Respondent Type	Number of Responses	Biospecimens Overall	Definition of Human Subjects	*Alternative Proposals	Broad Consent	Notice	Opt- out	Waiver	Single IRB	Extending Common Rule	Safeguards	Posting Consent	Revise and Republish
Patients	245	Responded: 230 (94%) Support: 6 (1Q)(3%) Oppose: 224 (97%)	Responded: 21 (9%) Support: 2 (10%) Oppose: 19 (90%)	A = 3	Responded: 33 (13%) Support: 5 (2Q) (15%) Oppose: 28 (85%)	NA	NA	Responded: 205 (84%) Support: 0 Oppose: 205 (100%)	Responded: 0	Responded: 0	Responded: 0	Responded: 1 Support: 1 Opposed: 0	NA
General Public	906	Responded: 692 (76%) Support: 310 (15Q)(45%) Oppose: 382 (55%)	Responded: 568 (63%) Support: 221 (15Q)(39%) Oppose: 347 (61%)	A = 189 A & B = 1	Responded: 562 (62%) Support: 266 (83Q)(47%) Oppose: 296 (53%)	13 (1%)	29 (3%)	Responded: 115 (13%) Support: 48 (42%) Oppose: 67 (58%)	Responded: 25 (3%) Support: 12 (2Q) (48%) Oppose: 13 (52%)	Responded: 6 (1%) Support: 4 (67%) Oppose: 2 (33%)	Responded: 1 Support: 0 (0%) Oppose: 1 (100%)	Responded: 9 (1%) Support: 2 (1Q) (22%) Oppose: 7 (78%)	21 (2%)
Researchers	401	Responded: 276 (69%) Support: 16 (1Q)(6%) Oppose: 260 (94%)	Responded: 248 (62%) Support: 14 (2Q)(6%) Oppose: 234 (94%)	A = 48 B = 3	Responded: 196 (49%) Support: 65 (53Q)(33%) Oppose: 131 (67%)	58 (14%)	66 (16%)	Responded: 126 (31%) Support: 0 (0%) Oppose: 126 (100%)	Responded: 56 (14%) Support: 48 (86%) Oppose: 8 (14%)	Responded: 8 (2%) Support: 4 (50%) Oppose: 4 (50%)	Responded: 48(12%) Support: 48 (100%) Oppose: 0 (0%)	Responded: 4 (1%) Support: 2 (50%) Oppose: 2 (50%)	8 (2%)
Universities/Medical Centers/IRBs	204	Responded: 145 (71%) Support: 9 (3Q)(6%) Oppose: 136 (94%)	Responded: 117 (57%) Support: 7 (3Q)(6%) Oppose: 110 (94%)	A = 22 B = 1 None = 9	Responded: 129 (63%) Support: 12 (6Q)(10%) Oppose: 117 (91%)	20 (10%)	17 (8%)	Responded: 55 (27%) Support: 1 (2%) Oppose: 54 (98%)	Oppose: 106 (89%)	Responded: 29 (14%) Support: 8 (6Q)(28%) Oppose: 21 (72%)	Responded: 28 (14%) Support: 6 (3Q)(22%) Oppose: 22 (78%)	Responded: 47 (23%) Support: 1 (2%) Oppose: 46 (98%)	50 (25%)
Industry	31	Responded: 27 (87%) Support: 1Q (4%) Oppose: 26 (96%)	Responded: 26 (84%) Support: 0 (0%) Oppose: 26 (100%)	A = 2 B = 1 None = 3	Responded: 17 (84%) Support: 9 (53%) Oppose: 8 (47%)	4 (13%)	4 (13%)	Responded: 1 (3%) Support: 0 (0%) Oppose: 1 (100%)	Responded: 15 (48%) Support: 14 (4Q)(93%) Oppose: 1 (7%)	Responded: 1 (3%) Support: 0 (0%) Oppose: 1 (100%)	Responded: 4 (13%) Support: 1 (25%) Oppose: 3 (75%)	Responded: 9 (29%) Support: 1Q (11%) Oppose: 8 (89%)	2 (6%)
Tribal Nations	13	Responded: 10 (77%) Support: 7 (70%) Oppose: 3 (30%)	Responded: 7 (54%) Support: 7 (100%) Oppose: 0 (0%)	NA	Responded: 10 (77%) Support: 0 (0%) Oppose: 10 (100%)	NA	NA	Responded: 6 (46%) Support: 6 (100%) Oppose: 0 (0%)	Responded: 11 (85%) Support: 0 (0%) Oppose: 11 (100%)	NA	NA	NA	6 (46%)
Advisory and Related Groups	6	Responded: 5 (83%) Support: 0 (0%) Oppose: 5 (100%)	Responded: 4 (67%) Support: 0 (0%) Oppose: 4 (100%)	B = 2	Responded: 3 (50%) Support: 0 (0%) Oppose: 3 (100%)	2 (33%)	2 (33%)	Responded: 2 (33%) Support: 0 (0%) Oppose: 2 (100%)	Responded: 4 (67%) Support: 1 (25%) Oppose: 3 (75%)	NA	Responded: 1 (%) Support: 0 (0%) Oppose: 1 (100%)	Responded: 3 (50%) Support: 1Q (33%) Oppose: 2 (67%)	3 (50%)
Independent IRBs	12	Responded: 3 (25%) Support: 1 (33%) Oppose: 2 (67%)	Responded: 2 (17%) Support: 1Q (50%) Oppose: 1 (50%)	NA	Responded: 3 (25%) Support: 1 (33%) Oppose: 2 (67%)	1 (8%)	NA	Responded: 2 (17%) Support: 0 (0%) Oppose: 2 (100%)	<u>Responded:</u> 6 (50%) <u>Support:</u> 5 (83%) <u>Oppose:</u> 1 (17%)	Responded: 2 (17%) Support: 2 (1Q)(100%) Oppose: 0 (0%)	Responded: 1 (8%) Support: 1 (100%) Oppose: 0 (0%)	Responded: 3 (25%) Support: 1 (33%) Oppose: 2 (67%)	NA
