A Study to Evaluate the Effect of Investigator Attendance on the Efficiency of IRB Review

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Figure 1: Abstraction Form Domains

PI Characteristics
PI home department
PI faculty title/rank
PI gender

Protocol Characteristics
Funding source
Whether a clinical trial (i.e., a research project designed to evaluate a new medical treatment, drug, or medical device)
Single vs. multicenter trial
Inclusion of vulnerable population(s)
Health status of subject population
Domestic or international

Review Characteristics
JHMI IRB assignment
Evidence of administrative review
Evidence of external reviews (e.g., conflict of interest, radiation, external IRB)

Outcome Variables
Time elapsed from receipt to approval
Total number of correspondence pieces (including both substantive e-mail and paper)
Number of convened reviews

Table 1: Protocol and Review Characteristics (n = 125)

Clinical trials[a]	66 (52%)
Multisite trial	44 (35%)
Domestic trial	121 (97%)
Includes vulnerable population[b]	31 (25%)
Health status of population	
Healthy	24 (19%)
At risk of disease	6 (5%)
Combination with disease/at-risk of disease	17 (14%)
Diagnosed with disease/medical condition	78 (62%)
Funding source	
Federal	68 (54%)
Industry	18 (14%)
Other	20 (15%)
None	19 (15%)
Administrative review conducted	97 (78%)
Reviewed by additional committee	76 (60%)
Mean time from submission to approval	75 calendar days
Mean number of correspondence pieces per protocol	5.6 pieces
Mean number of convened meetings at which protocol reviewed	1.8

a. Clinical trial was defined as a research program designed to evaluate a new medical treatment, drug, or device. The ultimate purpose of the clinical trial had to be the discovery of new and improved methods of treating diseases and conditions. As such, Phase I studies were considered clinical trials because, although their purpose does not meet the definition above, they are a necessary precursor to efficacy evaluation. On the other hand, studies testing new diagnostic procedures were not defined as clinical trials because they did not include a treatment component.

b. Sample population was considered vulnerable if any of the following were targeted for inclusions: prisoners; staff/employees; students; nursing home residents; terminally ill; pregnant women; fetus/fetal tissue; poor/uninsured; illiterate; institutionalized; handicapped; mentally disabled; cognitively impaired; and emergency department patients. That is, almost any study could encounter a potential subject who was in some way vulnerable. However, this alone would not necessitate the vulnerable population designation. On the other hand, if a study were specifically enrolling subjects with cognitive impairment, etc., then the designation would apply.

Table 2: Cross-Sectional Comparison among IRBs

Review Outcomes	*IRB 1*	*IRB 2*	*IRB 3*	*IRB 5*
Mean time from submission to approval (in calendar days)	74.16 SD = 40.19 Range 24-199	56.56 SD = 40.79 Range 19-218	61.32 SD = 47.32 Range 17-178	69.88 SD = 31.76 Range 27-160
Mean number of correspondence pieces per protocol	4.56 SD = 2.43 Range 1-9	5.08 SD = 2.80 Range 1-9	4.56 SD = 3.24 Range 1-12	6.24 SD = 2.70 Range 1-14
Mean number of convened meetings at which protocol was reviewed	1.76 SD = 0.66 Range 1-3	1.44 SD = 0.51 Range 1-2	1.56 SD = 0.77 Range 1-4	1.68 SD = 0.69 Range 1-3

Table 3: Historical within IRB Comparison: No PI v. PI in Attendance

Review Outcomes	*No PI Attendance* *n = 25*	*PI in Attendance* *n = 25*	*p-value*
Mean time from submission to approval (in calendar days)	113.76 SD = 77.28 Range 23-386	69.88 SD = 31.76 Range 27-160	0.012
Mean number of correspondence per protocol	7.76 SD = 3.47 Range 3-16	6.24 SD = 2.70 Range 1-14	0.090
Mean number of convened meetings at which protocol was reviewed	2.40 SD = 1.19 Range 1-5	1.68 SD = 0.69 Range 1-3	0.009

Diagram 1: Samples