Research on Medical Practices (ROMP): Attitudes of IRB Personnel about Randomization and Informed Consent

Figure 1.
Percent Agreement among PRIM&R Members regarding Which Activities Should Always Trigger Full IRB Review

- Using standard clinical pathways to determine patients’ treatments (n = 536)
- Collecting and analyzing patient data with the intention of improving future practice within a health system (n = 535)
- Collecting and analyzing patient data with the intention of testing hypotheses for generalizable knowledge (n = 534)
- Collecting and analyzing patient data with the intention of publishing the results (n = 535)
- Sharing deidentified patient data with the intention of testing hypotheses for generalizable knowledge (n = 537)
- Randomly assigning patients to receive specific treatments (n = 537)
- Randomly assigning hospitals or clinics to use specific treatments (n = 536)
**Table 1.**
Responses of PRIM&R Members regarding Who May Ethically Obtain Informed Consent for a Study That Randomizes Patients to Different Forms of Usual Care (n = 527)

<table>
<thead>
<tr>
<th>Option</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>260 (49.2%)</td>
</tr>
<tr>
<td>All but the patient’s clinician</td>
<td>166 (31.4%)</td>
</tr>
<tr>
<td>Only the patient’s clinician</td>
<td>50 (9.5%)</td>
</tr>
<tr>
<td>All but a research nurse or study coordinator who is not involved with the patient’s care</td>
<td>27 (5.1%)</td>
</tr>
<tr>
<td>All but an investigator who is not involved with the patient’s care</td>
<td>14 (2.7%)</td>
</tr>
<tr>
<td>Only a research nurse or study coordinator who is not involved with the patient’s care</td>
<td>7 (1.3%)</td>
</tr>
<tr>
<td>Only an investigator who is not involved with the patient’s care</td>
<td>3 (0.6%)</td>
</tr>
</tbody>
</table>

**Table 2.**
Preferences of PRIM&R Members regarding Who Should Obtain Informed Consent for a Study That Randomizes Patients to Different Forms of Usual Care*

<table>
<thead>
<tr>
<th>Option</th>
<th>Most preferred (n = 535)</th>
<th>Least preferred (n = 506)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient’s clinician</td>
<td>189 (35.3%)</td>
<td>276 (54.5%)</td>
</tr>
<tr>
<td>An investigator who is not involved with the patient’s care</td>
<td>160 (29.9%)</td>
<td>100 (19.8%)</td>
</tr>
<tr>
<td>A research nurse or study coordinator who is not involved with the patient’s care</td>
<td>186 (34.8%)</td>
<td>130 (25.7%)</td>
</tr>
</tbody>
</table>

*Participants responded to this prompt: “In your opinion, please indicate your preference for who should obtain informed consent. (Please rank from most preferred to least preferred. Only one selection is allowed for each column.)” Participants used a table similar to this but with a third choice of “less preferred” appearing between the “most preferred” and “least preferred” options.
Figure 2.
Acceptability among PRIM&R Members regarding Waiving Informed Consent for a Study That Randomizes Patients to Different Forms of Usual Care (n = 506)

- Never acceptable: 36.8%
- Rarely acceptable: 25.9%
- Sometimes acceptable: 2.8%
- Usually acceptable: 34.8%

*p < .0001

Figure 3.
Percentage of Agreement among PRIM&R Members regarding Minimum Acceptable and Preferred Approaches to Informed Consent

- Minimum acceptable approach (n = 536):
  - No notification: 2.4%
  - General information: 11.9%
  - Discussion & verbal permission: 16.0%
  - Discussion & written permission*: 69.6%

- Preferred approach (n = 535):
  - No notification: 1.1%
  - General information: 5.2%
  - Discussion & verbal permission: 12.7%
  - Discussion & written permission*: 80.9%

*p ≤ .0001