

# The BASES Expert Statement on Ethics and Participation in Research of Young People

Produced on behalf of the British Association of Sport and Exercise Sciences by Assoc Prof Craig A. Williams FBASES, Rev Mark Cobb, Prof Thomas Rowland and Prof Edward Winter FBASES

Research with children and adolescents is both valuable and legitimate, but at the same time it is essential that the welfare of young people<sup>1</sup> as participants in research is upheld (Royal College of Paediatrics and Child Health, 2000). Two basic issues underpin this statement: 1. That the child is likely to gain personal benefit from the procedure or intervention and 2. The risks of the research. Most research in exercise/sport fits into the category of “minimal risk, no direct benefit to participant,” and in this category the criterion is usually that any research intervention in children is ethical if procedures are no different from those that the child would encounter in everyday life. Thus, X-rays, phlebotomy, maximal exercise testing are all ethical, but a muscle biopsy is not.



Above: It is essential that the welfare of young people as participants in research is upheld  
Courtesy Associate Prof Craig Williams FBASES

Therefore, all sport and exercise research that involves young people should:

- have formal ethics approval that confirms the relevance/merits of the project, the risk/benefit ratio, the quality of care provided by the research team and the extent to which young participants (and guardians) have been properly informed.
- conform to current good practice in safeguarding (according to the Every Child Matters guidance, DfE, 2004).
- be conducted by researchers/technicians who have been trained in safeguarding by a recognised body and have completed full Criminal Records Bureau or equivalent checks (e.g., in Scotland checks would be carried out by Disclosure Scotland under the *Protecting Vulnerable Groups Scheme* and legislation).

## Statutory requirements

### Informed consent

Participation in research requires adherence to the principle of informed consent. Normally, this consent is characterised by parental (or legal guardian) consent because participants are minors.

Technically, a minor in England is someone who is below the age of 18 years<sup>2</sup> but arising from a ruling by Lord Fraser in 1985 in the House of Lords, someone below this age can consent, even when this is counter to the wishes of their parent or guardian (Winter & Cobb, 2009).

Consent is defined as “the positive agreement of an individual” while providing assent is “to go along with” (RCPCH, 2000). Gaining valid consent is legally recognised when those who are under 18 years of age participate, whilst the provision of assent is a sign of good practice but with no legal basis. We recommend that the young person’s agreement be sought to prevent coercion and empower the participant. A young person’s willingness to consent to participate in a study while their parents refuse to give consent poses a dilemma.<sup>3</sup> In such a situation, it is recommended that the participant becomes involved only when parental consent has been obtained.

In Scotland the legislative basis of consent is different. Under the Age of Legal Capacity (Scotland) Act 1991 and The Children (Scotland) Act 1995 young people are considered capable of giving consent when they are deemed (e.g., by a health professional, researcher or teacher) competent to do so because they are capable of understanding what is being asked of them. This is not specified as a precise age as it will differ between individuals and depend upon what is being asked. It is widely understood that a court would not overturn the decision of a competent child or adolescent, and that parents should guide young people but cannot over-rule them. Research practice in Scotland has therefore generally involved the provision of information both to parents and participants, and requires formal consent from both child and parent except where the child is clearly unable to provide consent (e.g., in the pre-school or early school years).

The two principles of providing parental consent and assent by young people are that it is freely given and is informed:

- language needs to be developmentally appropriate and technical terms avoided.
- written words should be supported by verbal explanations in a face-to-face session.
- after consent and assent have been obtained, further clarification might still be required.

It is necessary to ensure that:

1. No inducements or coercion have occurred.
2. A contact person is available to answer questions throughout the project.
3. The philosophy of consent should not be just a single Yes/

1. The term “young people” is referred throughout this expert statement to encompass both children and adolescents (up to 18 years) and acknowledges the legal controversy of the definition of a minor and an adult.

2. Under the Clinical Trials Regulations (MHRA, 2004) a minor is a person under 16 years, if these regulations do not apply, the age of majority is 18.

3. For children under 16, who are considered to have the capacity to consent, their consent is valid and the consent of someone with parental responsibility is not required, although it is good practice to gain their agreement.

No response but on a continuum of “phased consent”. Participants should believe they have the right to withdraw from the project at a later date without reproach.

4. Medically-related research must also satisfy the European Union issue Directive 2001/20/EC that is concerned with “the approximation of the laws, regulations and administrative provisions of the member state relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.”

### Criminal records bureau (CRB)

It is a legal requirement in England, Wales and Northern Ireland that those in regular contact with youngsters should undertake formal checking (the CRB). In Scotland legal requirements apply through Disclosure Scotland. We recommend that:

- a full enhanced disclosure CRB check is obtained.
- staff work in pairs, avoiding situations that would leave an adult member of the team alone with a participant.
- for international research students, a police check in their home country is obtained, any references are followed up and they should sign a self-declaration.
- researchers stay informed of current guidelines, i.e., the Independent Safeguarding Authority (ISA) and the Safeguarding Vulnerable Groups Act (2006).

