BY KATHRYN M. PORTER, MILDRED K. CHO, STEPHANIE A. KRAFT, DIANE M. KORNGIEBEL, MELISSA CONSTANTINE, SANDRA SOO-JIN LEE, MAUREEN KELLEY, CYAN JAMES, ELLEN KUWANA, ADRIENNE MEYER, DOUGLAS DIEKEMA, ALEXANDER M. CAPRON, DAVID MAGNUS, AND BENJAMIN S. WILFOND

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)

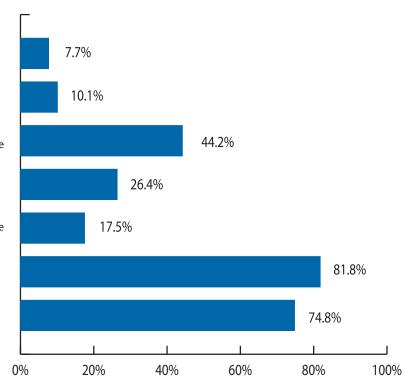
Collecting and analyzing patient data with the intention of testing hypotheses for generalizable knowledge (n = 534)

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)



IRB: Ethics & Human Research January-February 2017

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)

All	260 (49.2%)
All but the patient's clinician	166 (31.4%)
Only the patient's clinician	50 (9.5%)
All but a research nurse or study coordinator who is not involved with the patient's care	27 (5.1%)
All but an investigator who is not involved with the patient's care	14 (2.7%)
Only a research nurse or study coordinator who is not involved with the patient's care	7 (1.3%)
Only an investigator who is not involved with the patient's care	3 (0.6%)

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*

	Most preferred (n = 535)	Least preferred (n = 506)
The patient's clinician An investigator who is not involved with the patient's care A research nurse or study coordinator who is not involved with the patient's care	189 (35.3%) 160 (29.9%) 186 (34.8%)	276 (54.5%) 100 (19.8%) 130 (25.7%)

^{*}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.

JANUARY-FEBRUARY 2017 IRB: ETHICS & HUMAN RESEARCH

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)

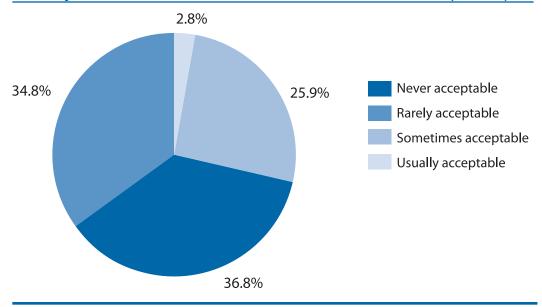
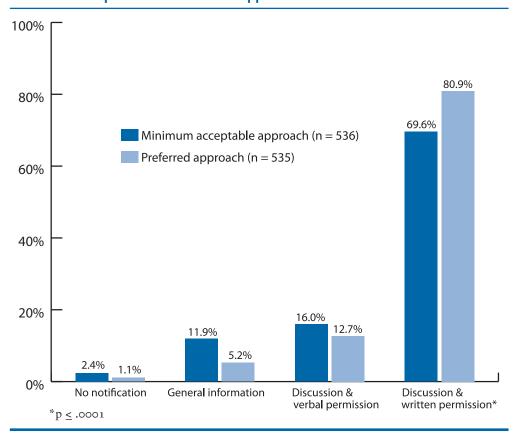


Figure 3.

Percentage of Agreement among PRIM&R Members regarding Minimum

Acceptable and Preferred Approaches to Informed Consent



IRB: Ethics & Human Research January-February 2017