FEI Veterinary Science and Sport Welfare Research Project Application

# INTRODUCTION

Formed in 1921, the Fédération Equestre Internationale (FEI) is the governing body for all international events in Jumping, Dressage and Para-Equestrian Dressage, Eventing, Driving and Para-Equestrian Driving, Endurance, Vaulting and Reining. It establishes the regulations and approves equestrian programmes for Championships, Continental and Regional Games as well as the Olympic & Paralympic Games. The FEI promotes equestrianism in all its forms and encourages the development of the FEI equestrian disciplines throughout the world, keeping the welfare of the horse at the heart of all activities. Today, the FEI has 133 member National Federations and there are over 3,700 international events annually, including a number of FEI Championships and global FEI series. Over 90,000 riders and horses are registered and women and men compete as equals.

The FEI Veterinary Committee is the committee that advises the FEI on policy questions relating to veterinary matters. It is responsible for the FEI Veterinary Regulations and for supporting their implementation, as well as for providing advice and support for any Horse welfare related matters.

The Veterinary Committee, in conjunction with the relevant Sport Disciplines, is responsible for ensuring that all research with equine athletes at FEI sanctioned/recognized competitions, events and programs is conducted in accordance with certain ethical principles, namely:

* whether legally informed consent is obtained from the Persons Responsible;
* whether the benefits of the research outweigh the risks to the participants;
* whether the research activity is conducted in a responsible manner with sufficient details to assess eventual risk as identified by the researcher. As sport participation never is ‘free of risk’, the researcher will have the responsibility to explain in the detailed instructions to subjects and in the informed consent that the set procedures when applied correctly will ensure minimal to no potential for injury;
* whether the research interferes with the logistical operations of FEI sanctioned events;
* whether the application or information obtained interferes with fair sport, or affects the function or format of competition.

All individuals or groups wishing to conduct research must complete in full the following form in duplicate, including two copies of all materials (the original form and one photocopy of the form, plus two copies of the consent form or cover letter, questionnaire, etc.) and return to the FEI Veterinary Committee **no later than 6 months in advance of the project date (\*)**.

*(\*): Late applications may not necessarily be processed in time and projects may not be conducted in absence of FEI Veterinary Committee approval.*

Incomplete forms and/or insufficient information will delay consideration of any proposed project. Electronic submissions are acceptable and encouraged, but must include electronic signatures where required. Studies cannot be approved if data are collected prior to receiving approval. Approx. 6 months of review may be necessary by the FEI Veterinary Committee.

For successful applicants, accreditation to the competition will be limited only to relevant venues and for the duration of the research. The FEI may not be in a position to guarantee the applicant access to FEI events. Such access may be subject to the Organising Committee’s permission or consent. Upon approval by the FEI Veterinary Committee, successful applicants are invited to liaise with the Organising Committee for accreditation matters.

Successful applicants, while at FEI events, are not and should not state that they are representatives of the FEI or have any authority in relation to FEI matters.

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E caterina.termine@fei.org

# SECTION 1 – GENERAL INFORMATION

## Project Title

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* 1. **Project Timeline**

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| Project dates\* | Begins |      /     /      | Ends |      /     /      |
| Event dates | Begins |      /     /      | Ends |      /     /      |
| Sumbisson of Final Report\*\* |      /     /      |

\* Project dates should include only the period of time involving data collection

\*\* Deadline of submission of the final report is one (1) year after the completion of the last event

* 1. **FEI Sanctioned Events or Programs**

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| Place/Country | Date | Event |

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* 1. **Funding Sources**

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# SECTION 2 – INVESTIGATORS

## Contact Details and Declaration

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| Role | [ ]  Principal Investigator | [ ]  Co-Investigator |
| Title | [ ]  Prof. [ ]  Dr [ ]  Mr [ ]  Mrs | [ ]  Prof. [ ]  Dr [ ]  Mr [ ]  Mrs |
| Name |       |       |
| Rank | [ ]  Undergraduate[ ]  Masters[ ]  Doctoral[ ]  Other, please specify      \_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Undergraduate[ ]  Masters[ ]  Doctoral[ ]  Other, please specify \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Professional affiliation |       |       |
| Mailing address |       |       |
| City, Country |       |       |
| Email |       |       |
| Daytime phone No. |       |       |
| Signature\* |       |       |

\* With your signature, you agree to comply with all applicable rules and regulations regarding the use of human and animal subjects, and that the research you perform with the human and animal subjects will be in accordance with the methods and procedures approved herein. You also agree to submit significant changes in procedures and/or instruments to the FEI Veterinary Committee for prior approval, and to inform the FEI Veterinary Committee of any unanticipated risks to research participants which may occur.

