

PVDOMICS Study

Quality Control Committee (QCC)

MOP Chapter 9: Quality Control and Site Monitoring

Kristin Highland, MD, MSCR

Agenda

- QC Committee members and responsibilities
- QC Reports, planned
- Form completeness
- Item completeness, select forms
- Deviations
- Site visits

Committee Members

- Kristin Highland, MD, Chair
- Steven Mathai, MD, PI Rep
- Erika Berman-Rosenzweig, MD, PI Rep
- Melissa Ricketts, Coordinator Rep
- Heidi Erickson, Coordinator Rep
- Jacqueline Sharp, DCC Rep
- Susan Sherer, DCC Rep
- Margaret (Koko) Park, DCC Rep
- Jose Ramos, DCC Rep
- Suzy Comhair, DCC Rep
- Laura Peterson, DCC Rep
- Milena Radeva, DCC Rep

- Other volunteers?

QCC Responsibilities

- Generation of Reports
 - Adherence to protocol
 - Missing forms/data items
 - Data quality/ invalid data
 - Data inquiries
- Reporting
 - Clinical Centers
 - Steering Committee
 - NHLBI Program Office (including OSMB)
- Site Visits
 - In-person
 - Remote
- Monthly teleconferences



*Data needed in order
to do this!*

Planned QC Reports

- Call attendance
- Enrollment (weekly)
- Form completion (weekly)
 - Overall
 - Patient level
- Adverse events
- Serious adverse events
- Exceptions
- Extensions
- Deviations
- Missing data, by form
- Data quality report
 - By form
 - Cross-check of duplicate data fields
- Core quality data
- Outstanding data queries
- Completion report
- *Others?*

Form Completeness

02/27/2018

Red = <60%

Yellow 61-79%

Green = >80%

Ideally complete forms within 3 days

Enrollment (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 102 Entered N (%)	Completed Study Form 102 Entered N (%)	Overall Form 104 Entered N (%)	Completed Study Form 104 Entered N (%)	Dropped out N
11. Brigham and Women's	79	79	76 (96)	76 (96)	64 (81)	64 (81)	0
21. Columbia	47	45	46 (98)	44 (98)	47 (100)	45 (100)	2
22. Cornell	80	72	74 (93)	70 (97)	77 (96)	72 (100)	0
31. Johns Hopkins	61	55	32 (52)	32 (58)	44 (72)	40 (73)	0
41. Mayo Clinic	138	121	104 (75)	97 (80)	136 (99)	121 (100)	0
51. U. of Arizona	116	100	89 (77)	88 (88)	111 (96)	100 (100)	2
61. Vanderbilt	61	52	58 (95)	52 (100)	60 (98)	52 (100)	1
Total	582	524	479 (82)	459 (88)	539 (93)	494 (94)	5

*Based on Form 100 Initial Enrollment Date

Form 102: PVD Assessment Form

Form 104: Demographics, Employment and Income Form

History Forms (1) (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 103 Entered N (%)	Completed Study Form 103 Entered N (%)	Overall Form 105 Entered N (%)	Completed Study Form 105 Entered N (%)	Overall Form 106 Entered N (%)	Completed Study Form 106 Entered N (%)
11. Brigham and Women's	79	79	64 (81)	64 (81)	56 (71)	56 (71)	63 (80)	63 (80)
21. Columbia	47	45	46 (98)	44 (98)	45 (96)	43 (96)	45 (96)	43 (96)
22. Cornell	80	72	75 (94)	72 (100)	74 (93)	69 (96)	69 (86)	66 (92)
31. Johns Hopkins	61	55	40 (66)	36 (65)	44 (72)	40 (73)	43 (70)	39 (71)
41. Mayo Clinic	138	121	136 (99)	121 (100)	136 (99)	121 (100)	136 (99)	121 (100)
51. U. of Arizona	116	100	110 (95)	100 (100)	110 (95)	99 (99)	111 (96)	100 (100)
61. Vanderbilt	61	52	58 (95)	52 (100)	60 (98)	52 (100)	60 (98)	52 (100)
Total	582	524	529 (91)	489 (93)	525 (90)	480 (92)	527 (91)	484 (92)

Form 103: Non-PVD Comorbidity, Medical and Surgical History

Form 105: Exposure History Form

Form 106: Thrombophilia History Form

History Forms (2) (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 107 Entered N (%)	Completed Study Form 107 Entered N (%)	Overall Form 110 Entered N (%)	Completed Study Form 110 Entered N (%)	Overall Form 121 Entered** N (% of Female)	Completed Study Form 121 Entered** N (% of Female)	Overall Form 206 Entered** N (% of Female)	Completed Study Form 206 Entered** N (% of Female)
11. Brigham and Women's	79	79	63 (80)	63 (80)	61 (77)	61 (77)	28 (54)	28 (54)	37 (71)	37 (71)
21. Columbia	47	45	47 (100)	45 (100)	47 (100)	45 (100)	31 (91)	29 (91)	34 (100)	32 (100)
22. Cornell	80	72	77 (96)	72 (100)	72 (90)	70 (97)	48 (92)	45 (96)	51 (98)	47 (100)
31. Johns Hopkins	61	55	44 (72)	40 (73)	44 (72)	40 (73)	26 (67)	22 (67)	23 (59)	23 (70)
41. Mayo Clinic	138	121	136 (99)	121 (100)	135 (98)	120 (99)	66 (97)	61 (98)	64 (94)	61 (98)
51. U. of Arizona	116	100	110 (95)	100 (100)	111 (96)	100 (100)	79 (96)	72 (100)	68 (83)	68 (94)
61. Vanderbilt	61	52	60 (98)	52 (100)	60 (98)	52 (100)	39 (100)	34 (100)	39 (100)	34 (100)
Total	582	524	537 (92)	493 (94)	530 (91)	488 (93)	317 (87)	291 (88)	316 (86)	302 (91)

Form 107: Review of Family History of Pulmonary Hypertension Form Form 121:
 Female Reproductive History Form
 Form 206: Center Pregnancy Test Results

