

ANNEX 3
Preliminary Report:
Reasons why research proposals are not granted PAHOERC approval

Number of Proposals		
Total proposals	47	
Total proposals given full review	42	
Original proposals	32	
Original proposals given full review	26	
Accepted proposals	11	23%
rejected proposals	21	45%
Conditionally approved proposals	9	19%
Exempt proposals	5	11%
Pending Proposal	1	2%
Number of proposals requiring revisions	30	64%

Number of Problems by Category		% of proposals reviewed w/issues
Social Value	17	57%
<i>Two or more problems in category</i>	6	20%
<i>Three or more problems in category</i>	1	3%
Scientific Validity	30	100%
<i>Two or more problems in category</i>	27	90%
<i>Three or more problems in category</i>	17	57%
Risk/Benefit Ratio	9	30%
<i>Two or more problems in category</i>	4	13%
<i>Three or more problems in category</i>	0	0%
Informed Consent	20	67%
<i>Two or more problems in category</i>	12	40%
<i>Three or more problems in category</i>	4	13%
Fair Subject Selection	20	67%
<i>Two or more problems in category</i>	8	27%
<i>Three or more problems in category</i>	1	3%
Respect for Enrolled Subjects	10	33%
<i>Two or more problems in category</i>	3	10%
<i>Three or more problems in category</i>	0	0%
Common Other Problems		
Should include more information	15	50%
Community Approval	4	13%

Number of Problems by Sub-Category		
Social Value		
Generalizable knowledge	5	17%
Worthwhile hypothesis	10	33%
Results that can be disseminated	3	10%
No overlap with proven results	6	20%
Scientific validity		
Practicably feasible	5	17%
Valid methods	17	57%
Generally problematic	3	10%
Methods do not address objectives	4	13%
Methods are not explained	9	30%
Test the methods	2	7%

Clear scientific objective	15	50%
The objectives need adjustment	8	27%
The objectives are inconsistent	2	7%
The objectives are not developed	8	27%
Statistical Power	20	67%
Precision	6	20%
Sample Size	17	57%
Lacks general description of stat plan	6	20%
Plausible data-analysis plan	12	40%
Reduces bias/control outside factors	12	40%

Risk/benefit ratio		
Maximized benefits	3	10%
Minimized risks	6	20%
Favorable ratio	4	13%

Informed Consent		
Consent form	20	67%
Clear language	8	27%
Explains risks and benefits	6	20%
Explains objectives	1	3%
Explains basics of study	7	23%
Explains alternatives	4	13%
Include PIs contact information	2	7%
If incapacitated, appropriate proxy	1	3%
Assent for minors	5	17%
Voluntariness--no coercion	2	7%

Fair subject selection		
Selection based on scientific criteria	10	33%
Lacks justification	7	23%
Selection not based on SC	3	10%
Exclusion/inclusion is justified	13	43%
High risk groups are excluded	5	17%
Groups who bear the risks should benefit	0	0%

Respect for enrolled subjects		
Privacy	4	13%
Opportunity to withdraw w/o penalty	0	0%
Provided with new information gained	1	3%
Wellbeing monitored	7	23%