Please submit information on all investigators. Photocopy this page, if necessary.

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| --- | --- | --- |
| Role | [ ]  Principal Investigator | [ ]  Co-Investigator |
| Title | [ ]  Prof. [ ]  Dr [ ]  Mr [ ]  Mrs | [ ]  Prof. [ ]  Dr [ ]  Mr [ ]  Mrs |
| Name |       |       |
| Rank | [ ]  Undergraduate[ ]  Masters[ ]  Doctoral[ ]  Other, please specify      \_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Undergraduate[ ]  Masters[ ]  Doctoral[ ]  Other, please specify      \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Professional affiliation |       |       |
| Mailing address |       |       |
| City, Country |       |       |
| Email |       |       |
| Daytime phone No. |       |       |
| Signature\* |       |       |

\* With your signature, you agree to comply with all applicable rules and regulations regarding the use of human and animal subjects, and that the research you perform with the human and animal subjects will be in accordance with the methods and procedures approved herein. You also agree to submit significant changes in procedures and/or instruments to the FEI Veterinary Committee for prior approval, and to inform the FEI Veterinary Committee of any unanticipated risks to research participants which may occur.

## Other Cooperating Institutions

Specify other cooperating institutions (such as universities, medical centres, etc.) which are involved in your study.

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# SECTION 3 – DESCRIPTION OF RESEARCH

Please read Section 4 carefully for explanations and notes before completing the following questions.

## Previous Research

Have you previously submitted research on this topic to the FEI Veterinary Committee? If so, provide name of the principal investigator, title and date(s) below.

 Yes  No

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## Abstract

State rationale and research question or hypothesis (why the study is important and what you expect to learn).

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## Design

Identify your research design, data collection strategies and specific factors (such as independent variables), conditions or groups in your study and any control conditions. Include the setting in which the interaction occurs and your relationship to this setting. Indicate the number of research participants and animal subjects assigned to each condition or group.

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## Research Participants – Human Athletes

1. Sample

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| Discipline(s) | Number | Age Group | Gender |

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1. Method of selection/recruitment of research participants. Include recruitment instruments with the application. Specify each source of participants and researcher(s’) working relationship (if any) with sources of participants.

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1. Describe any incentives, follow-ups or compensation to be used with individual participants.

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## Research Subjects – Equine Athletes

1. Sample

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| Disciplines | Number | Age | Sex | Breed |
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1. Method of selection of research subjects. Include selection instruments with the application. Specify each source of subjects and researcher(s’) working relationship (if any) with sources of subjects.

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1. Rationale for use of animals in research. Have alternatives to animals been considered (ex. mathematical models, etc.)? Specify why the use of sport horses is compulsory for the quality of the study.

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## Procedures and Materials

1. State in chronological order what the researcher will be doing during the data collection, what research participants/animal subjects are expected to do, and what the researcher will be doing during the interaction.

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1. List below all questionnaires and/or tasks given to research participants and attach a labelled copy of all written instruments to each copy of the application. Do not write “see attachments.”

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1. Describe data analysis and identify any dependent variables or basic concepts to be explored. Detail how they will be measured and/or how data will be collected.

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1. Describe the type of facilities needed, including space, electricity, waste disposal, equipment and the need for insurance on equipment.

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## Risks

1. CURRENT RISKS: Describe any welfare, social, legal, economic or physical discomfort, stress or harm (above and beyond those risks inherent in sports participation) that might occur to research participants and equine subjects. How will these be held to the absolute minimum? What remediation is offered? (If no risks are foreseen, state “No risks are foreseen”)

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1. FUTURE RISKS: How will the data be stored? How are all research participants protected from potentially harmful future use of the data collected in this project? Specify whether participation will be anonymous or confidential (it cannot be both) and specify measures planned to ensure anonymity or confidentiality. If audio or videotapes are used, state specifically who will see them and the date (month and year) they will be erased. (Remember to include this information on the consent form as well)

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1. Before the FEI Veterinary Committee can grant permission for the research project, your institution and all performance sites involved in animal work must have an Animal Welfare Assurance on file with relevant national animal welfare institutions and provide certification of approval.

Describe relevant certification of approval, and attach certification documents.

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## Benefits

The FEI policy requires that any risk associated with research participation is outweighed by potential benefits to research participants and to humankind in general.

1. Identify any beneficial effects that the research may have on participants.

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1. Identify any benefits that humankind in general may gain from this research.

