International Paralympic Committee

IPC RESEARCH APPLICATION

Policies and Procedures to Apply for Authorization of Research Projects at IPC Events

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International Paralympic Committee

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1 Introduction

The International Paralympic Committee (IPC) is the international representative organization of sports for athletes with an impairment. The IPC organizes, supervises and coordinates the Paralympic Games and other multi-sports competitions.

The IPC Sports Science Committee (IPC SSC) is responsible for establishing policies and guidelines in order to enhance scientific knowledge and to promote sports science education and research in the Paralympic Movement. To this end, the IPC SSC requires prior review and approval for all research and programs conducted at or associated with the Paralympic Games, IPC Sports, IPC Sanctioned/Recognized multi-sport events, and/or any other activities or events of the Paralympic Movement that take place under IPC jurisdiction (the "IPC Events").

The IPC SSC, in collaboration with the associated Sport, is responsible for ensuring that all research with human participants at IPC Events is conducted in accordance with certain ethical principles, namely:

(1) legally and ethically informed consent (as approved by the researcher's home institution) is obtained from research participants (including parental/legal guardian consent and subject assent if the participant is a minor);
(2) the benefits of the research outweigh the risks to the participants;
(3) the research activity must be conducted in a responsible manner with sufficient detail 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 or interference with sport competition); and
(4) the research does not interfere with the logistical operations of IPC Events.

No research projects may be conducted in absence of the IPC SSC approval.

2 Procedure

The Application Forms are available from the IPC Website (www.paralympic.org – section ‚The IPC' – ‚What we do' – ‚Research').

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.

All investigators must sign the Initial and Detailed Research Application, not just the Principal Investigator. In the event of a multi-centred team, an accompanying letter on institutional letterhead signed by the co-investigator(s) can accompany the application.

An IPC Research Application is a 2-step process:

2.1 Initial Research Application

In the Initial Research Application the Principal Investigator declares his intention to conduct research at the Paralympic Games or at an IPC Sport event, or in conjuction with an IPC (multi-sport) event. The Application identifies the purpose of the research project and a brief outline of the design, methodology and practical operations.

Upon approval of this Initial Application, the Principal Investigator will be asked to submit a full proposal ("Detailed Research Application“).

2.2 Detailed Research Application

The Detailed Research Application expands on the description of the research. At this stage, the Application must be complemented with copies of all material related to the study (athlete consent form, copies of questionnaires and/or formulars) and a copy of the researcher’s home institution Ethical Committee approval.

3 Informed Consent

All proposed research projects must first be approved by the principal investigator’s home institution. A copy of the approval must accompany the proposal. In the event the host institution does not have a human subject’s protection review committee, the principal investigator must alert the IPC SSC 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 IPC SSC requires that each human participant (or parent(s) or guardian(s)) express their informed consent by signing two copies of a consent form approved by the IPC SSC. 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 and be available for IPC SSC review.

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 IPC SSC 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 contains the minimum elements which the IPC SSC 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.

4 Timelines

Initial Research Applications must be submitted to the IPC SSC no later than:

- one year prior to the Paralympic Games;
- 6 months prior to any other IPC competition or event.

Upon receipt of the Initial Research Application the IPC SSC will initiate the review process. Successful Applications will in principle be announced by the IPC within 6 months (Paralympic Games) or 3 months (other IPC Events).

After the proposal is approved, it is the responsibility of those conducting research to report immediately to the IPC SSC any significant changes, unanticipated problems with the project, or the need for extension of approval for the collection of data. Changes and/or problems may influence the judgment of the IPC SSC.

Late applications may not be processed in time, and projects may not be conducted in absence of IPC SSC approval.

5 Approval

Once a Research Application is approved, the Principal Investigator will receive a formal letter from the IPC SSC and an Agreement to be signed. The approval is only effective upon receipt by the IPC of the signed Agreement.

A copy of the letter and Agreement will go to the event organizer and the responsible person from the Sport.

The letter will include a request for consideration of initial accreditation to the event.

6 Unauthorized Data Collection

In case of unauthorized data collection, the Principal Investigator and co-Investigators will be suspended from conducting research at IPC events for two years from the initial identification of the infraction. The IPC SSC has the right to inform Publishers and Journal Editors of any publications resulting from unauthorized data collection.

A second infraction of this policy will ban the Principal Investigator and co-Investigators from conducting research at IPC Events for life.

Ignorance of this IPC policy toward conducting research at IPC Events will not be an excuse for violating this policy.

7 Special Provisions for Paralympic Games Research

Research at the Paralympic Games will only be authorized under the following conditions:

- The Principal Investigator has a proven record of data collection in the sport or at major events;
- The Principal Investigator has the support of the Sport(s) to which the project applies (support letters must be provided);
- The Project cannot successfully be accomplished at another Event other than the Paralympic Games;
- The Project does not interfere with the complex organizational and logistical requirements associated with hosting the Paralympic Games.

8 Reporting

The Principal Investigator is expected to submit a report of its findings to the IPC SSC within six months after the completion of the event at which the study took place, unless otherwise agreed to by the IPC SSC and the Principal Investigator.

It is expected that the research project be submitted to an international peer reviewed journal. The Principal Investigator must provide a copy of the submission acceptance or letter from the Editor-in-Chief of the journal to the IPC. The IPC must be acknowledged in all written and oral reports as follows:

"This study was approved and supported by the International Paralympic Committee"

In the event the report is not received by the IPC SSC within six months, the Principal Investigator and Co-Investigator(s) will be suspended from conducting research at IPC sanctioned competitions for two years. If the research was conducted at a Paralympic 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.

9 Project Funding

The IPC will not fund any research project including travel to the event. Funding must be secured by the Principal Investigator and/or his/her Institution.

All funding sources must be disclosed to the IPC SSC prior to approval of any Project.

The IPC SSC can, upon request of the Principal Investigator, provide a letter of support indicating approval of the Project on its scientific merits.

10 Contact Information

All communication with regards to IPC Research Applications are coordinated through the IPC Medical & Scientific Director (peter.vandevliet@paralympic.org).

The Principal Investigator must provide a contact detail where he/she can be reached during regular office hours (an indicating the time zone using GMT).

11 How to Complete your Application

Carefully read all the instructions. Most items of the Application are self-explanatory. Should you require additional information, do not hesitate to contact the IPC Medical & Scientific Director for clarification.

Complete fully and accurately each section of the application forms. If the IPC SSC is required to contact you for additional information or wait for additional information to support your application, approval of your study will be delayed.

The IPC SSC does not require all the details you might present in a scientific publication, but you should detail sufficient information to judge whether your study meets the methodologically accepted standards for protection of human research subjects and non-interference with the logistics and operations of IPC Events.

Carefully write your consent form(s) or cover letter(s). Tell the research participants as much as possible on their level of understanding (fifth grade reading level – 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.

Where possible, your participants should be "anonymous" (i.e., no one, investigator included, can identify individual results). Otherwise, you must state in the consent form that their personally identifying data will remain confidential unless disclosure is required by law. "Confidential" means the investigator(s) may be able to identify a participant's results, but will not reveal the participant's identify 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.

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.

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., child 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.

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. 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 IPC SSC understands the benefits of your study to judge whether they exceed the risk to the participant. You MUST also list possible benefits in order for your study to be approved.

You must detail the potential risks a research participant 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 stress/injury. Benefits must outweigh the risk in any research project.

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