

Attachment 1

IRB Approval: Chesapeake IRB (EXACT)



Chesapeake IRB

Providing Human Research Protections Services
IRB Services • Consultation • Education
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PROTOCOL APPROVAL

DATE: 19 Jun 2013

TO: Barry Tarter, MBA
EXACT Sports

PROTOCOL: National Institute on Drug Abuse / National Institutes of Health - no protocol number, Rapid Throughput Standardized Evaluation of Transmissible Risk for SUD in Youth: Validation Study (Pro00008535)

IRB APPROVAL: 18 Jun 2013

IRB EXPIRATION: 18 Jun 2014

IRB APPROVED DOCUMENTATION:

- Consent Templates:**
- Adult Twins Informed Consent Form (REVIEW ONLY).
 - Parental Informed Consent Form (REVIEW ONLY).
- Other Materials:**
- University of Pittsburgh Approval (Dated 4/11/2013).
 - University of Pittsburgh Protocol (Print Date 4/12/2013).
 - Rutgers University Approval (Dated May 30, 2013).
 - Rutgers Protocol Review (Print Date 4/17/2013).
 - Rutgers Protocol (Dated 11/27/12).
 - About your Twin Questionnaire (Not Dated).
 - Short Survey (Not Dated).
 - Award/Contract (Effective Date 09/17/2012).

The IRB approved the above referenced protocol on 18 Jun 2013.

The IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects.

The IRB determined that the research study meets the criteria found in the risk category described as follows:

- 45 CFR 46.404: *“Research not involving greater than minimal risk.” Permission of one parent is required.*

It is the understanding of the IRB that EXACT Sports will act as a coordinating center and local IRBs (Rutgers and Pittsburgh) will have oversight of the informed consent process and informed consent forms.

Please review the Sponsor and CRO Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage (“My Home”) and select the “Reference Materials” tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under “Reference Materials”.

Thank you for selecting Chesapeake IRB to provide oversight for your research project.