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## Consent Form

How will legally effective informed consent be obtained from all research participants (and/or their legal guardian(s))? For horse subjects, as per the FEI General Regulations (GRs Article 118), the Person Responsible (PR) is strictly liable and responsible for their Horse(s) at all times. Legally effective informed consent must be obtained from Persons Responsible for all horse subjects.

Attach copies of form(s) to be used (see Appendix 1 for sample consent form). If deception is necessary, justify and describe, and submit debriefing procedures, which will explain how and why the research participants were deceived.

All proposed research projects must first be approved by the principal investigator’s home institution. Attach a copy of the approval. **In the event the host institution does not have an animal subject’s protection review committee, the principal investigator must alert the FEI Veterinary Committee prior to submission of the research application**.

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APPROVAL INSTITUTION:

APPROVAL NUMBER:

## Minors and Other Vulnerable Participants

If minors or other vulnerable participants are involved, outline procedures to obtain their agreement (assent) to participate, in addition to the consent of parent(s) or guardian(s).

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## Illegal Activities

Do the data to be collected relate to illegal activities? If so, please explain. [ ]  Yes [ ]  No

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# SECTION 4 – EXPLANATIONS & NOTES

GENERAL GUIDELINES FOR SUCCESSFUL APPLICATIONS

* + - CAREFULLY read all the instructions.
		- Fully and accurately complete each section of the application form. If the FEI Veterinary Committee is required to contact you for additional information or wait for additional information to support your application, approval of your study will be delayed. Ensure the telephone number or email address you provide on the form is one where you can be reached during the day or a message can be left for you.
		- Carefully write your consent form(s) or cover letter(s). Tell the research participants as much as possible on their level of understanding (avoid technical jargon), and without compromising your study. If you cannot give them all the details, let them know you are withholding certain information, that they are not at risk and that you will provide a full explanation at the end of the study.
		- The FEI Veterinary Committee will attempt to consider all applications as quickly as possible.
		- If you do not receive some communication from the FEI Veterinary Committee within a reasonable period of time, please contact the FEI Veterinary Department at Headquarters to seek guidance on the status of your application.
		- Submit the application at least 6 months in advance of the project date to: Dr. Caterina Termine MRCVS

Veterinary Advisor

FEI Veterinary Department Fédération Equestre Internationale HM King Hussein I Building Chemin de la Joliette 8

1006 Lausanne Switzerland

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T +41 21 310 47 60

E caterina.termine@fei.org

## 1.4 Funding Sources

The FEI Veterinary Committee will not fund any research project. Funding must be secured by the PI and/or his/her institution. All funding sources must be disclosed to the FEI Veterinary Committee prior to approval of any research project. The FEI Veterinary Committee can, upon request of the PI, assist the PI with a letter of support indicating approval of the project based on its scientific merit.

## Contact Details and Declaration

Provide a telephone number or email address where you can be reached or a message left for you during the day. Ensure all investigators have signed the application. Incomplete applications will not be considered and will be returned to applicant.

## Other Cooperating Institutions

Evidence of other cooperating institutions’ approval (such as a letter from these institutions’ internal review board or similar approving entity) should be submitted in written form for review.

## - 3.6 Description of Research

The FEI Veterinary Committee does not require all the details you might present in a professional journal, but you should detail sufficient information to judge whether your study meets the methodologically accepted standards for protection of animal and/or human research subjects and non-interference with the logistics of FEI Competitions/Events. Most items are self-explanatory. Should you require additional information do not hesitate to contact the FEI for clarification.

It is your responsibility to report immediately to the FEI Veterinary Committee any significant changes, unanticipated problems in your project, or the need for extension of approval for the collection of data. Changes and/or problems may influence the final decision of the FEI Veterinary Committee.

For example: the addition of other treatment conditions or groups; using instruments different from those submitted; adding participants unable to give informed consent (such as children under the age 18 or the intellectually or cognitively disabled), and introducing procedures that may affect animal subjects or participants physiologically. Consult the FEI Veterinary Advisor if you have questions or if you are not sure you have a significant change.

## Use of animals in research

When planning your research, consider whether you can achieve your scientific objectives while reducing the number of animals, refining the use of animals by minimizing their pain or distress, using a lower order species, or designing your experiments to avoid using animals at all:

* + - Limit animal involvement by using the minimum number required to obtain valid results.
		- Use non-animal methods, such as mathematical models, computer simulation or *in vitro* biological systems.
		- Avoid or minimize animal discomfort, distress and pain as is consistent with sound scientific practices.
		- Use appropriate sedation, analgesia or anesthesia when your procedures will cause more than momentary pain or distress. Do not perform surgical or other painful procedures on non-anesthetized animals.
		- If animals are necessary, consider selecting the lowest phylogenetic species appropriate for the experiment.

