Please complete the questionnaire before we begin

Recruiting Healthy Volunteers in Clinical Research

Would you consider enrolling in (choose all that apply):

- Malaria vaccine study  Yes ☐ No ☐
- An H1N1 vaccine study  Yes ☐ No ☐
- Challenge study for enterotoxigenic E. coli  Yes ☐ No ☐
- Other study  Yes ☐ No ☐

If YES to ANY  If NO to ALL

Rank the following reasons:
1 = Very Important; 2 = Important; 3 = Somewhat Important; 4 = Least Important

Altruism ☐  Fear ☐
Compensation ☐  Uncertainty of Risks ☐
For the experience ☐  Time / Inconvenient ☐
Know someone with the disease ☐  No Interest ☐

K. Chargers, MPH, BSN. JHSPH Center for Immunization Research, 624 N. Broadway, B3 217

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Recruiting Healthy Volunteers in Clinical Research

CENTER FOR IMMUNIZATION RESEARCH (CIR)

KAREN CHARRON
ALFREDA ANDERSON
E. WANGECI KAGUCIA

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Karen Charron, BSN, MPH, CCRC

- Faculty, JHSPH
  - Department of International Health
  - Global Disease Epidemiology and Control
- Assistant Director of Academic Programs
- Instructor
  - Clinical Vaccine Trials and Good Clinical Practice
  - http://distance.jhsph.edu/vactrial/
- 18 years of clinical vaccine trials experience
- Director of CIR GCP training program
  - 11 countries
  - >1000 participants
- Principal Investigator
- Supervisor of CIR regulatory team

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CIR Regulatory Team

- Alfreda Anderson, BS
- E. Wangeci Kagucia, MHS
About the CIR

- Founded in 1985
- 9 faculty; 40 staff members
- Focus primarily on phase I and II clinical vaccine research and good clinical practice training
- Funding from NIH, Gates/PATH, & industry
Current Areas of Emphasis

• 270 research protocols to date
• 15 active clinical research protocols
  • General adult & pediatric screening protocols (Charron, Casey)
  • Dengue virus vaccines (Durbin)
  • Enteric vaccines (Harro, D. Sack)
  • H1N1 influenza (Talaat, Karron)
  • Malaria (Talaat, Durbin)
  • Pediatric respiratory viruses (RSV, HMPV, parainfluenza) (Karron)
General Screening and Recruitment Protocol

- “JH200” Screening Protocol
- PI: Karen Charron
- Coordinator: Sabrina Drayton

2009 Summary

- # Contacted: 1,968
- # Screened: 954* (48%)
- # Enrolled: 243* (12%)

*Enrolled in screening protocol
* Enrolled in vaccine or intervention study
Screening Protocol

- General inclusion/exclusion criteria
- Uniform source documents
- Procedures
  - Phone screen
  - JH200 screening visit
    - Consent
    - Medical History, PE
    - Specimen collection, depending on screening needs
- If healthy, follow-up study-specific screening and enrollment
Screening Process

- Standardized visit flow during screening visits

STATION 5

STUDY SPECIFIC INFO
Screening Consent

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
INFORMED CONSENT DOCUMENT

Study Title: Screening of Adult Subjects for Eligibility to Participate in Clinical Studies Evaluating Investigational Vaccines, Antimicrobial Agents, Other Disease Prevention Measures or the Pathogenesis of Infectious Agents

Principal Investigator: Karen Charron, MPH
IRB No.: H.22.04.02.19.A2
PI Version Date: December 16 2009, Version 5.0

What you should know about this study
- This is a screening study to determine if you are eligible to join a research study. You are not joining a research study.
- This consent form explains the screening study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
Comprehension Assessment

Please answer the following questions with a short answer or by circling the correct answer.

<table>
<thead>
<tr>
<th>Subject Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>We are asking you to join a screening study.</td>
</tr>
<tr>
<td>1. The purpose of this screening study is to determine if you are <strong>healthy</strong> enough to participate in future studies.</td>
</tr>
<tr>
<td>2. At the CIR, we test vaccines that may protect against <strong>germs</strong> (one example).</td>
</tr>
<tr>
<td>3. What are the direct benefits of participating in the study? <strong>No benefit</strong></td>
</tr>
<tr>
<td>4. What are TWO risks of participating in the study?</td>
</tr>
<tr>
<td>a) <strong>Pain</strong></td>
</tr>
<tr>
<td>b) <strong>Bruising</strong></td>
</tr>
</tbody>
</table>
Training

- New staff
- Ongoing training
  - Consistency
  - Changing staff
  - Protocol adherence
  - Changes to JH200
- Responsibility log
Relationship with Vaccine/Intervention Studies

- Screening protocol conducted in compliance with:
  - 21CFR50, 56, 312
  - 45CFR46
  - ICH GCP

- Screening documents become part of study-specific record

- Referenced in study protocols

- JH200 records monitored during:
  - Sponsor monitoring visits
  - Independent audits
  - FDA inspections
  - IRB audit
Would you consider enrolling in *(choose all that apply)*:

<table>
<thead>
<tr>
<th></th>
<th>#YES</th>
<th>#NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria Vaccine Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An H1N1 Vaccine Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Challenge Study for enterotoxigenic <em>E.coli</em> (ETEC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Study</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Reasons I Would Not Enroll

<table>
<thead>
<tr>
<th>If NO to <strong>ALL</strong></th>
<th>Rank 1</th>
<th>Rank 2</th>
<th>Rank 3</th>
<th>Rank 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Uncertainty of Risks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Time/Inconvenient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Not interested</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Challenges: Healthy Volunteers

- Risks associated with vaccine/intervention studies
  - Rash
  - Diarrhea
  - DHF/DSS
  - (False) Positive HIV test result
  - Unknown risks

