Promoting responsible research processes using digital technology, and its impact on research conduct – an experience from Pakistan

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Research Regulation in Pakistan

- Drug Regulatory Authority of Pakistan (DRAP)
  - Biostudy rules 2017
  - Drug research rules
  - Clinical study committee
  - Licensing requirement for CROs, sites, sponsors - 2017
- Pakistan Health Research Council (PHRC) - National Institutes of Health (NIH)
  - National Bioethics Committee (NBC) – Ethics review committee (ERC)
  - Institutional Review Boards (IRBs) or Ethics Review Committees (ERCs)

- No Mechanism for post approval oversight except progress reports requested by few ERCs including NBC ERC that rely upon transparency in investigator reporting
Organization Profile

**Annual budget** Rs. 28 billion (Year 2022)

**Philanthropic spending to date** Rs. 65.635 billion (US$ 586 Million)
- Inpatient & ICU Beds 195
- New registrations 120,18
- Staff 3544

**Hospital Mission Statement**: “To act as a model institution to alleviate the suffering of patients with cancer through the application of modern methods of curative and palliative therapy irrespective of their ability to pay, the education of health care professionals and the public and perform research into the causes and treatment of cancer.”
SKMCH&RC is involved in investigator-initiated studies and participate in clinical trials being conducted at the hospital.
Research Review and Oversight at SKMCH&RC

1. Submission Received
2. Scientific Review & Approval
   - Scientific Review Committee
3. Ethical Review & Approval
   - Institutional Review Board
4. Continuing Review
In 2018 SKM started a central research oversight and archival system, to promote compliance to ethics review standards and responsible research conduct.

Investigators are provided with training of Research conduct on following aspects:

- Good Clinical Practice (GCP)
- IRB approvals & amendments notification
- Management of study records
- Consents process & its documentation
- Appropriate tasks delegation
- Conflict of interest & its management
- Quality Improvement Opportunity (QIO) & Adverse Drug Reaction (ADR) reporting
Oversight Process

1. GCP & Responsible conduct Training
2. Study Initiation
3. Study Follow-up
4. Study Close-out
Evolution during COVID-19 and beyond

- F2F sessions replaced by virtual meetings
- Initial informal discussions with investigators supplemented with video trainings and post training assessments. Additional open access online training resources adopted
- Use of structured templates, regular review of research records leading to timely identification of issues, root cause analysis (RCA) as well as corrective and preventive actions (CAPA)
- Periodic reviews ensured that identified issues are addressed systemically through changes in organizational policy and culture
Demographics of Researchers

- A total of 141 studies were assisted through this system from April 2018 to November 2022.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>75</td>
<td>56%</td>
</tr>
<tr>
<td>Female</td>
<td>58</td>
<td>44%</td>
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</table>

<table>
<thead>
<tr>
<th>Designation</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resident</td>
<td>72</td>
<td>58%</td>
</tr>
<tr>
<td>Fellow</td>
<td>8</td>
<td>6.40%</td>
</tr>
<tr>
<td>Consultants</td>
<td>14</td>
<td>11%</td>
</tr>
<tr>
<td>Nurse</td>
<td>18</td>
<td>15%</td>
</tr>
<tr>
<td>Others</td>
<td>12</td>
<td>10%</td>
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<table>
<thead>
<tr>
<th>Previous Research Experience</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>18</td>
<td>16%</td>
</tr>
<tr>
<td>No</td>
<td>123</td>
<td>84%</td>
</tr>
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</table>
Kirkpatrick Model

- **Level I: Reaction**
  How Does Participants feel about the training?

- **Level II: Learning**
  To what extend participants improve knowledge, skills & attitude

- **Level III: Impact/ Behavior**
  Impact of training, to what extend participants apply what they learned

- **Level IV: Results**
  Was it worth it ? Or is there a positive change in trainees?

For first level assessment 5-point Likert scale and open-ended questions were used.

<table>
<thead>
<tr>
<th>Quality of Training</th>
<th>Very Bad</th>
<th>Bad</th>
<th>Average</th>
<th>Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>29%</td>
<td>71%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Instructor's Effectiveness</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>1%</td>
<td>20%</td>
<td>79%</td>
</tr>
</tbody>
</table>

No specific recommendation to improve the training program received from trainees.
Learning evaluation was done by pre-test and post-test.
We evaluated the third level based on key essential elements of training including proper consent documentation, appropriate task delegation, management of study team changes, protocol amendment approvals records management.

<table>
<thead>
<tr>
<th>Sr.</th>
<th>Contents</th>
<th>Percentage Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>1</td>
<td>Appropriate delegation of tasks</td>
<td>68%</td>
</tr>
<tr>
<td>2</td>
<td>Proper Consent Documentation</td>
<td>66%</td>
</tr>
<tr>
<td>3</td>
<td>Management of Team Changes</td>
<td>52%</td>
</tr>
<tr>
<td>4</td>
<td>Protocol Amendment Approvals</td>
<td>67%</td>
</tr>
<tr>
<td>5</td>
<td>Good Records Management</td>
<td>62%</td>
</tr>
<tr>
<td>6</td>
<td>GCP training</td>
<td>83%</td>
</tr>
</tbody>
</table>
Clinical Research
Ensuring all research studies are meeting essential requirements for record keeping
Target = 100%

*This is a new indicator; department is working to improve compliance by focusing on investigator's training.
Challenges

- Shifting from informal trainings to formal training of investigators
- Balancing an advisory role and open communication while ensuring compliance
- Having defined consequences for misconduct but keeping the intent non-punitive
- Human resource managing the programme: limited staff managing an expanding portfolio
Future Plans

We further aim to enhance Video Education Series to include training on

- Data Sharing and Ownership
- Good Publication Practices
- Research Misconduct
“IF YOU THINK TRAINING IS EXPENSIVE, TRY IGNORANCE.”

and, remember, the definition of ignorance is repeating the same behavior, over and over, and expecting different results!

FOOD FOR THOUGHT!
Thank You