**Reducing Consent Form Length: Stakeholder Support, Evidence-Based Strategies, and Regulatory Requirements**

**BY AMY CORNELI AND JEREMY SUGARMAN**

**Table 1.**
**Study Populations, n (%).**

<table>
<thead>
<tr>
<th>Conference respondents</th>
<th>Conference 1 n = 233</th>
<th>Conference 2 n = 50</th>
<th>Total n = 283</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB member</td>
<td>31 (13.3)</td>
<td>16 (32.0)</td>
<td>47 (16.6)</td>
</tr>
<tr>
<td>IRB administrator</td>
<td>39 (16.7)</td>
<td>19 (38.0)</td>
<td>58 (20.5)</td>
</tr>
<tr>
<td>Clinical investigator</td>
<td>8 (3.4)</td>
<td>4 (8.0)</td>
<td>12 (4.2)</td>
</tr>
<tr>
<td>Research support staff member</td>
<td>127 (54.5)</td>
<td>4 (8.0)</td>
<td>131 (46.3)</td>
</tr>
<tr>
<td>Research sponsor</td>
<td>2 (0.9)</td>
<td>2 (4.0)</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td>Representative of a clinical research organization</td>
<td>3 (1.3)</td>
<td>1 (2.0)</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td>Representative of a contract research organization</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Government regulator</td>
<td>1 (0.4)</td>
<td>1 (2.0)</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Other member of the clinical research community</td>
<td>8 (3.4)</td>
<td>0 (0)</td>
<td>8 (2.8)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (5.6)</td>
<td>3 (6.0)</td>
<td>16 (5.7)</td>
</tr>
</tbody>
</table>

**EDICT stakeholders**

<table>
<thead>
<tr>
<th></th>
<th>First online survey n = 53</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPTN research participants</td>
<td>16 (30.2)</td>
</tr>
<tr>
<td>HPTN chairs, site investigators, site staff members, core staff members</td>
<td>14 (26.4)</td>
</tr>
<tr>
<td>Community representatives</td>
<td>6 (11.3)</td>
</tr>
<tr>
<td>Institutional officials</td>
<td>4 (7.5)</td>
</tr>
<tr>
<td>IRB members</td>
<td>8 (15.1)</td>
</tr>
<tr>
<td>DAIDS representatives</td>
<td>5 (9.4)</td>
</tr>
</tbody>
</table>

1 Some total column percentages do not equal 100 due to rounding.
IRB—institutional review board
EDICT—Effective Delivery of Informed Consent study
HPTN—HIV Prevention Trials Network
DAIDS—Division of AIDS
Table 2.
Agreement Distribution for Statements about the Length of Informed Consent Forms, n (%).1

<table>
<thead>
<tr>
<th>Statement 1</th>
<th>Agreement</th>
<th>Conference 1 n = 243</th>
<th>Conference 2 n = 54</th>
<th>Conference Total n = 297</th>
<th>EDICT stakeholders2 n = 37</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Informed consent forms [ICFs] are generally too long.</strong></td>
<td>Strongly agree</td>
<td>138 (56.8)</td>
<td>39 (72.2)</td>
<td>177 (59.6)</td>
<td>16 (43.2)</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>95 (39.1)</td>
<td>15 (27.8)</td>
<td>110 (37.0)</td>
<td>19 (51.4)</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>8 (3.3)</td>
<td>0 (0)</td>
<td>8 (2.7)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>2 (0.8)</td>
<td>0 (0)</td>
<td>2 (0.7)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement 2</th>
<th>Agreement</th>
<th>Conference 1 n = 238</th>
<th>Conference 2 n = 55</th>
<th>Conference Total n = 293</th>
<th>EDICT stakeholders2 n = 53</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>As long as the essential information is retained, ICFs should be made shorter in length.</strong></td>
<td>Strongly agree</td>
<td>190 (79.8)</td>
<td>46 (83.6)</td>
<td>236 (80.5)</td>
<td>34 (64.2)</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>46 (19.3)</td>
<td>9 (16.4)</td>
<td>55 (18.8)</td>
<td>17 (32.1)</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>1 (0.3)</td>
<td>2 (3.8)</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>1 (0.3)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

1 The total number of conference respondents who answered each question varied, as audience members could choose to answer each question individually. Some total column percentages do not equal 100 due to rounding.
2 HPTN study participants were not asked this question.
Table 3. Support of Strategies for Reducing ICF Length, n (%).  

<table>
<thead>
<tr>
<th>Strategy 1</th>
<th>Agreement</th>
<th>Conference 1 n = 202</th>
<th>Conference 2 n = 49</th>
<th>Conference total n = 251</th>
<th>EDICT, 2 stakeholders n = 53</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grouping study procedures by frequency instead of by study visit</td>
<td>Strongly agree</td>
<td>143 (70.8)</td>
<td>38 (77.6)</td>
<td>181 (72.1)</td>
<td>31 (58.5)</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>51 (25.2)</td>
<td>9 (18.4)</td>
<td>60 (23.9)</td>
<td>13 (24.5)</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>7 (3.5)</td>
<td>1 (2.0)</td>
<td>8 (3.2)</td>
<td>8 (15.1)</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>1 (0.5)</td>
<td>1 (2.0)</td>
<td>2 (0.8)</td>
<td>1 (1.9)</td>
</tr>
</tbody>
</table>

| Strategy 2 | Agreement | Conference 1 n = 177 | Conference 2 n = 47 | Conference total n = 224 | EDICT stakeholders n = 51  
2 |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing reference information about specific study procedures per study visit in an appendix</td>
<td>Strongly agree</td>
<td>101 (57.1)</td>
<td>26 (55.3)</td>
<td>127 (56.7)</td>
<td>21 (41.2)</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>57 (32.2)</td>
<td>16 (34.0)</td>
<td>73 (32.6)</td>
<td>17 (33.3)</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>15 (8.5)</td>
<td>5 (10.6)</td>
<td>20 (8.9)</td>
<td>8 (15.7)</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>4 (2.3)</td>
<td>0 (0)</td>
<td>4 (1.8)</td>
<td>5 (9.8)</td>
</tr>
</tbody>
</table>

| Strategy 3 | Agreement | Conference 1 n = 198 | Conference 2 n = 49 | Conference total n = 247 | EDICT stakeholders n = 44  
4 |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Listing duplicative side effects once instead of for each drug</td>
<td>Strongly agree</td>
<td>64 (32.3)</td>
<td>26 (53.1)</td>
<td>90 (36.4)</td>
<td>22 (50.0)</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>94 (47.5)</td>
<td>14 (28.6)</td>
<td>108 (43.7)</td>
<td>13 (29.5)</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>39 (19.7)</td>
<td>8 (16.3)</td>
<td>47 (19.0)</td>
<td>8 (18.2)</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>1 (0.5)</td>
<td>1 (2.0)</td>
<td>2 (0.8)</td>
<td>1 (2.3)</td>
</tr>
</tbody>
</table>

1 The total number of conference respondents who answered each question varied, as audience members could choose to answer each question individually. Some total column percentages do not equal 100 due to rounding.
2 The EDICT (Effective Delivery of Informed Consent study) data presented here are from the first online survey because the first conference was held prior to the analysis of EDICT’s second online survey.
3 Data are missing from two stakeholders.
4 Only stakeholders associated with the one HPTN study that evaluated multiple drugs were asked this question.