

**Paralympic Research and Sport Science Consortium of the
United States Olympic Committee**

APPLICATION TO CONDUCT RESEARCH

INTRODUCTION

The mission of the Paralympic Research and Sport Science Consortium (PRSSC) of the United States Olympic Committee (USOC) is to conduct, promote and support Paralympic research and sport science through collaborative study.

The PRSSC is responsible for establishing policies and guidelines in order to enhance scientific knowledge and to promote Paralympic sport science and research. To this end, the PRSSC requires prior review and approval for all research and programs conducted at or associated with the U.S. Paralympics (USP) and United States Olympic Committee (USOC) sanctioned events or programs. This specifically includes, but is not limited to, training camp, National Championship, and World Cup events. Do not hesitate to contact the PRSSC for clarification if you are uncertain whether or not review is required.

The PRSSC, in conjunction with the relevant Sport, has the authority to approve, require modifications, or reject all research requests at these events. The PRSSC is responsible for ensuring that all research with human subjects at USP/USOC sanctioned competitions, events and programs is conducted in accordance with certain ethical principles, namely:

- (1) whether the research meets Federal requirements for the protection of human subjects
- (2) whether the research is approved by the principal investigator's Institutional Review Board (IRB)
- (3) whether the benefits of the research outweigh the risks to the participants
- (4) whether the research interferes with the logistical operations of the sanctioned events

APPLICATION PROCESS

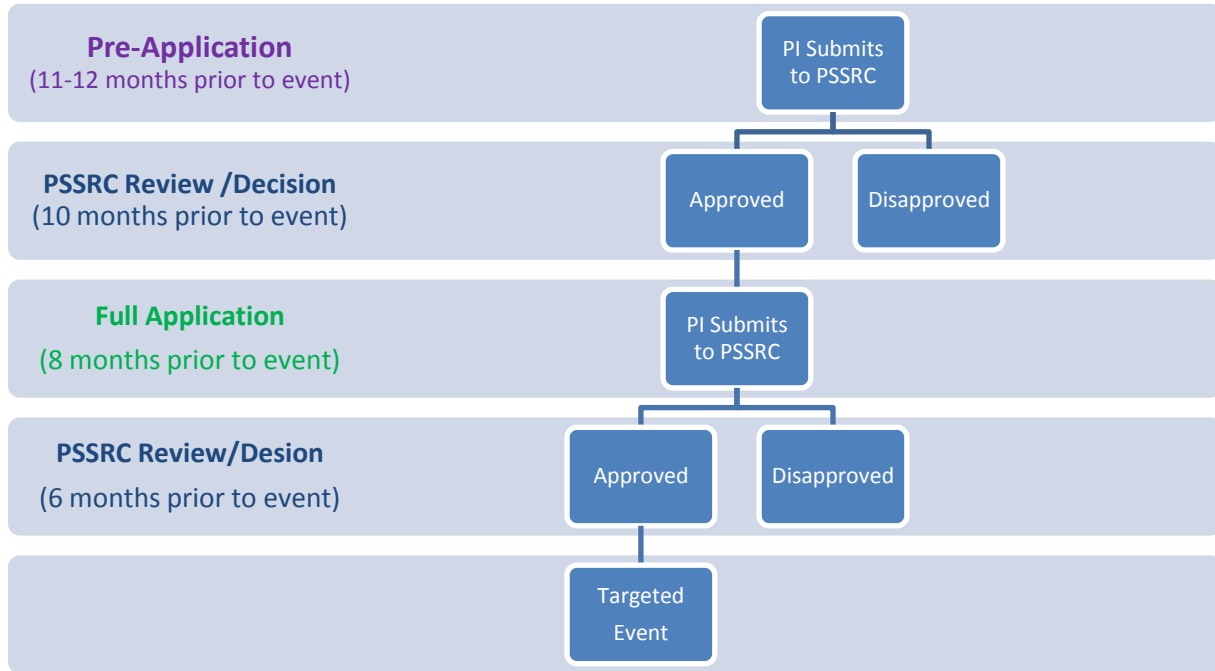
The PRSSC has developed a two step application process, involving a pre-application, followed by a full application which will be accepted by invitation only. The Principal Investigator interested in conducting the research must first complete the pre-application process. The intent of the pre-application is to enable the PRSSC to assess the scope of the research to be conducted and to

determine the feasibility of each study with regard to available resources (e.g., study population, space requirements, etc.). Documentation of IRB approval from the Principal Investigator's home institution is not a requirement for the submission of a pre-application. The PRSSC will review the pre-applications within 30 days of the submission deadline and will immediately notify the Principal Investigator whether or not approval has been granted to proceed with submission of the full application. Full applications for research conducted in the United States at USP or USOC sanctioned events are due a minimum of **eight months** prior to the event at which the research activities will take place. Full applications for research conducted at international events must follow the guidelines set forth by the International Paralympic Committee Sport Science Committee (IPC SSC) [http://www.paralympic.org/Science_Education/Science/Research/].