## Risks

You must detail the potential risks a research participant or equine subject may encounter as a result of data collection and any that may arise in the future. In both cases, carefully describe any such risks and how you plan to minimize and/or remediate them. The latter must include the availability and limits of treatment for sustained physical (or emotional) injuries. Benefit must outweigh risk in any research project.

Where possible, Human/Equine Athlete/Person Responsible names as well as personally identifying data (FEI ID number, etc.) should be “anonymous” (i.e. no one, investigator included, can identify the results). Otherwise, you must state in the consent form that their personally identifying data will remain confidential unless disclosure is required by law (see 3.10). “Confidential” means the investigator(s) may be able to identify a participant’s results, but will not reveal the participant’s identity to anyone else. Describe your plans to maintain confidentiality and state that will have access to the data and in what role. Justify retention of identifying information on any data or forms.

Any incident directly related to research participation causing significant discomfort, stress or harm should be reported to the FEI Veterinary Committee immediately.

## Benefits

State the benefits the participants will gain from participation in the study and the benefits that humankind may receive. Participants may receive money or some material reward (not to exceed minimum wage in country of event, plus expenses). However, it is hoped that participants will derive educational benefits. You must also indicate how your project will benefit humankind (e.g. advance the knowledge of some phenomenon or assist in solving a practical problem). It is important that the FEI Veterinary Committee understands the benefits of your study to judge whether they exceed the risk to the participant. You MUST list possible benefits in order for your study to be approved.

## Informed Consent

All proposed research projects must first be approved by the principal investigator’s home institution. Attach a copy of the approval. In the event the host institution does not have an animal subject’s protection review committee, the principal investigator must alert the FEI Veterinary Department prior to submission of the research application.

The informed consent means the knowing consent of an individual (or parent(s) or guardians(s)) able to exercise free choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. The FEI Veterinary Department further requires that each the Persons Responsible of animal subjects, as well as the human participants (or parent(s) or guardian(s)) express their informed consent by signing two copies of a consent form approved by the FEI Veterinary Committee. Never use a photocopy of a participant’s signature. The investigator must also sign both copies and give one copy to each participant. Participants’ consent forms must be retained for a period of at least three years after completion of the research.

If deception is used in your study, describe how participants will be deceived, why it is necessary and how you will debrief the participants. Provide the FEI Veterinary Department with an original and one copy of a written debriefing. Also include in the consent form a statement such as “In order to make this study a valid one, some information about my participation will be withheld until completion of the study.”

The Format Guide for Consent Form (see Appendix 1) contains the minimum elements which the FEI Veterinary Department requires for use of human participants in research. Its format is recommended, with information relative to your study to be supplied as indicated in parentheses. Different consent forms may be used. If mailing a questionnaire/survey to participants, a cover letter may be required rather than a consent form. The consent form or the cover letter should include at least the information indicated. It may be necessary in some cases to use separate consent forms for various aspects of a study, such as different participant groups or individual phases of a multi- phase study.

If written consent will not be obtained, a full explanation of the reasons must be submitted for approval, including assurance that risk to the participant will be minimal.

## Minors and Other Vulnerable Participants

When the research includes minors (Under age 18 years) or other individuals unable to give informed consent, informed consent must be obtained from parent(s) or guardian(s).

An understandable explanation of your procedures should also be presented to minors and other participants unable to give informed consent and they should be given an opportunity to volunteer their participation. This is called “assent.” Without assent, there will be no participation in the study.

## Illegal Activities

Participants must be assured their data will remain confidential, but you must also inform research participants that you may not be able to guarantee confidentiality if disclosure should be required by law, no matter how mundane the data may be.

This is especially true if data relates to illegal activities (some activities must be reported, e.g. animal abuse). When anonymous questionnaires are used but written informed consent is necessary, consent forms may be signed and returned separately. This procedure avoids any possibility of linking names to the data.

APPROVAL OF RESEARCH

Successful candidates will be asked to sign a “Non-Disclosure Agreement” as well as a “Liability Waiver and Indemnity” form prior to receiving approval by the FEI Veterinary Committee.

Once a research application is approved, the principal investigator will receive a formal letter from the FEI Veterinary Committee. A copy of the letter will go to the event organiser and the responsible person from the Sport. The letter will include a request for consideration of initial accreditation to the event. The FEI may not be in a position to guarantee the applicant access to FEI events. Such access may be subject to the Organising Committee’s permission or consent. Successful applicants are hence invited to liaise with the Organising Committee for accreditation matters following the approval by the FEI Veterinary Committee.