Physical Exam Forms (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 120 Entered N (%)	Completed Study Form 120 Entered N (%)	Overall Form 131 Entered N (%)	Completed Study Form 131 Entered N (%)	Overall Form 132 Entered N (%)	Completed Study Form 132 Entered N (%)
11. Brigham and Women's	79	79	64 (81)	64 (81)	59 (75)	59 (75)	60 (76)	60 (76)
21. Columbia	47	45	47 (100)	45 (100)	45 (96)	43 (96)	43 (91)	42 (93)
22. Cornell	80	72	72 (90)	69 (96)	75 (94)	71 (99)	74 (93)	70 (97)
31. Johns Hopkins	61	55	43 (70)	39 (71)	45 (74)	41 (75)	59 (97)	53 (96)
41. Mayo Clinic	138	121	136 (99)	121 (100)	136 (99)	121 (100)	135 (98)	120 (99)
51. U. of Arizona	116	100	111 (96)	100 (100)	111 (96)	100 (100)	109 (94)	98 (98)
61. Vanderbilt	61	52	59 (97)	51 (98)	59 (97)	51 (98)	59 (97)	51 (98)
Total	582	524	532 (91)	489 (93)	530 (91)	486 (93)	539 (93)	494 (94)

Form 120: Study Visit Vital Signs Form

Form 131: Waist/Hip Measure Form

Form 132: Bioelectrical Impedance (BIA) Form

Pulmonary Physiology (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 133 Entered N (%)	Completed Study Form 133 Entered N (%)	Overall Form 270/271 Entered N (%)	Completed Study Form 270/271 Entered N (%)
11. Brigham and Women's	79	79	28 (35)	28 (35)	46 (58)	46 (58)
21. Columbia	47	45	41 (87)	41 (91)	39 (83)	39 (87)
22. Cornell	80	72	73 (91)	69 (96)	62 (78)	59 (82)
31. Johns Hopkins	61	55	60 (98)	54 (98)	22 (36)	22 (40)
41. Mayo Clinic	138	121	135 (98)	120 (99)	132 (96)	120 (99)
51. U. of Arizona	116	100	92 (79)	92 (92)	78 (67)	78 (78)
61. Vanderbilt	61	52	57 (93)	49 (94)	56 (92)	50 (96)
Total	582	524	486 (84)	453 (86)	435 (75)	414 (79)

Form 133: 6 Minute Walk Test (6MWT) Form
 Form 270: Pulmonary Function Testing Form
 Form 271: Historical Pulmonary Function Testing

Sleep Forms (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 150 Entered N (%)	Completed Study Form 150 Entered N (%)	Overall Form 151 Entered N (%)	Completed Study Form 151 Entered N (%)	Overall Form 152/155 Entered N (%)	Completed Study Form 152/155 Entered N (%)
11. Brigham and Women's	79	79	50 (67)	50 (67)	8 (24)	8 (24)	8 (24)	8 (24)
21. Columbia	47	45	43 (98)	41 (98)	3 (75)	3 (75)	3 (75)	3 (75)
22. Cornell	80	72	56 (80)	55 (89)	34 (65)	34 (76)	47 (90)	45 (100)
31. Johns Hopkins	61	55	42 (71)	39 (74)	41 (69)	39 (74)	41 (69)	39 (74)
41. Mayo Clinic	138	121	127 (96)	112 (97)	119 (94)	105 (96)	121 (96)	106 (97)
51. U. of Arizona	116	100	21 (19)	19 (20)	20 (18)	18 (19)	20 (18)	18 (19)
61. Vanderbilt	61	52	55 (90)	47 (90)	57 (93)	49 (94)	58 (95)	50 (96)
Total	582	524	394 (71)	363 (73)	282 (63)	256 (65)	298 (67)	269 (68)

Form 150: Clinical Center Participant Initial Sleep Form

Form 151: Participant Sleep Study Questionnaire

Form 152: Clinical Center Sleep Download and Transmittal Form

Form 155: Clinical Center Historical Sleep Study Report Transmission Form

Forms 150/151 not expected if historical sleep study F155 is submitted

HRQoL (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 170 Entered N (%)	Completed Study Form 170 Entered N (%)	Overall Form 171 Entered N (%)	Completed Study Form 171 Entered N (%)	Overall Form 172 Entered N (%)	Completed Study Form 172 Entered N (%)
11. Brigham and Women's	79	79	40 (51)	40 (51)	41 (52)	41 (52)	40 (51)	40 (51)
21. Columbia	47	45	41 (87)	39 (87)	42 (89)	40 (89)	42 (89)	40 (89)
22. Cornell	80	72	76 (95)	69 (96)	74 (93)	68 (94)	75 (94)	68 (94)
31. Johns Hopkins	61	55	60 (98)	54 (98)	60 (98)	54 (98)	60 (98)	54 (98)
41. Mayo Clinic	138	121	135 (98)	120 (99)	135 (98)	120 (99)	135 (98)	120 (99)
51. U. of Arizona	116	100	110 (95)	99 (99)	110 (95)	99 (99)	110 (95)	99 (99)
61. Vanderbilt	61	52	60 (98)	52 (100)	60 (98)	52 (100)	60 (98)	52 (100)
Total	582	524	522 (90)	473 (90)	522 (90)	474 (90)	522 (90)	473 (90)

Form 170: Survey Instrument (SF-36v2) Form

Form 171: Minnesota Living With Heart Failure Questionnaire

Form 172: emPHasis-10 Quality of Life Form

Lung Imaging (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 252/253 Entered N (%)	Completed Study Form 252/253 Entered N (%)	Overall Form 254 Entered N (%)	Completed Study Form 254 Entered N (%)
11. Brigham and Women's	79	79	52 (66)	52 (66)	55 (70)	55 (70)
21. Columbia	47	45	45 (96)	44 (98)	45 (96)	44 (98)
22. Cornell	80	72	68 (85)	68 (94)	70 (89)	69 (96)
31. Johns Hopkins	61	55	13 (21)	13 (24)	21 (40)	21 (46)
41. Mayo Clinic	138	121	123 (89)	114 (94)	107 (86)	100 (91)
51. U. of Arizona	116	100	72 (62)	72 (72)	100 (92)	94 (99)
61. Vanderbilt	61	52	55 (90)	49 (94)	51 (93)	47 (98)
Total	582	524	428 (74)	412 (79)	449 (82)	430 (87)