### Broadcasting of results

Information collected during a study must satisfy ethical requirements and fulfil those of the Data Protection Act. The anonymity and privacy of participants should be maintained and staff cannot disclose personal data unless the child and those with parental responsibility have understood and consented to its use, e.g., use of a video clip of a child performing an exercise.

### Practical guidelines – conduct during and after a research study

Professional practice is built on the fundamental premise that the conduct of research staff should at all times safeguard and promote the rights, dignity, welfare and safety of the young people involved.

#### 1. A risk-based approach

An important part of conducting research is the identification and implementation of ways to reduce known hazards that can cause harm. Harm can result from physical or psychological damage or distress, but can also result from social disruption or damage, e.g., by revealing information that affects a person’s social standing in a group.

#### 2. Safeguarding young people involved in research

Safeguarding is the process by which youngsters are protected from abuse, impairment of their health and development and the provision of optimum life chances. Safeguarding is a proactive response to risks and involves a framework of measures that promotes a safe and positive environment for research and minimises avoidable risks. Currently, there is no specific framework for sport and exercise science involving young people, but there are standards developed by the Child Protection in Sport Unit (2005).

In relation to the conduct of sport and exercise research:

- participants and guardians/parents should be provided with information about how the organisation promotes a safe and positive environment and whom to contact if they have concerns.
- staff should have clear guidance on behaviour when working with youngsters.
- there should be procedures for the reporting of concerns about youngsters and for responding to them, which include a:
  - step-by-step guide on what action to take if there are concerns about a child’s safety or welfare.
  - procedure to respond to allegations made against staff involved in the study.

- process for recording concerns, reported or witnessed events, and referrals.

### 3. Conduct of research staff during the study

Staff must act at all times to safeguard and protect the interests of the child, even when this is to the detriment of the research study. All reasonable steps should be taken to ensure that young people are not put at risk by researchers’ behaviour, actions or omissions, or that of their colleagues, or by placing them in a situation that will put the health or safety of the young person at risk.

The Council for Healthcare Regulatory Excellence has produced guidance for healthcare professionals, which should be adopted by researchers in sport and exercise science. Sport England set out basic standards for adults who work with young people including:

- dressing appropriately.
- appropriate use of language.
- avoiding unnecessary physical contact with youngsters.

A research study might require physical contact with youngsters, e.g., anthropometry. The need for this contact should be explained and participants should not be in any doubt about the reason for the contact and how it will happen. Immediately before procedures involving touch, a clear explanation should be provided. A refusal by the child should be respected and not overridden.

### Summary

Adherence to these guidelines will help to ensure that harm to young people is minimised and research with their participation is beneficial for everyone. ■

#### Associate Prof Craig Williams

FBASES is Director of the Children’s Health and Exercise Research Centre, Sport & Health Sciences, University of Exeter.



#### Reverend Mark Cobb MA

is the Clinical Director and Senior Chaplain at Sheffield Teaching Hospitals and lectures at the Universities of Sheffield and Liverpool.



#### Prof Tom Rowland

is Director of Pediatric Cardiology at the Baystate Medical Centre in Springfield, Massachusetts.



#### Prof Edward Winter FBASES

is Professor of Physiology of Exercise at Sheffield Hallam University.



### References

- Child Protection Support Unit. (2005).** Standards for Safeguarding and Protecting Children in Sport. Available: [www.thecpsu.org.uk](http://www.thecpsu.org.uk)
- Department for Education. (2004).** Every Child Matters. London: Department for Education. Available: [www.education.gov.uk/childrenandyoungpeople/safeguarding](http://www.education.gov.uk/childrenandyoungpeople/safeguarding)
- Directive 2001/20/EC of the European Parliament and of the Council.** Available: [ec.europa.eu/health/human-use/clinical-trials/index\\_en.htm](http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm)
- Fraser Guidelines. (1986).** Available: [www.hrcr.org/safrica/childrens\\_rights/Gillick\\_WestNorfolk.htm](http://www.hrcr.org/safrica/childrens_rights/Gillick_WestNorfolk.htm)
- Royal College of Paediatrics and Child Health: Ethics Advisory Committee. (2000).** Guidelines for the ethical conduct of medical research involving children. Archives of Disease in Childhood, 82, 177-182.
- Sport England. (2004).** Funding support pack: Child protection guidelines.
- Winter, E.M. & Cobb, M. (2009).** Ethics in paediatric research: Principles and practices. In N. Armstrong & W. van Mechelen (Eds.), Paediatric exercise science and medicine (pp. 3-12). Routledge: London.

PDF Download Download a PDF of this article [www.bases.org.uk/BASES-Expert-Statements](http://www.bases.org.uk/BASES-Expert-Statements)

### Copyright © BASES, 2011

Permission is given for reproduction in substantial part. We ask that the following note be included: “First published in The Sport and Exercise Scientist, Issue 29, Autumn 2011. Published by the British Association of Sport and Exercise Sciences – [www.bases.org.uk](http://www.bases.org.uk)”