REPORTS

The principal investigator is expected to submit a report of its findings to the FEI Veterinary Committee within one year after the completion of the event at which the study took place.

The principal investigator is expected to comply with the “Non-Disclosure Agreement” document at all times, namely in the publication of the research project.

Should the research project be submitted to an international peer reviewed journal, a copy of manuscripts submitted to scientific journals must be forwarded to the FEI Veterinary Committee in advance for approval, prior to the time of submission to the peer reviewed journal. Unless an agreement has been made by the principal investigator and the FEI Veterinary Committee for a delay, the principal investigator should submit a manuscript within 18 months after the completion of the event at which the study took place or sanctions maybe imposed on the principal investigator and co-investigators).

The FEI Veterinary Committee must be acknowledged in all written and oral reports as follows: “This study was approved and supported by the FEI Veterinary Committee”.

In the event the report is not received by the FEI Veterinary Committee within one year, the principal investigator and co-investigator(s) will be suspended from conducting research at FEI sanctioned competitions for two years. If the research was conducted at FEI Games, the suspension shall continue until at least the end of the next World Championship even if that is more than two years. If the research was conducted at a World Championship, the suspension shall continue until the end of the next World Championships of the same sport even if that is more than two years.

APPENDIX 1 - FORMAT GUIDE FOR CONSENT FORM

I agree (OR, I give my consent for) to participate in the research titled [Title of the Research], which is being conducted by [investigator’s name, institution name and telephone number where investigator can be contacted]. I understand that this participation is entirely voluntary; I can withdraw my consent (OR, I or my child can withdraw consent) at any time without penalty and have the results of the participation, to the extent that it can be identified as mine (OR, my child’s or horse’s), returned to me, removed from the research records, or destroyed.

The following points have been explained to me (and my child):

1. The reason for the research is [give a short justification].
2. The benefits I may expect from it are [list specific benefits to the participant, if any]
3. The procedures are as follows:

[Describe what will happen to the participant, including the time, place and duration. If administering questionnaires, give a brief descriptive phrase about each. In clinical studies involving experimental treatments, identify the parts which are new or experimental, and indicate how they differ from other procedures which could be followed. If deception is necessary, state: “In order to make this study a valid one, some information about my (or my child’s/my horse’s) participation will be withheld until after the study.”

Start typing here]

1. The discomforts or stresses that may be faced during this research are [...].

OR, if none are foreseen, the entire comment for #4 should read: 4. No discomforts or stresses are foreseen.

1. Participation entails the following risks: [If risks exist, list all potential welfare, physical, psychological, social or legal risks. Also list the steps to be taken if harm should come to the participant or its equine athlete, including any availability of medical/veterinary treatment or referrals if needed. Start typing here]

OR, if no risks are foreseen, the entire comment for #5 should read: 5. No risks are foreseen.

1. The results of this participation will be anonymous.

OR, The results of this participation will be confidential and will not be released in any individually identifiable form without my prior consent, unless otherwise required by law.

[Any special procedures regarding anonymity or confidentiality should be described here. NOTE: If the identity of the participant (human or equine athlete) can be traced through the data by you or anyone else, participation is NOT anonymous. Participation CANNOT be both anonymous and confidential. Any taping to be done should be addressed here: and, give a date (month and year) for erasing the tapes. If tapes are to be kept indefinitely, so state, with purpose for retention. Start typing here]

6. The investigator will answer any further questions about research, now or during the course of the project.

I hereby release the Fédération Equestre Internationale (FEI), its employees, officers, trustees, directors, employees, committee members and agents and their assigns from any liability for any injury or loss I might incur in connection with participation in these activities and waive and release forever any and all rights for claims and damages I may have against the FEI, its trustees, officers, employees, committee members and agents and their assigns in any manner due to any personal injury or property loss sustained by me as a result of my participation in these activities.

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| Date:  | Signature of Investigator |
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| Date: | Signature of Human Athlete |
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| Date | Signature of Person Responsible |
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| Date | Signature of Parent/Guardian |
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PLEASE SIGN BOTH COPIES OF THIS FORM. KEEP ONE AND RETURN THE OTHER TO THE INVESTIGATOR.

*Research for FEI Sanctioned Competitions/Events, which involves animal participants, is overseen by the FEI Veterinary Committee. Questions or problems regarding your rights as a Person Responsible should be addressed to the FEI Veterinary Committee.*

*NOTE: The above oversight paragraph in the box at the bottom of the format guide must be included verbatim at the bottom of each consent form or cover letter. Do not put the oversight paragraph in the body of the consent form or cover letter.*