If the pre-application is accepted, the Principal Investigator will be provided with a written letter of support from the PRSSC with invitation to submit a full application. The full application must include documentation that the Principal Investigator has submitted to their local IRB and a copy of all materials (e.g., consent form or cover letter, questionnaire, etc.) must be provided for committee review. Although contingent approval may be granted by the PRSSC, the research cannot be conducted until documentation of final IRB approval is provided. Invitation to submit a full application does not guarantee that the Principal Investigator will be approved to conduct research at the specified event. Successful applications will be announced by the PRSSC within six months of U.S. competitions or events.

Incomplete forms and/or insufficient information will delay consideration of any proposed project. After the proposal is approved, it is the responsibility of the Principal Investigator to report immediately to the PRSSC 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 PRSSC. The Principal Investigator is also required to submit a final report for review by the PRSSC within six months of completion of the event. Failure to provide this documentation will impact future consideration to conduct research at a USP/USOC sanctioned event.

TIMEFRAME FOR REVIEW



The timeframe for deadlines to submit the pre and full application and review turnaround times have been summarized. Refer to the diagram. These timelines have been developed to ensure timely reviews by the PRSSC committee and to encourage investigators to conduct research at these events. The application process for events held in the United States will begin eleven to twelve (11-12) months prior to the event. The PRSSC will review the pre-applications within 30 days of submission and notify the PI of the decision. Investigators invited to submit a full application will have a minimum of 60 days to prepare their submission and submit to the PRSSC for review. The PRSSC will review the full applications within 60 days of submission and successful applications will be announced by the PRSSC within six months of U.S. competitions or events. Any changes to the application process and schedule will be posted on the website.

PRE-APPLICATION

The PRSSC pre-application 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 human research subjects and non-

interference with the logistics of USP/USOC competitions/events. Most items are self-explanatory. Should you require additional information do not hesitate to contact the PRSSC for clarification.

FULL APPLICATION

The full application is to be completed only if you have received notification that your pre-application has been approved and you have been invited to submit a full application. Invitation to submit a full application does not guarantee that the Principal Investigator will be approved to conduct research at the specified event(s). The PRSSC Committee will review all complete applications and the PI will be notified within six months prior to events in the United States. Applications for research at international events must be submitted to the IPC SSC following their guidelines: http://www.paralympic.org/Science_Education/Science/Research/

The full application must include documentation that the Principal Investigator has submitted to their local IRB and a copy of all materials (e.g., consent form or cover letter, questionnaire, recruitment materials etc.) must be provided for committee review. If otherwise approved, contingent approval will be granted by the PRSSC until documentation of final IRB approval is provided. Refer to the “APPLICATION CHECKLIST” for a list of all required documents.

The following information is required to be disclosed in the protocol and consent documents: “It is possible that authorized representatives from the Paralympic Research and Sport Science Consortium (PRSSC) of the United States Olympic Committee (USOC) may review your data for the purpose of monitoring the conduct of this study.”

GENERAL GUIDELINES FOR SUCCESSFUL APPLICATIONS

- CAREFULLY read all the instructions.
- Complete fully and accurately each section of the application forms. If the PRSSC is required to contact you for additional information or wait for additional information to support your application, approval of your study will be delayed.
- Do not forget to sign the application form on the first page of the pre-application.

PROJECT FUNDING

The PRSSC 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 PRSSC prior to approval of any research project.

APPROVAL OF RESEARCH

Once a research application is approved, the PI will receive a formal letter from the PRSSC. A copy of the letter will go to the event organizer.

MODIFICATIONS/ PROTOCOL DEVIATIONS/ ADVERSE EVENTS

It is your responsibility to report immediately to the PRSSC any significant changes, unanticipated problems, adverse events or the need for extension of approval for the collection of data. Changes and/or problems may influence the final decision of the PRSSC.

FINAL REPORTS

The PI is expected to submit a project completion report to the PRSSC within **six months** after data collection has finished. The final report is required to include an overall summary of the project and a 2-page lay article which includes an interpretation of the results and how that information can be applied to the sport and/or population under study. The lay article must be suitable for dissemination to both coaches and athletes. A copy of manuscripts submitted to scientific journals must also be forwarded to the PRSSC as part of the final report. The PRSSC must be acknowledged in all written and oral reports as follows:

“This study was approved and supported by the Paralympic Research and Sport Science Consortium of the United States Olympic Committee”.

In the event the report is not received by the PRSSC within six months, the PI and Co-Investigator(s) may be suspended from conducting research at USP/USOC sanctioned competitions for up to two years.

PARALYMPIC RESEARCH AND SPORT SCIENCE CONSORTIUM (PRSSC)
UNITED STATES OLYMPIC COMMITTEE

REQUEST TO CONDUCT RESEARCH
PRE-APPLICATION

PRINCIPAL INVESTIGATOR (PI) CONTACT INFORMATION

Prefix: Ms. Mr. Dr. Prof.