Form 252: Center Chest CT Scan Data Transmittal Form
 Form 253: Center Historical Chest CT Data Transmittal Form
 Form 254: Ventilation/Perfusion (V/Q) Lung Scan Results
 Form 254 is not completed for healthy control patients

Cardiac Imaging (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 250 Entered N (%)	Completed Study Form 250 Entered N (%)	Overall Form 251 Entered N (%)	Completed Study Form 251 Entered N (%)
11. Brigham and Women's	79	79	22 (28)	22 (28)	53 (67)	53 (67)
21. Columbia	47	45	47 (100)	45 (100)	45 (96)	44 (98)
22. Cornell	80	72	75 (94)	71 (99)	69 (86)	68 (94)
31. Johns Hopkins	61	55	26 (43)	26 (47)	36 (59)	36 (65)
41. Mayo Clinic	138	121	135 (98)	121 (100)	120 (87)	115 (95)
51. U. of Arizona	116	100	112 (97)	100 (100)	106 (91)	100 (100)
61. Vanderbilt	61	52	59 (97)	51 (98)	56 (92)	50 (96)
Total	582	524	476 (82)	436 (83)	485 (83)	466 (89)

250: Echocardiogram (ECHO) Transmittal Form Form

251: Cardiac MRI Transmittal Form

Cardiac Physiology (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 245 Entered N (%)	Completed Study Form 245 Entered N (%)	Overall Subjects without Control PIDs Enrolled* N	Completed Study Subjects without Control PIDs N	Overall Form 280 Entered N (%)	Completed Study Form 280 Entered N (%)	Overall Form 290/291 Entered N (%)	Completed Study Form 290/291 Entered N (%)
11. Brigham	79	79	56 (71)	56 (71)	79	79	63 (80)	63 (80)	54 (68)	54 (68)
21. Columbia	47	45	47 (100)	45 (100)	47	45	43 (91)	41 (91)	42 (89)	42 (93)
22. Cornell	80	72	76 (95)	72 (100)	79	72	71 (90)	69 (96)	64 (80)	64 (89)
31. Johns Hopkins	61	55	41 (67)	35 (64)	52	46	36 (69)	36 (78)	22 (36)	22 (40)
41. Mayo Clinic	138	121	129 (93)	118 (98)	125	110	71 (57)	70 (64)	16 (12)	16 (13)
51. U. of Arizona	116	100	109 (94)	100 (100)	109	95	91 (83)	90 (95)	19 (16)	19 (19)
61. Vanderbilt	61	52	60 (98)	52 (100)	55	48	54 (98)	48 (100)	58 (95)	52 (100)
Total	582	524	518 (89)	478 (91)	546	495	429 (79)	417 (84)	275 (47)	269 (51)

Form 245: Center Electrocardiogram (ECG) Data Transmittal Form
 Form 290: Center Cycle Ergometer Non-Invasive CPET

Form 280: Clinical Center Right Heart Catheterization
 Form 291: Center Cycle Ergometer Invasive CPET

Study Center (Clinical) Labs (1) (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 200 Entered N (%)	Completed Study Form 200 Entered N (%)	Overall Form 201 Entered N (%)	Completed Study Form 201 Entered N (%)	Overall Form 202 Entered N (%)	Completed Study Form 202 Entered N (%)
11. Brigham and Women's	79	79	48 (61)	48 (61)	47 (59)	47 (59)	28 (35)	28 (35)
21. Columbia	47	45	42 (89)	40 (89)	44 (94)	42 (93)	43 (91)	41 (91)
22. Cornell	80	72	73 (91)	67 (93)	58 (73)	52 (72)	59 (74)	52 (72)
31. Johns Hopkins	61	55	33 (54)	33 (60)	34 (56)	34 (62)	32 (52)	32 (58)
41. Mayo Clinic	138	121	129 (93)	119 (98)	129 (93)	119 (98)	127 (92)	117 (97)
51. U. of Arizona	116	100	86 (74)	86 (86)	96 (83)	96 (96)	88 (76)	88 (88)
61. Vanderbilt	61	52	60 (98)	52 (100)	60 (98)	52 (100)	55 (90)	51 (98)
Total	582	524	471 (81)	445 (85)	468 (80)	442 (84)	432 (74)	409 (78)

Form 200: Center CBC with Differential Results

Form 201: Center Complete Metabolic Panel (CMP) Results Form 202:

Center Antinuclear Antibody (ANA) Results

Study Center (Clinical) Labs (2) (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 203 Entered N (%)	Completed Study Form 203 Entered N (%)	Overall Form 204 Entered N (%)	Completed Study Form 204 Entered N (%)	Overall Form 205 Entered N (%)	Completed Study Form 205 Entered N (%)	Overall Form 207 Entered N (%)	Completed Study Form 207 Entered N (%)
11. Brigham and Women's	79	79	12 (15)	12 (15)	15 (19)	15 (19)	46 (58)	46 (58)	50 (63)	50 (63)
21. Columbia	47	45	42 (89)	40 (89)	42 (89)	40 (89)	44 (94)	42 (93)	45 (96)	43 (96)
22. Cornell	80	72	72 (90)	66 (92)	60 (75)	55 (76)	64 (80)	60 (83)	0 (0)	0 (0)
31. Johns Hopkins	61	55	35 (57)	35 (64)	35 (57)	35 (64)	36 (59)	36 (65)	6 (9.8)	6 (11)
41. Mayo Clinic	138	121	127 (92)	117 (97)	126 (91)	117 (97)	124 (90)	114 (94)	124 (90)	113 (93)
51. U. of Arizona	116	100	95 (82)	95 (95)	91 (78)	91 (91)	94 (81)	94 (94)	0 (0)	0 (0)
61. Vanderbilt	61	52	58 (95)	52 (100)	57 (93)	51 (98)	58 (95)	50 (96)	0 (0)	0 (0)
Total	582	524	441 (76)	417 (80)	426 (73)	404 (77)	466 (80)	442 (84)	225 (39)	212 (40)