Health Departments	17	Responded: 14 (82%) Support: 3 (2Q)(21%) Oppose: 11 (79%)	Responded: 12 (71%) Support: 4 (2Q)(33%) Oppose: 8 (67%)	A = 2 B = 2	Responded: 11 (65%) Support: 4 (2Q)(36%) Oppose: 7 (64%)	2 (12%)	6 (35%)	Responded: 4 (24%) Support: 2 (50%) Oppose 2 (50%)	Responded: 4 (24%) : Support: 2 (1Q)(50%) Oppose: 2 (50%)	Responded: 2 (12%) Support: 1 (50%) Oppose: 1 (50%)	Responded: 4 (24%) Support: 3 (1Q)(75%) Oppose: 1 (25%)	NA	NA
Biorepositories	13	Responded: 12 (92%) Support: 4 (1Q) (33%) Oppose: 8 (67%)	Responded: 7 (58%) Support: 1 (14%) Oppose: 6 (86%)	A = 3	Responded: 11 (85%) Support: 5 (2 Q) (45%) Oppose: 6 (55%)	1 (8%)	NA	Responded: 5 (38%) Support: 1 (20%) Oppose 4 (80%)	<u>:</u> NA	NA	Responded: 1 (8%) Support: 0 (0%) Oppose: 1 (100%)	NA	NA
Disease Registries	6	Responded: 4 (67%) Support: 1 (25%) Oppose: 3 (75%)	Responded: 3 (50%) Support: 0 (0%) Oppose: 3 (100%)	A = 1	Responded: 2 (33%) Support: 0 (0%) Oppose: 2 (100%)	2 (33%)	NA	Responded: 4 (67%) Support: 1 (25%) Oppose 3 (75%)	Responded: 4 (67%) : Support: 3 (75%) Oppose: 1 (25%)	Responded: 2 (33%) Support: 0 (0%) Oppose: 2 (100%)	NA	Responded: 1 (17%) Support: 0 (0%) Oppose: 1 (100%)	NA
Professional Associations	86	Responded: 58 (67%) Support: 15 (2Q)(26%) Oppose: 43 (74%)	Responded: 44 (51%) Support: 15 (6Q)(34%) Oppose: 29 (66%)	A = 4 B = 2	Responded: 48 (56%) Support: 19 (9Q)(40%) Oppose: 29 (60%)	8 (9%)	11 (13%)	Responded: 20 (23%) Support: 3 (1Q)(15%) Oppose: 17 (85%)	Responded: 43 (50%) Support: 35 (5Q)(81%) Oppose: 8 (19%)	Responded: 13 (15%) Support: 8 (1Q)(62%) Oppose: 5 (38%)	Responded: 20 (23%) Support: 14 (2Q)(70%) Oppose: 6 (30%)	Responded: 6 (7%) Support: 3 (1Q)(50%) Oppose: 3 (50%)	13 (15%)
Advocacy Groups	60	Responded: 44 (73%) Support: 23 (52%) Oppose: 21 (48%)	Responded: 24 (40%) Support: 13 (54%) Oppose: 11 (46%)	A = 1 B = 1	Responded: 30 (50%) Support: 17 (9Q) (57%) Oppose: 13 (43%)	3 (5%)	3 (5%)	Responded: 10 (17%) Support: 2 (20%) Oppose 8 (80%)	Responded: 21 (35%) : Support: 17 (5Q) (81%) Oppose: 4 (19%)	Responded: 12 (20%) Support: 9 (75%) Oppose: 3 (25%)	Responded: 8 (13%) Support: 5 (62.5%) Oppose: 3 (37.5%)	Responded: 3 (5%) Support: 2 (67%) Oppose: 1 (33%)	9 (15%)
Not Applicable	134	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Extension Requests	52	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Total	2186	Responded: 1,520 (76%*) Support: 396 (26Q)(26%) Oppose: 1,124 (74%)	Responded: 1,083 (54%*) Support: 285 (29Q)(26%) Oppose: 798 (74%)	*A = 320 A&B = 1 B = 12 None = 12	Responded: 1,055 (53%*) Support: 403 (166Q)(38%) Oppose: 652 (62%)	114 (6%*)	138 (7%*)	Responded: 555 (28%*) Support: 64 (1Q)(12%) Oppose: 491 (88%)	Responded: 308 (15%*) Support: 150 (20Q)(49%) Oppose: 158 (51%)	Responded: 75 (4%*) Support: 36 (8Q)(48%) Oppose: 39 (52%)	Responded: 116 (6%*) Support: 78 (6Q)(67%) Oppose: 38 (33%)	Responded: 86 (4%*) Support: 14 (4Q)(16%) Oppose: 72 (84%)	112 (6%*)

*Q indicates the "N = 2,000, which excludes number of extension requests and responses that comments that were deemed not applicable to with qualifiers.

*Note - Almost without exception, those recommending Alternatives opposed the proposal to expand the definition of "human subject" and suggested that if OHRP were to move forward with one of the proposals, Alternative A (or in some instances B) would have the least negative impact on research and human health.