First Name: Last Name:

Credentials (e.g. BS, MS, PhD, MD):

Affiliation(s):

Job Title(s):

Mailing Address:

Mailing Address:

City: State: Zip Code:

Daytime Telephone Number:

Cell Phone Number:

Fax Number:

E-mail Address:

The PI's curriculum vitae has been submitted for review (Required)

PI CERTIFICATION

As PI, have you verified that all members of the research team have the appropriate expertise and credentials to perform those research procedures that are their responsibility as outlined in the IRB protocol?

Yes No

Have any possible conflicts of interest, concerning this project, been identified?

Yes, a description of the COI(s) and management plan has been included
 No

Signature/Date, Principal Investigator

PROJECT INFORMATION

Project Title:

Funding Source(s):

Co-Investigator(s) Name(s):

Affiliated Institutional Review Board (IRB):

WHAT IS THE SUBMISSION STATUS OF THE ABOVE IRB(S)?

Not Submitted

Submitted: /...../....., Pending Review

Approved: /...../.....

Approval Number:

Expiration Date: /...../.....

Level of Review: Full Board

Expedited

Exempt

WHAT IS THE ANTICIPATED RISK TO RESEARCH SUBJECTS?

Minimal Risk

Greater than Minimal Risk

HAVE YOU PREVIOUSLY SUBMITTED RESEARCH ON THIS TOPIC FOR PRSSC REVIEW?

Not Submitted

Submitted: /...../....., Title:_____

PROPOSAL

The following information should be included in the proposal.

1. **OBJECTIVES:** What is the overall purpose of this research study?
2. **SPECIFIC AIMS:** List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).
3. **SIGNIFICANCE:** Why is it important that this research be conducted? Specifically, include the impact on sport activity for individuals with physical and/or visual disabilities including training and competition for athletes at the recreational, developmental, emerging and/or elite levels.
4. **RESEARCH DESIGN:** Identify the study design.
5. **METHODS:** Briefly describe the study procedures. Do not exceed 500 words.

6. STUDY POPULATION:

Number of participants anticipated:

Age range:

Does the study involve children (less than 18 years of age)? Yes No

Gender: Both Male Female

Disabilities:

List the specific criteria for inclusion of potential participants.

List the specific criteria for exclusion of potential participants.

7. **RISKS:** Describe potential risks (physical, psychological, social, legal, economic or other) associated with this study and the steps that will be taken to prevent or to minimize the severity of the potential risks.

8. **BENEFITS:** Describe any direct benefits to the research participants and the general benefits to society (e.g., increased knowledge; improved safety; better health; technological advancement) that may result from the conduct of this research study.

LOCATION and DATES

USOC Sanctioned Event or Program:

Location:

Competition Date(s) (mm/dd/yy): Begin:/...../..... End:/...../.....

Project Date(s)* (mm/dd/yy): Begin:/...../..... End:/...../.....

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

STUDY PERSONNEL

Please List the Names and Roles of All Study Personnel in Attendance:

<u>Name</u>	<u>Role</u>
-------------	-------------

RESOURCES

Describe Any Physical Space Required (e.g., size, layout, tables, chairs, etc.):

Describe Any Power Sources and Information Technology Required (e.g., electrical outlets, internet access, telephone, etc.):

Describe Any Special Services Required (e.g., waste disposal, etc.):

PRSSC Use Only – Do Not Write Below This Line

=====

Received:/...../..... Reviewed:/...../.....

Pre-Application Review Action: PI Notified of Decision:/...../.....

- Approved/Invitation to submit full application
- Pending modification
- Deferred
- Rejected

Signature/Date, Research Consortium Chairperson

**PARALYMPIC RESEARCH AND SPORT SCIENCE CONSORTIUM (PRSSC)
UNITED STATES OLYMPIC COMMITTEE**

**REQUEST TO CONDUCT RESEARCH
FULL APPLICATION (INVITE ONLY)
CHECKLIST**

PI'S CONTACT INFORMATION

- There are no changes from the pre-application
- The PI's contact information has been updated*
(*resubmit page 1 of the pre-application)

WHAT IS THE SUBMISSION STATUS TO THE AFFILIATED IRB(S)?

It is required that the research study be submitted to the IRB and pending review in order for the full application to be reviewed by the PRSSC committee. Documentation of final IRB approval is required prior to the PRSSC granting final approval to conduct the study at any USP or USOC sanctioned event or program.

Submitted: /...../....., **Pending Review**

Approved: /...../.....

Approval Number:

Expiration Date:/...../.....

Level of Review: **Full Board** **Expedited** **Exempt**

- Research Proposal
- Consent/Assent/HIPAA Authorization Forms
- Documentation of Human Research Ethics Training (within 3 years) for the study PI and all co-investigators
- IRB Approval Letter
- Recruitment Materials (e.g. advertisements, phone scripts, recruitment letters)
- Study Instruments (e.g. questionnaires, case report forms)
- Any additional Committee and Regulatory approvals (e.g. FDA)