Form 203: Center HIV Antigen/Antibody Screen Result
Form 204: Center Hepatitis Screen Result
Form 205: Center Prothrombin Time (PT) Results

Two Week Telephone Follow-Up (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled* N	Completed Study Subjects N	Overall Form 185 Entered N (%)	Completed Study Form 185 Entered N (%)
11. Brigham and Women's	61	61	2 (3.3)	2 (3.3)
21. Columbia	34	32	24 (71)	24 (75)
22. Cornell	58	48	32 (55)	32 (67)
31. Johns Hopkins	47	40	10 (21)	10 (25)
41. Mayo Clinic	81	55	42 (52)	25 (45)
51. U. of Arizona	89	70	68 (76)	65 (93)
61. Vanderbilt	54	41	48 (89)	39 (95)
Total	424	347	226 (53)	197 (57)

Biorepository Collection 1 (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled N	F300: Drawing N (% of enrolled)	F301: Processing N (%)	F335: RT Shipment Log N (%)	F320: Urine Collection N (%)	F321: Urine Processing N (%)	F330: Storage Log N (%)	Completed Study Subjects* N	Completed Study Blood C1 Done** N (%)
11. Brigham and Women's	79	60 (75.9)	60 (75.9)	68 (86.1)	57 (72.2)	29 (57)	72 (91.1)	79	79 (100.0)
21. Columbia	47	27 (57.4)	25 (53.2)	42 (89.4)	45 (95.7)	7 (88)	41 (87.2)	47	43 (91.5)
22. Cornell	80	68 (85.0)	75 (93.8)	78 (97.5)	70 (87.5)	56 (90)	77 (96.3)	72	71 (98.6)
31. Johns Hopkins	61	42 (68.9)	43 (70.5)	58 (95.1)	44 (72.1)	41 (69)	50 (82.0)	55	52 (94.5)
41. Mayo Clinic	138	130 (94.2)	130 (94.2)	138 (100.0)	130 (94.2)	128 (93)	138 (100.0)	120	120 (100.0)
51. U. of Arizona	117	116 (99.1)	114 (97.4)	116 (99.1)	114 (97.4)	106 (98)	116 (99.1)	100	100 (100.0)
61. Vanderbilt	61	59 (96.7)	60 (98.4)	61 (100.0)	60 (98.4)	60 (98)	61 (100.0)	52	52 (100.0)
Total	583	502 (86.1)	507 (87.0)	561 (96.2)	520 (89.2)	427 (88)	555 (95.2)	525	517 (98.5)

Biorepository Collection 2 (as of 02/27/2018)

Clinic Center	Overall Subjects Enrolled N	F304/7: Drawing* N (%)	F305/8: PAXgene Processing* N (%)	F306/9: Processing* N (%)	F330: Storage Log N (%)	Completed Study Subjects** N	Completed Study Blood C2 Done*** N (%)
11. Brigham and Women's	79	50 (63.3)	50 (63.3)	50 (63.3)	73 (92.4)	79	73 (92.4)
21. Columbia	47	26 (55.3)	24 (51.1)	24 (51.1)	41 (87.2)	47	41 (87.2)
22. Cornell	80	63 (78.8)	73 (91.3)	73 (91.3)	76 (95.0)	72	71 (98.6)
31. Johns Hopkins	61	39 (63.9)	22 (36.1)	24 (39.3)	38 (62.3)	55	38 (69.1)
41. Mayo Clinic	138	126 (91.3)	115 (83.3)	126 (91.3)	135 (97.8)	120	120 (100.0)
51. U. of Arizona	117	113 (96.6)	111 (94.9)	111 (94.9)	113 (96.6)	100	100 (100.0)
61. Vanderbilt	61	59 (96.7)	59 (96.7)	59 (96.7)	61 (100.0)	52	52 (100.0)
Total	583	476 (81.6)	454 (77.9)	467 (80.1)	537 (92.1)	525	495 (94.3)

Item Completeness, select forms

11/03/2017

Form 200: CBC (as of 11/03/2017)

Factor	11. Brigham and Women's (N=8)		21. Columbia (N=12)		22. Cornell (N=52)		31. Johns Hopkins (N=31)		41. Mayo Clinic (N=79)		51. U. of Arizona (N=69)		61. Vanderbilt (N=31)	
	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)
Total WBC (K/ul)		(5.30, 10.9)		(3.50, 11.6)		(2.10, 12.6)		(4.40, 12.1)		(2.70, 14.1)		(2.90, 15.4)		(3.50, 13.5)
Hemoglobin (g/dL)		(11.7, 14.9)		(10.7, 18.0)		(8.90, 18.6)		(8.00, 17.1)		(8.80, 18.3)		(9.50, 20.2)		(10.7, 17.2)
Hematocrit (%)		(35.0, 44.7)		(32.7, 56.6)		(26.0, 53.9)		(27.0, 57.6)		(29.0, 55.7)		(30.0, 63.5)		(34.0, 50.0)
Platelet count (K/ul)		(130.0, 418.0)		(115.0, 268.0)		(71.0, 900.0)		(98.0, 409.0)		(53.0, 507.0)		(65.0, 349.0)		(67.0, 386.0)
Mean Platelet Volume (MPV)(fL)		(10.1, 13.3)		(9.90, 12.7)		(7.20, 10.9)		(9.00, 12.4)	79	(., .)		(7.00, 12.4)		(9.30, 13.5)
Neutrophils (%)		(53.2, 73.5)		(43.8, 80.3)		(27.8, 83.1)		(38.0, 89.4)	1	(42.9, 93.5)		(43.0, 85.0)		(31.9, 86.7)
Lymphocytes (%)		(14.1, 33.2)		(12.6, 48.9)		(8.10, 48.8)		(5.20, 52.0)	1	(3.10, 45.5)		(7.50, 44.0)		(7.50, 60.0)
Monocytes (%)		(4.40, 11.7)		(4.20, 8.70)		(2.70, 14.8)		(4.00, 11.4)	1	(3.30, 23.7)		(3.00, 96.3)		(3.30, 13.9)
Basophils (%)		(0.33, 1.32)		(0.29, 1.59)		(0.00, 1.85)	23	(0.00, 6.30)	1	(0.10, 2.37)		(0.00, 9.88)		(0.20, 1.56)
Eosinophils (%)		(0.20, 6.80)		(0.80, 15.5)		(0.00, 11.4)		(0.00, 20.0)	1	(0.00, 9.50)		(0.30, 9.00)		(0.00, 6.60)

