Compensation for Participation Guidelines

ICMR 2006

ICH GCP

CIOMS

Schedule Y, Drugs and Cosmetics Act, Amendment 2005

Indian GCP

National Conference on Ethics, TMH, 5-6 Nov 2011
Background: ICMR 2006

“Participants may be paid for the inconvenience and time spent and should be reimbursed for expenses incurred, in connection with their participation in research.”

“All payments, reimbursement and medical services to be provided to research participants should be approved by Ethics Committee.”
Compensation or undue inducement

Compensation is deemed **undue** and therefore troublesome if it is so “... attractive that [it can] **blind prospective subjects** to potential risks or impair their ability to exercise proper judgment ..”

National Conference on Ethics, TMH, 5-6 Nov 2011
How to decide compensation?

- Minimal guidance to help investigators determine how much to pay participants
- Responsibility of Ethics Committees to ensure that compensation is ethically acceptable
- ECs also operate with minimal guidance
- Payment practices vary widely
Compensation for Participation in Research: Review of Projects Submitted to Three Ethics Committees in Mumbai

Marathe PA, Tripathi RK, Kamat SK,
Shetty YC, Kuyare SS, Thatte UM

Seth GSNC & KEM Hospital, Mumbai
Objectives

- To review provision of compensation given to participants
- To find out how much compensation was approved by Ethics Committee for study related activities
- To identify issues related to compensation raised by Ethics Committees
Methods

Retrospective analysis of research projects reviewed by Ethics Committees during January 2009 to December 2010
Methods

2 Institutional Ethics Committees and 1 Non-institutional Ethics Committee

Appropriate permissions obtained

Strict confidentiality maintained.

National Conference on Ethics, TMH, 5-6 Nov 2011
Methods: Review of Study Records

Compensation clause in Informed Consent Documents

Queries raised by ECs related to compensation

Responses by investigators

Amount of compensation accepted by EC

Data analysis using descriptive statistics
## Results: Type of Studies Reviewed

\( N = 227 \)

<table>
<thead>
<tr>
<th>EC</th>
<th>Pharma Funded</th>
<th>GOVT Funded</th>
<th>Investigator initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional (179)</td>
<td>54</td>
<td>20</td>
<td>105</td>
</tr>
<tr>
<td>Non-institutional (48)</td>
<td>48</td>
<td>NA</td>
<td>NA</td>
</tr>
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</table>
# Results: Type of Studies Reviewed

\[ N = 227 \]

<table>
<thead>
<tr>
<th>EC</th>
<th>Interventional</th>
<th>Observational</th>
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</thead>
<tbody>
<tr>
<td><strong>Institutional (179)</strong></td>
<td>62</td>
<td>117</td>
</tr>
<tr>
<td><strong>Non-institutional (48)</strong></td>
<td>33</td>
<td>15</td>
</tr>
</tbody>
</table>
# Results

<table>
<thead>
<tr>
<th>Observations</th>
<th>Institutional EC</th>
<th>Non-institutional EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compensation clause in Informed Consent Document</td>
<td>44/65</td>
<td>25/25</td>
</tr>
<tr>
<td>Queries raised by EC</td>
<td>21/65 (32%)</td>
<td>No</td>
</tr>
<tr>
<td>No. of investigators accepting EC recommendations</td>
<td>14/21 (67%)</td>
<td>NA</td>
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</tbody>
</table>
## Travel Compensation (Rs.): Sponsored Studies

<table>
<thead>
<tr>
<th>EC</th>
<th>≤ 200</th>
<th>201–500</th>
<th>501–1000</th>
<th>&gt;1000</th>
<th>As per actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inst. (56)</td>
<td>17</td>
<td>22</td>
<td>4</td>
<td>2</td>
<td>11 (20%)</td>
</tr>
<tr>
<td>Non Inst. (25)</td>
<td>5</td>
<td>8</td>
<td>1</td>
<td>–</td>
<td>11 (44%)</td>
</tr>
</tbody>
</table>

- Higher travel allowance for participants from outside Mumbai
- Rs.2500 per 24 hrs. hospitalization for 2 BA/BE studies
## Amount of Compensation (≤ Rs. 200)

<table>
<thead>
<tr>
<th>EC</th>
<th>Type of Studies</th>
<th>No. of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional EC</td>
<td>Pharma sponsored</td>
<td>10/45 (22%)</td>
</tr>
<tr>
<td></td>
<td>GOVT sponsored</td>
<td>7/11 (64%)</td>
</tr>
<tr>
<td></td>
<td>Investigator initiated</td>
<td>9/9 (100%)</td>
</tr>
<tr>
<td>Non-institutional EC</td>
<td>Pharma sponsored</td>
<td>5/25 (20%)</td>
</tr>
</tbody>
</table>

Amount of compensation depends on degree of study and budget constraints.
What did participants receive compensation for?

- 61/90 – (68%) reimbursement of travel expenses
- 10/90 – travel and inconvenience
- 12/90 – travel and loss of wages / time / meal / accommodation
- 7/90 – blood collection

Phase IV and observational studies – compensation paid only for additional follow-up visits
Results:

- Participants were not paid for studies done during hospitalization (n=9)
- EC asked for compensation to be provided for initial hospitalization of patient in addition to travel compensation of Rs. 100/visit (n=1)
- Participants were not paid for additional blood samples in phase 2 and phase 3 studies (n=2)
Summary

Compensation was provided mainly for travel expenses and amount was modest (up to Rs. 250 per visit)

Variability within the pharma sponsored and investigator initiated studies with respect to amount offered for reimbursement of travel expenses

No compensation related queries were sent to investigators by non institutional EC

Recommendations were suggested by Institutional ECs in 32% of studies and compliance of investigators to the recommendations was 67%
Ethical dilemma

Optimum travel expenses – based on distance and mode of transport?

Should one consider reimbursement of non-monetary expenses? How can we quantify inconvenience, discomfort, time lost, loss of wages?

Should hospitalised patients not be paid for participation?

Do we need to pay patients for additional blood samples?

Should payment depend on risks / activities involved?
Conclusion

National and International guidelines needed

Policies to be developed by Institutions and local Ethics Committees
Thank You