRB review and approval, and Informed Consent. Student researchers using their own body fluids are exempt from this requirement.

Self-sampling of capillary blood for analysis (e.g. glucometer reading) may be conducted in a home setting.

Studies involving embryonic human stem cells must be conducted in a Regulated Research Institution and reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) or by the national animal care and use committee (CONEP).

6.6 Main recommended sources for additional technical information

The following sources are recommended for additional information:

a) National Health Surveillance Agency[9];

b) World Health Organization – Laboratory Safety Manual[10];

c) National Biosafety Technical Commission – commission that supports the Ministry of Science, Technology and Innovation related to Biosafety[11];

d) United States Occupational Safety and Health Administration (OSHA), Subsection that addresses the use and handling of blood for research[12];

e) National Health Council – National research Ethics Committee[13];

f) Ministry of Health - General Guidelines for Work with Biological Agents in Containment[14].

6.7 The following forms are requires:

a) Research Paper;

b) Review Form -1;

c) Regulated Research Institution/Industrial Form - 1C, when applicable;

d) Qualified Scientist Form - 2, when applicable;

e) Risk Assessment Form - 3;

f) Potentially Hazardous Biological Agents Research Form - 6A;

g) Human Beings and Vertebrate Animal Tissue Form - 6B - for all studies involving tissues and body fluids.

7 RULES FOR RESEARCH PROJECTS USING CONTROLLED SUBSTANCES

Controlled substances, prescription drugs, alcohol and tobacco must be acquired and used according to local, state and federal laws.

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[9] http://portal.anvisa.gov.br/wps/portal/anvisa/home

[10] http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

[11] http://www.ctnbio.gov.br

[12] https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

[13] http://conselho.saude.gov.br/web_comissoes/conep/index.html

[14] http://portal.saude.gov.br/portal/arquivos/pdf/dire_trabalho_agentes_biol_3ed.pdf

7.1 Regulations

Research studies using controlled substances must be approved by the Institutional Review Board (IRB) before starting experimentation and the student researchers must adhere to all federal laws governing controlled substances in particular:

a) alcohol production is controlled by federal laws and the student researchers must contact the Office in charge of alcohol, tobacco and firearms regulation;

b) only under the supervision of a Qualified Scientist or a Designated Supervisor a student researcher may use an experimental substance for therapy controlled by federal laws;

c) students under 21 are prohibited by state and federal laws to purchase and/or manipulate black or smokeless powder for science projects. For more information, students should check the appropriate agency of firearms and explosives;

d) any proposal for change in the research paper after the initial IRB approval, a subsequent approval must be obtained prior changes are made, and prior to the onset or continuation of experimentation.

7.2 The following forms are required

a) Research Paper;
b) Review Form -1;
c) Regulated Research Institutional/Industrial Setting Form - 1C, if applicable;
d) Qualified Scientist Form - 2, if applicable;
e) Risk Assessment Form - 3.

8 RULES FOR ALL PROJECTS INVOLVING HAZARDOUS CHEMICALS, ACTIVITIES AND DEVICES

Hazardous activities are those that involve a level of risk above and beyond that encountered in the student's everyday life. The following rules apply to research using hazardous chemicals, devices and/or activities. Prior the initiation of a research study using hazardous chemicals, devices and/or activities, students are required to consult the local IRB.

8.1 Regulations

The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Designated Supervisor, except those involving substances controlled by federal laws which require supervision by a Qualified Scientist.

The Qualified Scientist or the Designated Supervisor MUST assess risk of the research work prior the experimentation. Risk assessment must be documented on the Risk Assessment Form - 3.

8.1.1 Acquisition and use of controlled substances

Student researchers must acquire and use regulated substances in accordance with country laws. For additional information, contact the appropriate country regulatory agencies in your country.

For all chemicals, devices or activities requiring a Federal and/or State Permit, the student/supervisor must obtain the permit prior to the onset of experimentation. A copy of the permit must be attached to Risk Assessment Form - 3 and be submitted for MOSTRATEC SRC approval.

The student researcher must minimize the impact of an experiment on the environment. Examples include using minimal quantities of chemicals that require subsequent disposal, ensuring that all disposals are done in an environmentally safe manner.

8.2 Guidelines for risk assessment of hazardous chemicals, devices and radiation

The following criteria must be observed to assess risk of hazardous chemicals, devices and radiation.

8.2.1 Hazardous Chemicals

Risk assessment of hazardous chemicals must include factors, such as levels of toxicity, reactivity, corrosiveness, flammability.

Some principles of Environmentally Responsible Chemistry must be adopted. The purpose of these principles is to avoid the use or production of hazardous substances during a

chemical process. Whenever possible, these principles must be incorporated into the research paper:

a) waste prevention;

b) use of safer chemicals and products;

c) design of the least possible hazardous chemical syntheses;

d) use of renewable materials;

e) use of catalysts;

f) use of solvents and reaction conditions that are as safe as possible;

g) maximization of energy efficiency;

h) minimization of potentially risk accidents;

i) use of adequate disposal methods.

8.2.2 Hazardous devices

Risk assessment for projects using hazardous devices must consider all possible risks to the student researcher during their use and operation. Although many domestic devices (drills, saws, etc.) offer risks if not used correctly, Risk Assessment Form - 3 is required only when the student researcher operates potentially hazardous laboratory devices, or other devices requiring moderate knowledge for safe operation.