Form 201: CMP (as of 11/03/2017)

Factor	11. Brigham and Women's (N=7)		21. Columbia (N=9)		22. Cornell (N=39)		31. Johns Hopkins (N=33)		41. Mayo Clinic (N=77)		51. U. of Arizona (N=67)		61. Vanderbilt (N=31)	
	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)	N Miss	(min, max)
Total protein (g/dL)		(5.70, 8.60)		(7.00, 8.70)		(5.40, 8.60)		(5.80, 8.70)	2	(5.40, 8.20)		(5.80, 9.00)		(6.20, 8.60)
Albumin (g/dL)		(2.90, 4.20)		(3.80, 4.60)		(3.20, 4.70)		(3.40, 5.50)	1	(2.80, 4.80)		(3.10, 4.60)		(3.30, 4.40)
Calcium (mg/dL)		(8.60, 9.30)		(8.80, 9.60)		(8.60, 11.5)		(8.70, 10.4)	1	(8.40, 11.1)		(8.00, 10.9)		(8.50, 10.0)
Total bilirubin (mg/dL)		(0.30, 1.10)		(0.30, 0.90)		(0.20, 3.70)		(0.20, 3.50)	2	(0.20, 5.40)		(0.20, 2.30)		(0.30, 1.60)
Alkaline phosphatase (U/L)		(48.0, 165.0)		(36.0, 196.0)		(34.0, 228.0)		(35.0, 135.0)	3	(34.0, 238.0)		(30.0, 263.0)		(32.0, 131.0)
Aspartate aminotransferase (AST) (U/L)		(17.0, 94.0)		(8.00, 130.0)		(9.00, 82.0)		(12.0, 160.0)	3	(12.0, 77.0)		(7.00, 64.0)		(15.0, 47.0)
Alanine aminotransferase (ALT) (U/L)		(8.00, 85.0)		(10.0, 50.0)		(10.0, 60.0)		(10.0, 40.0)	2	(11.0, 119.0)		(6.00, 86.0)		(6.00, 52.0)
Glucose (mg/dL)		(73.0, 100.0)		(53.0, 134.0)		(69.0, 241.0)		(37.0, 165.0)	1	(74.0, 209.0)		(65.0, 230.0)		(63.0, 127.0)
Blood urea nitrogen (BUN) (mg/dL)		(9.00, 35.0)		(6.00, 33.0)		(9.00, 35.0)		(10.0, 32.0)	1	(7.00, 49.0)		(6.00, 98.0)		(7.00, 48.0)
Serum Creatinine (mg/dL)		(0.80, 1.27)		(0.48, 1.55)		(0.45, 1.60)		(0.60, 2.20)	1	(0.50, 2.60)		(0.54, 2.90)		(0.60, 2.52)
Sodium (mmol/L)		(133.0, 144.0)		(137.0, 144.0)		(134.0, 144.0)		(136.0, 147.0)	1	(132.0, 147.0)		(133.0, 143.0)		(134.0, 143.0)
Potassium (mmol/L)		(3.40, 4.50)		(3.40, 4.80)		(3.00, 5.10)		(3.40, 5.00)	1	(3.50, 5.40)		(3.10, 6.00)		(2.80, 4.40)
Chloride (mmol/L)		(95.0, 108.0)		(98.0, 104.0)		(94.0, 109.0)		(94.0, 109.0)	1	(90.0, 111.0)		(91.0, 111.0)		(92.0, 114.0)
CO2 (mmol/L)		(20.0, 30.0)		(19.0, 27.0)		(21.0, 33.0)		(20.0, 39.0)	2	(19.0, 33.0)		(18.0, 37.0)		(17.0, 32.0)

Form 202 (ANA) and Form 205 (PT) (as of 11/03/2017)

Factor	11. Brigham and Women's		21. Columbia		22. Cornell		31. Johns Hopkins		41. Mayo Clinic		51. U. of Arizona		61. Vanderbilt	
Antinuclear Antibody (ANA) (Form 202)	N Miss	N (%) (N = 8)	N Miss	N (%) (N = 9)	N Miss	N (%) (N = 40)	N Miss	N (%) (N = 31)	N Miss	N (%) (N = 82)	N Miss	N (%) (N = 64)	N Miss	N (%) (N = 30)
Obtained by IFA	4	4(50.0)		7(77.8)	7	33(82.5)	24	7(22.6)	1	1(1.22)		27(42.2)		25(83.3)
Obtained by Immunoassay		0 (0)		2(22.2)		0 (0)		0 (0)		80(97.6)		45(70.3)		4(13.3)
Prothrombin Time Results (Form 205)		(min, max) (N=8)		(min, max) (N=10)		(min, max) (N=52)		(min, max) (N = 33)		(min, max) (N = 78)		(min, max) (N = 67)		(min, max) (N = 31)
PT Sec (sec)		(10.6, 29.2)		(12.6, 23.5)		(10.2, 35.9)		(9.80, 29.9)		(9.50, 39.7)		(9.90, 25.7)		(12.5, 26.4)
PT INR		(1.00, 2.80)		(1.00, 2.10)		(0.90, 3.00)		(0.90, 3.00)		(0.90, 3.60)		(0.90, 2.30)		(1.00, 2.50)

Form 280:Right Heart Catheterization (as of 11/03/2017)