- No direct benefit

**BENEFITS:**
You will not receive any benefit from taking part in this study. We hope that this information will lead to a dengue vaccine that could help many people around the world.
Volunteer Concerns/Questions

- Procedural risks
- Concerns about risk of contracting disease
- Varied public knowledge of:
  - Vaccines
  - Diseases
Discussing Risks vs. Benefits

- Ongoing informed consent
- Candid discussion
  - No health reason for enrollment
  - Understanding volunteer concerns
- Evaluate personal commitment to research and self-bias
  - ‘Recruiters but never participants’ syndrome
Other Recruitment Challenges

- Scheduling and time requirements
- Space constraints/ high volume of volunteers
- Internal competition for volunteers
- Funding constraints
  - No primary funding for JH200
  - No patient base
  - CIR funded completely by grants/contracts
  - Screening costs shared across studies
- Not a provider of clinical care
  - Glass half-empty – recruitment base
  - Glass half-full – minimize coercion?
More Challenges

- Lots of healthy volunteer research studies in Baltimore
- Concurrent enrollment concerns
  - No central volunteer database across JHU campuses or in Baltimore
  - Inherent ethical dilemma
  - Safety concerns
  - Eligibility
Compensation - Ethical Issues

- Autonomy
- Justice

The Recruitment of Normal Healthy Volunteers: A Review of The Literature on the Use of Financial Incentives

Carl L. Tishler, PhD, ABPP, and Suzanne Bartholomae, PhD

Unresolved issues of ethical, methodological, and legal concerns in the use of normal healthy volunteers persist. Financial incentives in their recruitment offer a unique ethical dilemma because of questions surrounding payment. A review of literature was conducted to obtain research systematically examining volunteer motivation and the role of financial incentives. The primary selection criterion was motivation and payment to volunteers; seven studies met the criterion for review. Studies that have systematically investigated volunteer motivation have found financial rewards to be an important motivator among normal healthy volunteers in their decision to participate in clinical trials. Also evident is that differences based on demographic characteristics exist in the motivation and rates of volunteerism. Ethical issues surrounding the use of normal healthy volunteers are discussed, with attention to the issue of financial incentives (e.g., economically vulnerable volunteers, undue inducements). Regulations, guidelines, and recommendations are discussed with regard to volunteers and financial incentives.

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Compensation

- No compensation provided for screening
  - Tokens
  - Parking validation
- Internal consensus for investigational study compensation
- Assessment of ‘market rate’
- Feedback from volunteers
- Fair work wage
Recruitment Methods

- JH200 is the recruitment mechanism for the CIR
- Branding: Project SAVE
- Print
  - Newspapers
  - Flyers
- Word of mouth
- Coffee sleeves
- Digital Media Screens
CIR Recruiting Messages

- Global health focus
- Focus group tested (JHSPH CCP)
- ‘Split faces’

…but I'm helping SAVE lives across the world.
Recruitment Reach

- General population (beyond Hopkins)

**RESEARCH STUDY RECRUITMENT**

I Live in Baltimore but I Help to Save Lives in Asia

Are You a Healthy Adult Between the Ages of 18-50?

Participate in a Vaccine Research Study at
The Center for Immunization Research

Call Today: 410-955-7283

Compensation for Time and Travel

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Volunteer Sources (2009)

- Print media – 48%
- Repeat volunteers – 25%
- Social networking
  - Friends - 15%
  - Referred from a previous volunteer – 3%
- Online & flyers – 9%
## Reasons Why I Would Enroll

<table>
<thead>
<tr>
<th>If YES to <strong>ANY</strong></th>
<th>Rank 1</th>
<th>Rank 2</th>
<th>Rank 3</th>
<th>Rank 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>• Altruism</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>• Compensation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>• For the experience</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>• Know someone with the disease</strong></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
### Volunteer Experiences

#### What were the good things about being in studies?

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>23</th>
<th>37</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>The people*</td>
<td>9</td>
<td>39</td>
<td>25</td>
<td>68</td>
</tr>
<tr>
<td>The money</td>
<td>14</td>
<td>61</td>
<td>19</td>
<td>51</td>
</tr>
<tr>
<td>Contributing to science/helping others **</td>
<td>15</td>
<td>65</td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td>Relaxing/nice break</td>
<td>4</td>
<td>17</td>
<td>14</td>
<td>38</td>
</tr>
<tr>
<td>Personal health and benefits</td>
<td>6</td>
<td>2b</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Non-monetary perks**</td>
<td>0</td>
<td>0</td>
<td>11</td>
<td>30</td>
</tr>
<tr>
<td>Knowledge/what I learned</td>
<td>3</td>
<td>13</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Convenience*</td>
<td>3</td>
<td>13</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Low side effects</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
</tr>
</tbody>
</table>

#### Positive experiences

Several interview items asked about positive and negative aspects of participation. Participants were asked if they were “glad (they) joined” healthy volunteer studies, “all the good things about studies”, and “the best thing about being in studies”. Almost all (97%) reported being glad they had enrolled (Table 4). Four themes consistently emerged in response to these three questions: contributing to science, making money, meeting people (staff and other volunteers), and studies seeming relaxing...
Retention

• Evaluate potential reliability prior to enrollment
  ○ More than one screening visit
  ○ Evaluation of social/medical history

• Relationship building
  ○ Friendly staff ‘culture’
  ○ Accommodate families - playroom
  ○ Word of mouth – social networking
  ○ 25% of our volunteers are re-enrolled
  ○ History/experience in research studies

• Education
Conclusion

- Common screening protocol is efficient
- Provides a mechanism for common recruitment
- Team building, consistency
- Way to improve retention
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Sabrina Drayton, CCRC
CIR research teams