8.2.3 Radiation

A risk assessment must be conducted when a student uses non-ionizing radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (MW), radiofrequency (RF) and extremely low frequency (ELF). Lasers usually emit visible, ultraviolet or infrared radiation. Lasers are classified into four classes based upon their safety. Manufacturers must label Class lasers II, III and IV.

Projects involving radioisotopes and X-rays must involve a careful examination of the risks associated with the study, and safe and appropriate measures should be taken. Depending upon the level of exposure, radiation released from these sources can present health risk. Most regulated research institutions working with radiation have internal committees which oversee the compliance of federal and international regulations in the institution.

Risk assessment should consider exposure time, distance and protection involved in the study.

8.3 Required forms

a) Research Paper;
b) Review Form -1;
c) Regulated Research Institutional/Industrial Setting Form - 1C, if applicable;
d) Qualified Scientist Form - 2, if applicable;
e) Risk Assessment Form - 3.

9 DISPLAY AND SAFETY REGULATIONS

The SRC and the Health and Safety Committee control the projects being exhibited at MOSTRATEC to guarantee the adherence to the rules according to the guidelines based on the Regulamento Sanitário Internacional/2005 - ANVISA (RSI/2005- ANVISA) - International Health Regulation/2005 – ANVISA.

9.1 Requirements to present at MOSTRATEC

a) a video with a minimum resolution of 480p 30fps must be recorded;
b) the presentation must be in Portuguese, Spanish or English and last up to 5 (five) minutes;
c) the presentation must focus on the student(s) work for this year's study. The title of the project must mention if it is a continuation of study (e.g., "Obtaining Alcohol from Grass. Part II").
d) credits for all visual material used, such as photographs, graphics, drawings, animations, videos, etc., must appear with the materials or at the end of the video.
e) practical demonstrations of any nature must be carried out with the PPE relevant to the activity.
f) photographs or videos of people can only be presented with consent that must be quoted in the end credits of the video.

9.2 Project Data Book

The Project Data Book is a demanding document which is checked by the Scientific Review Committee (SRC) and by the judges and must be available at the booth. The following items are observed: consulted reference, data, addresses, summarized transcripts of books, magazines, visits, conversations held with researchers, mentor´s opinion, and other records confirming the authorship of the work and its use as a systematic data recording tool.

9.3 Research Paper

The layout of the Research Paper is available on the MOSTRATEC website.

9.4 Forms

All the necessary forms must be submitted and signed at the moment of the registration.

The CRC may request correction and/or resubmission of forms deemed necessary for the submitted project at any time.

9.5 Student researcher´s attitude and booth organization

The student researchers´ attitude at MOSTRATEC (language, clothes, knowledge of the research) must be suitable and may influence judging and scoring.

9.6 Allowed for display at the video and at the booth under conditions:

The SRC will analyze all the videos previously and booths during the fair. Creativity, knowledge arousing curiosity of the public is of the student researchers' responsibility. However, a project may not disturb by noise neither by occupying part of the surrounding booths' room.

Acceptable items under conditions:

a) student researchers' email addresses, telephone numbers and/or fax numbers ONLY;

b) awards, medals, business card, flags, advertising and/or acknowledgements are subject to analysis.

c) photographs or visual presentations are allowed if:

- they are not deemed offensive or inappropriate by the SRC;

- they have a credit line of origin (credits) (e.g., "Photograph taken by ...", "Picture taken from ...", etc). If all photographs being displayed are of the student researcher's credit, a credit line is sufficient;

- they are from magazines, newspapers, Internet or from other sources and there are credit lines of origin. If all photographs/images are from the same source, a credit line is sufficient;

- they are the student researcher's photographs/visual depictions;

- It is a photograph or visual depiction of people whose consents must be described in the end credits of the video.

9.7 Not allowed at the video, banner or booth

The following items cannot be displayed at the video, banner or booth:

a) taxidermy specimens or parts;

b) preserved vertebrate or invertebrate animals:

c) human/animal parts or body fluids (for example, blood, urine);

d) all hazardous substances or devices [for example, poisons, drugs, firearms, weapons, ammunition or chemicals;

e) dry ice or other sublimating solids (solids turn into gas without passing through the liquid state);

f) sharp items (for example, syringes, needles, pipettes, knives);

g) flames or highly flammable materials;

h) batteries with open-top cells;

i) photographs or any other kind of visual depiction in which vertebrate animals are shown being subjected to surgical techniques, dissections, autopsies, or other laboratory techniques;

j) glass or objects made of glass, unless deemed by the SRC to be an integral and necessary part of the project (for example, glass that is an integral part of a commercial product such as a computer screen);

k) any apparatus deemed unsafe by the SRC, the Display/Health and Safety Committee and by the Translation Committee (for example, large vacuum tubes or dangerous ray-generating devices, empty tanks that previously contained combustible liquids or gases, pressurized tanks, etc.)

10 GLOSSARY

BSL-1 – BIOSAFETY LEVEL -1

BSL-2 – BIOSAFETY LEVEL -2

BSL-3 – BIOSAFETY LEVEL -3

BSL-4 – BIOSAFETY LEVEL -4

CONCEA – CONSELHO NACIONAL DE CONTROLE DE EXPERIMENTAÇÃO ANIMAL

CONEP – COMISSÃO NACIONAL DE ÉTICA EM PESQUISA

DS – DISIGNATED SUPERVISOR

IACUC- INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

IBC – INSTITUTIONAL BIOSAFETY COMMITTEE

IRB – INSTITUTIONAL REVIEW BOARD

SRC – SCIENTIFIC REVIEW COMMITTEE