Factor	BWH		Columbia		Cornell		Johns Hopkins		Mayo		Arizona		Vanderbilt	
	N m i s s		N m i s s		N m i s s		N m i s s		N m i s s		N m i s s		N m i s s	
		8/8		3/3		47/47		5/27		66/66		54/54		29/29
RHC done?	0	.	0	.	0	.	1	.	0	.	0	.	0	.
Yes		8 (100%)		3 (100%)		47 (100%)		25 (96%)		66 (100%)		54 (100%)		29 (100%)
No,		0		0		0		1 (4%)		0		0		0
LHC done?	0	.	0	.	1	.	0	.	0	.	0	.	0	.
No		8 (100%)		3 (100%)		45 (98%)		25 (100%)		56 (85%)		53 (98%)		23 (79%)
Yes		0		0		1 (2%)		0		10 (15%)		1 (2%)		6 (21%)
Venous access	0	.	0	.	1	.	0	.	0	.	0	.	0	.
1=Internal jugular		8 (100%)		3 (100%)		5 (11%)		24 (96%)		66 (100%)		0		26 (90%)
2=Antecubital vein		0		0		0		0		0		54 (100%)		0
3=Femoral vein		0		0		41 (89%)		1 (4%)		0		0		3 (10%)

Form 280:Right Heart Catheterization (as of 11/03/2017)

Factor	BWH		Columbia		Cornell		Johns Hopkins		Mayo		Arizona		Vanderbilt	
	N m i s s	Ns: Forms= 8	N m i s s	Ns: Forms=3	N m i s s	Ns: Forms= 47	N m i s s	Ns: Forms= 27 w/ RHC=25	N m i s s	Ns: Forms= 66	N m i s s	Ns: Forms= 54	N m i s s	Ns: Forms= 29
Arterial Oxygen Saturation (Art O2) (%)	8	[-., .]	3	[-., .]	47	[-., .]	24	[78.0, 78.0]	27	[69.0, 98.0]	54	[-., .]	29	[-., .]
Right Atrium (RA) Mean Pressure (Spontaneous Breathing)	0	[1.000, 23]	0	[1.000, 3.000]	1	[1.000, 21]	0	[0, 20]	2	[0, 24]	0	[0, 17]	0	[2.000, 19]
Right Atrium (RA) Mean Pressure (End-Expiratory Hold)	6	[0, 0]	0	[0, 3]	0	[0, 23]	0	[2.000, 20]	2	[1.000, 22]	0	[0, 18]	0	[5.000, 21]
RA Peak 'a wave' Pressure (Spontaneous Breathing)	0	[4.000, 21]	0	[3.000, 4.000]	1	[2.000, 25]	0	[1.000, 26]	2	[1.000, 37]	0	[2.000, 27]	1	[7.000, 24]
RA Peak 'a wave' Pressure (End-Expiratory Hold)	6	[0, 0]	0	[2.000, 6.000]	0	[3.000, 26]	0	[3.000, 25]	2	[3.000, 24]	0	[2.000, 25]	0	[7.000, 24]
RA Peak 'v wave' Pressure (Spontaneous Breathing)	0	[2.000, 29]	0	[2.000, 3.000]	1	[1.000, 22]	0	[2.000, 24]	2	[1.000, 40]	0	[0, 24]	1	[3.000, 23]
RA Peak 'v wave' Pressure (End-Expiratory Hold)	6	[0, 0]	0	[2.000, 6.000]	0	[0, 24]	0	[2.000, 22]	2	[1.000, 35]	0	[1.000, 23]	1	[5.000, 21]
RA Oxygen Saturation (RA sat) (%)	6	[0, 0]	0	[70.0, 73.0]	4	[43.0, 83.0]	0	[57.0, 81.0]	10	[41.0, 79.0]	0	[49.0, 76.0]	1	[50.0, 82.0]

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns: Forms= 8	N m i s s	Ns: Forms=3	N m i s s	Ns: Forms= 47	N m i s s	Ns: Forms= 27 w/ RHC=25	N m i s s	Ns: Forms= 66	N m i s s	Ns: Forms= 54	N m i s s	Ns: Forms= 29
RV SBP(Spontaneous Breathing)	0	[37.0, 78.0]	0	[52.0, 59.0]	1	[22.0, 125]	0	[16.0, 85.0]	2	[19.0, 119]	0	[22.0, 101]	0	[28.0, 106]
RV SBP (End-Expiratory Hold)	6	[0, 0]	0	[50.0, 51.0]	1	[23.0, 125]	0	[18.0, 86.0]	8	[19.0, 119]	0	[10.0, 99.0]	0	[29.0, 108]
RV EDP(Spontaneous Breathing)	0	[2.000, 17]	0	[0, 0]	2	[-4.000, 18]	0	[3.000, 19]	2	[0, 17]	0	[0, 52]	0	[4.000, 25]
RV EDP(End-Expiratory Hold)	6	[0, 0]	0	[0, 1]	1	[-5.000, 20]	0	[2.000, 18]	8	[0, 15]	0	[0, 23]	0	[5.000, 26]
PCWP mean (a wave) (Spontaneous)	0	[5.000, 21]	0	[5.000, 12]	2	[3.000, 29]	0	[5.000, 22]	2	[1.000, 31]	0	[3.000, 23]	0	[4.000, 33]
PCWP mean (a wave)(End-Exp)	6	[0, 0]	0	[7.000, 12]	2	[2.000, 30]	0	[4.000, 25]	2	[5.000, 32]	0	[2.000, 26]	0	[7.000, 41]
PCWP peak (a wave) (Spontaneous)	0	[6.000, 22]	0	[7.000, 16]	2	[4.000, 30]	0	[8.000, 25]	2	[1.000, 31]	0	[6.000, 35]	0	[6.000, 33]
PCWP peak (a wave) (End-Exp)	6	[0, 0]	0	[10.0, 20.0]	2	[3.000, 30]	1	[6.000, 25]	2	[3.000, 30]	0	[5.000, 35]	0	[8.000, 43]
PCWP peak (v wave) (Spontaneous)	0	[5.000, 23]	0	[6.000, 12]	2	[4.000, 38]	0	[6.000, 23]	2	[5.000, 55]	0	[6.000, 34]	0	[3.000, 59]
PCWP peak (v wave) (End-Expiratory)	6	[0, 0]	0	[9.000, 13]	2	[3.000, 38]	1	[4.000, 23]	2	[7.000, 50]	0	[5.000, 34]	0	[7.000, 41]
PCWP Oxygen Saturation %)	6	[0, 0]	0	[70.0, 73.0]	5	[48.0, 97.0]	1	[0, 99]	2	[58.0, 99.0]	11	[10.0, 100]	1	[55.0, 99.0]

