Supplemental Digital Table 1

Institutional Offices Conducting Activities in Support of Human Subject Research Not Conducted Under the Clinical and Translational Science Award, According to Part II of the Research Subject Advocacy (RSA) Taskforce Survey, 2010*

	Offices providing RSA services or conducting RSA activities						
Activity	Education	Research Subject Advocate	Quality assurance/ compliance	IRB	Human research protection program	Other	Not conducted
Human subject research training requirements and procedures							
Orientation of investigators/staff to HSP requirements, no. (% of 42)	5 (12)	0 (0)	4 (10)	8 (19)	20 (48)	5 (12)	0 (0)
Maintenance of institutional standard operating procedures for human subjects research, no. (% of 42)	0 (0)	0 (0)	2 (5)	12 (29)	19 (45)	7 (17)	2 (5)
Harmonization of policies for HSP training across departments, no. (% of 41)	1 (2)	1 (2)	3 (7)	9 (22)	20 (49)	3 (7)	4 (10)
Verification of human subject training certification							
Protocol-nonspecific research personnel (e.g. lab/data entry staff), no. (% of 42)	1 (2)	0 (0)	1 (2)	23 (55)	10 (24)	3 (7)	4 (10)
Protocol-specific research personnel, no. (% of 42)	1 (2)	0 (0)	0 (0)	25 (60)	11 (26)	4 (10)	1 (2)
Protocol development							
Study design support/service, no. (% of 41)	3 (7)	0 (0)	0 (0)	6 (15)	1 (2)	24 (59)	7 (17)
Recruitment of participants guidance, no. (% of 41)	3 (7)	0 (0)	0 (0)	11 (27)	3 (7)	18 (44)	6 (15)
Informed consent document development, no. (% of 41)	1 (2)	2 (5)	0 (0)	22 (54)	2 (5)	13 (32)	1 (2)
Informed consent process oversight, no. (% of 42)	1 (2)	3 (7)	3 (7)	20 (48)	6 (14)	6 (14)	3 (7)
HIPAA, no. (% of 42)	0 (0)	0 (0)	6 (14)	21 (50)	7 (17)	8 (19)	0 (0)

DSMP design/development, no. (% of 42)	1 (2)	3 (7)	1 (2)	17 (40)	2 (5)	10 (24)	8 (19)
Protocol review							
Design review, no. (% of 42)	0 (0)	1 (2)	0 (0)	24 (57)	5 (12)	11 (26)	1 (2)
Recruitment plan review, no. (% of 42)	1 (2)	1 (2)	0 (0)	22 (52)	6 (14)	9 (21)	3 (7)
Informed consent process review, no. (% of 42)	1 (2)	3 (7)	0 (0)	28 (67)	5 (12)	3 (7)	2 (5)
Informed consent document review, no. (% of 41)	1 (2)	2 (5)	3 (7)	27 (66)	5 (12)	3 (7)	0 (0)
DSMP review, no. (% of 42)	1 (2)	1 (2)	1 (2)	26 (62)	6 (14)	5 (12)	2 (5)
Protocol implementation							
Verification of initial IRB approval, no. (% of 41)	0 (0)	0 (0)	3 (7)	16 (39)	4 (10)	14 (34)	4 (10)
Verification of program readiness, no. (% of 39)	0 (0)	0 (0)	1 (3)	11 (28)	2 (5)	14 (36)	11 (28)
Monitoring of DSMB, no. (% of 42)	0 (0)	1 (2)	1 (2)	23 (55)	2 (5)	12 (29)	3 (7)
Protocol amendment/revision tracking							
IRB approval obtained (verify), no. (% of 40)	0 (0)	0 (0)	2 (5)	23 (58)	6 (15)	8 (20)	1 (3)
Re-consenting of participant (verify), no. (% of 39)	0 (0)	0 (0)	4 (10)	17 (44)	4 (10)	10 (26)	4 (10)
Addressing rights/safety concerns in real time							
Real-time compliance oversight, no. (% of 42)	0 (0)	5 (12)	9 (21)	14 (33)	5 (12)	5 (12)	4 (10)
Investigation of staff complaints about research conduct, no. (% of 42)	0 (0)	4 (10)	11 (26)	14 (33)	8 (19)	4 (10)	1 (2)
Investigation of participant complaints about research conduct, no. (% of 42)	0 (0)	5 (12)	6 (14)	19 (45)	9 (21)	3 (7)	0 (0)
Safety and compliance monitoring							
Monitoring of AEs tracking/reporting, no. (% of 42)	0 (0)	0 (0)	3 (7)	26 (62)	5 (12)	7 (17)	1 (2)
Monitoring of DSMP execution, no. (% of 41)	0 (0)	0 (0)	1 (2)	22 (54)	4 (10)	7 (17)	7 (17)
Monitoring of IND/IDE, no. (% of 41)	1 (2)	1 (2)	5 (12)	10 (24)	5 (12)	11 (27)	8 (20)

Monitoring of deviation/violation reporting, no. (% of 41)	0 (0)	0 (0)	3 (7)	26 (63)	7 (17)	4 (10)	1 (2)
Audits							
Conducts not-for cause audits, no. (% of 41)	0 (0)	1 (2)	9 (22)	13 (32)	8 (20)	5 (12)	5 (12)
Conducts for cause audits, no. (% of 41)	0 (0)	1 (2)	11 (27)	14 (34)	10 (24)	4 (10)	1 (2)

* HSP indicates human subject protection; HIPAA, Health Insurance Portability and Accountability Act; DSMP, data safety and monitoring plan; IRB, institutional review board; DSMB, Data and Safety Monitoring Board; AE, adverse event; IND/IDE, investigational new drug/investigational device exemption. Education was not assessed for activities not under the Clinical and Translational Science Award so it is not included here.