

**Initial Proposal Cover Sheet**

1. IRT-IRB Number: 15-009-1-FEA

Date Submitted: 5-12-15

2a.  This IRB form does not supersede any previous request.

2b.  This IRB form RELATES to previous application \_\_\_\_\_ approved on \_\_\_\_\_.

2c.  This IRB form SUPERSEDES \_\_\_\_\_ which was most recently approved on \_\_\_\_\_.

**3. Principal Investigator**

<b>Name: Alison Parker and Tracy Scull</b>	
<b>Phone:</b> 919-493-7700	<b>Email:</b> <a href="mailto:aparker@irtinc.us">aparker@irtinc.us</a> and <a href="mailto:tscull@irtinc.us">tscull@irtinc.us</a>
<b>Fax:</b> 919-493-7720	<b>Affiliation:</b> innovation Research & Training

4. Project Title/Familiar Name: Development of web-based resource for youth

5. Grant Name: Web-based resource for youth about clinical research

6. Project Type:  Just-in-Time  **Specific Project**

7.  Approval required from other institution (e.g., prison, school):  is attached  is pending

Name of institution(s): \_\_\_\_\_

8.  Indicate grant number and funding agency: Phase I SBIR contract #HHSN268201400051C and NHLBI

9. Principal Investigator's Recommendation:

FULL Board Review

**Expedited Review; Category number 7 IRB Manual Section VI.B.2**

Exempt from further review following initial IRB review; Category number \_\_\_\_\_ IRB Manual Section VI.A.2

\_\_\_\_\_  
Signed by Principal Investigator

5/12/2015  
Date

\_\_\_\_\_  
Signed by IRT President

5/12/2015  
Date

10. **IRB Decision:** (IRB use only)

Exempted; no further review needed unless there is a modification.

**Approved as Specific Project**

**45 CFR 46.404 applies—no more than minimal risk to children**

45 CFR 46.117 (c) (2) applies—waiver of requirement for documentation of consent through written signature

Approved as "Just-in-Time" (grant proposal) under 45 CFR 46.118. **Specific Project approval needed prior to data collection.**

Approved with special conditions, see attachment

Not Approved (this decision can only be made by the convened IRB)

*Barbara Davis Goldman*

5-21-2015  
Approval Date

IRT IRB approval of this project EXPIRES **5-20-2016**

Signed by Chair, iRT IRB  
Barbara Davis Goldman, Ph.D.