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns: Forms= 8	N m i s s	Ns: Forms=3	N m i s s	Ns: Forms= 47	N m i s s	Ns: Forms= 27 w/ RHC=25	N m i s s	Ns: Forms= 66	N m i s s	Ns: Forms= 54	N m i s s	Ns: Forms= 29
Pulmonary Artery (PA) Systolic Pressure (mmHg) (Spontaneous Breathing)	0	[33.0, 80.0]	0	[52.0, 52.0]	2	[19.0, 125]	0	[13.0, 85.0]	2	[19.0, 126]	0	[20.0, 99.0]	0	[12.0, 97.0]
Pulmonary Artery (PA) Systolic Pressure (mmHg) (End-Expiratory Hold)	6	[0, 0]	0	[50.0, 52.0]	1	[18.0, 120]	0	[14.0, 86.0]	3	[18.0, 124]	1	[21.0, 100]	0	[28.0, 105]
PA Diastolic Pressure (mmHg) (Spontaneous Breathing)	0	[14.0, 41.0]	0	[20.0, 28.0]	2	[10.0, 60.0]	0	[7.000, 44]	2	[2.000, 66]	0	[5.000, 40]	0	[9.000, 49]
PA Diastolic Pressure (mmHg) (End-Expiratory Hold)	6	[0, 0]	0	[22.0, 22.0]	1	[10.0, 62.0]	0	[7.000, 82]	3	[4.000, 55]	1	[4.000, 38]	0	[13.0, 55.0]
PA Mean Pressure measured from Mean PA line by machine (Spontaneous Breathing)	0	[25.0, 54.0]	0	[34.0, 36.0]	2	[14.0, 82.0]	0	[9.000, 53]	2	[12.0, 85.0]	0	[10.0, 63.0]	0	[10.0, 61.0]
PA Mean Pressure measured from Mean PA line by machine (End-Expiratory Hold)	6	[0, 0]	0	[32.0, 37.0]	1	[14.0, 80.0]	0	[10.0, 56.0]	3	[11.0, 83.0]	1	[9.000, 61]	1	[18.7, 71.7]
PA Mean Pressure (calculated) (Spontaneous Breathing)	0	[20.3, 53.0]	0	[30.7, 36.0]	2	[13.0, 81.7]	0	[9.000, 54.67]	2	[8.33, 81.33]	0	[10.0, 58.7]	0	[10.0, 59.7]
PA Mean Pressure (calculated) (End-Expiratory Hold)	6	[0, 0]	0	[31.3, 32.0]	1	[13.3, 77.3]	0	[10.0, 71.3]	3	[10.0, 78.0]	1	[9.67, 56.67]	0	[18.7, 71.7]
PA Oxygen Saturation (PA sat) (%)	0	[21.0, 69.0]	0	[70.0, 71.0]	1	[46.0, 81.0]	0	[56.0, 78.0]	0	[43.0, 82.0]	0	[49.0, 81.0]	0	[52.0, 82.0]

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns: Forms= 8	N m i s s	Ns: Forms=3	N m i s s	Ns: Forms= 47	N m i s s	Ns: Forms= 27 w/ RHC=25	N m i s s	Ns: Forms= 66	N m i s s	Ns: Forms= 54	N m i s s	Ns: Forms= 29
Were Resting RHC Thermodilution CO measurements done? 0=No 1=Yes	0	. . 8 (100%) 0	0	. . 1 (33%) 2 (67%)	0	. . 1 (2%) 46 (98%)	0	. . 0 25 (100%)	0	. . 0 66 (100%)	0	. . 2 (4%) 52 (96%)	0	. . 0 29 (100%)
TDCO (L/min) - measurement 1	.	--	0	[5.10, 5.10]	0	[2.20, 8.20]	0	[2.60, 50]	0	[2.60, 43.4]	0	[3.80, 10.7]	0	[2.20, 7.90]
TDCO (L/min) - measurement 2	.	--	0	[4.70, 4.70]	0	[2.40, 9.70]	0	[2.40, 47]	0	[2.50, 9.30]	0	[3.54, 11.8]	0	[2.23, 8.20]
TDCO (L/min) - measurement 3	.	--	0	[4.70, 4.70]	1	[2.40, 8.50]	0	[1.30, 51]	0	[2.50, 9.50]	2	[3.52, 10.5]	0	[2.23, 8.000]
N of measurements taken to get 3 measures with < 10% variability	.	[1.000, 8.000]	0	[4.000, 4.000]	0	[3.000, 5.000]	0	[3.000, 7.000]	2	[1.000, 6.000]	2	[3.000, 8.000]	0	[3.000, 5.000]
Were Direct Fick Cardiac Output Measurements done? 0=No 1=Yes	0	. . 0 8 (100%)	0	. . 3 (100%) 0	0	. . 47 (100%) 0	0	. . 25 (100%) 0	3	. . 8 (13%) 55 (87%)	0	. . 9 (17%) 45 (83%)	0	. . 29 (100%) 0
Resting VO2 (measured) (ml/kg/min)	5	[3.96, 50.7]	.	--	.	--	.	--	0	[1.43, 4.30]	1	[2.10, 4.15]	.	--
Direct Fick Cardiac Output (L/min)	0	[1.83, 6.73]	.	--	.	--	.	--	0	[1.80, 10.47]	0	[3.62, 7.000]	.	--
Direct Fick Cardiac Index (L/min/m2)	0	[1.01, 2.98]	.	--	.	--	.	--	0	[0.820, 4.45]	0	[1.99, 3.90]	.	--

RHC Challenges (as of 11/03/2017)

Factor	BWH		Columbia		Cornell		Johns Hopkins		Mayo		Arizona		Vanderbilt	
	N		N		N		N		N		N		N	
	M		M		M		M		M		M		M	
	I		I		I		I		I		I		I	
	S		S		S		S		S		S		S	
	S	N = 8	S	N = 3	S	N = 47	S	N = 25	S	N = 66	S	N=54	S	N=29
Oxygen Challenge? 1=Yes 2=No, contraindicated 3=No, logistical issues	0	. 5 (63%) 1 (13%) 2 (25%)	0	. 3 (100%) 0 0	0	. 47 (100%) 0 0	0	. 25 (100%) 0 0	1	. 65 (100%) 0 0	0	. 47 (87%) 7 (13%) 0	0	. 28 (97%) 0 1 (3%)
Was Vasodilatory Challenge done? 1=Yes 2=No, contraindicated 3=No, logistical issues	0	. 6 (75%) 2 (25%) 0	0	. 3 (100%) 0 0	0	. 42 (89%) 3 (6%) 2 (4%)	0	. 22 (88%) 2 (8%) 1 (4%)	1	. 60 (92%) 4 (6%) 1 (2%)	0	. 49 (91%) 5 (9%) 0	0	. 27 (93%) 2 (7%) 0
Fluid Challenge? 1=Yes 2=No, doing iCPET 3=No, logistical issues	0	. 0 3 (38%) 5 (63%)	0	. 3 (100%) 0 0	0	. 43 (91%) 0 4 (9%)	0	. 23 (92%) 0 2 (8%)	3	. 1 (2%) 59 (94%) 3 (5%)	0	. 14 (26%) 36 (67%) 4 (7%)	0	. 26 (90%) 0 3 (10%)

RHC Key Points

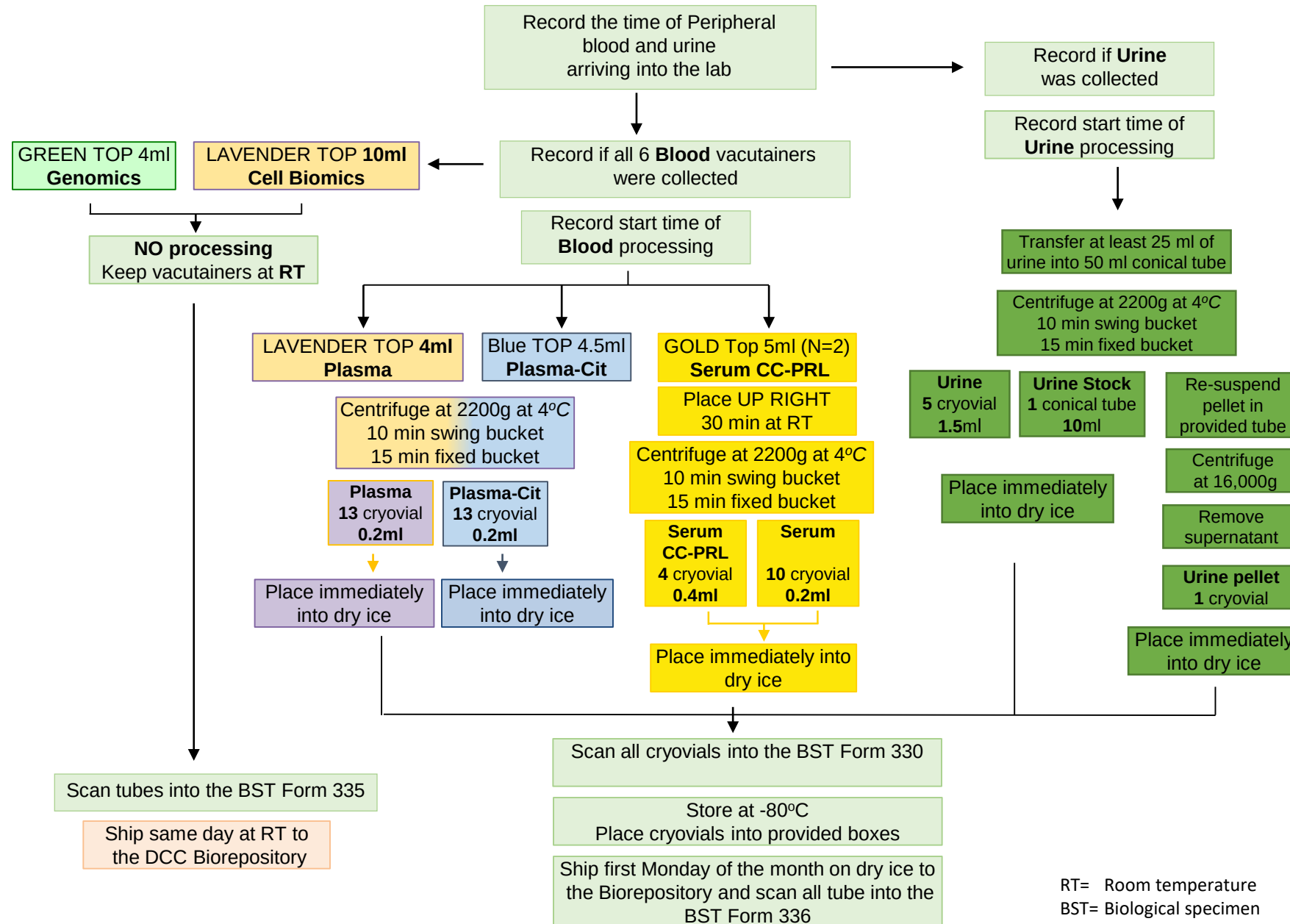
- Measurements during spontaneous breathing ***and*** end-expiratory hold ***during resting***
- **Thermodilution is required**, Fick is optional
 - 3 measurements within 10%
- PI or qualified provider (fellow) ***required to review/sign off*** of form

OMICS: Key points

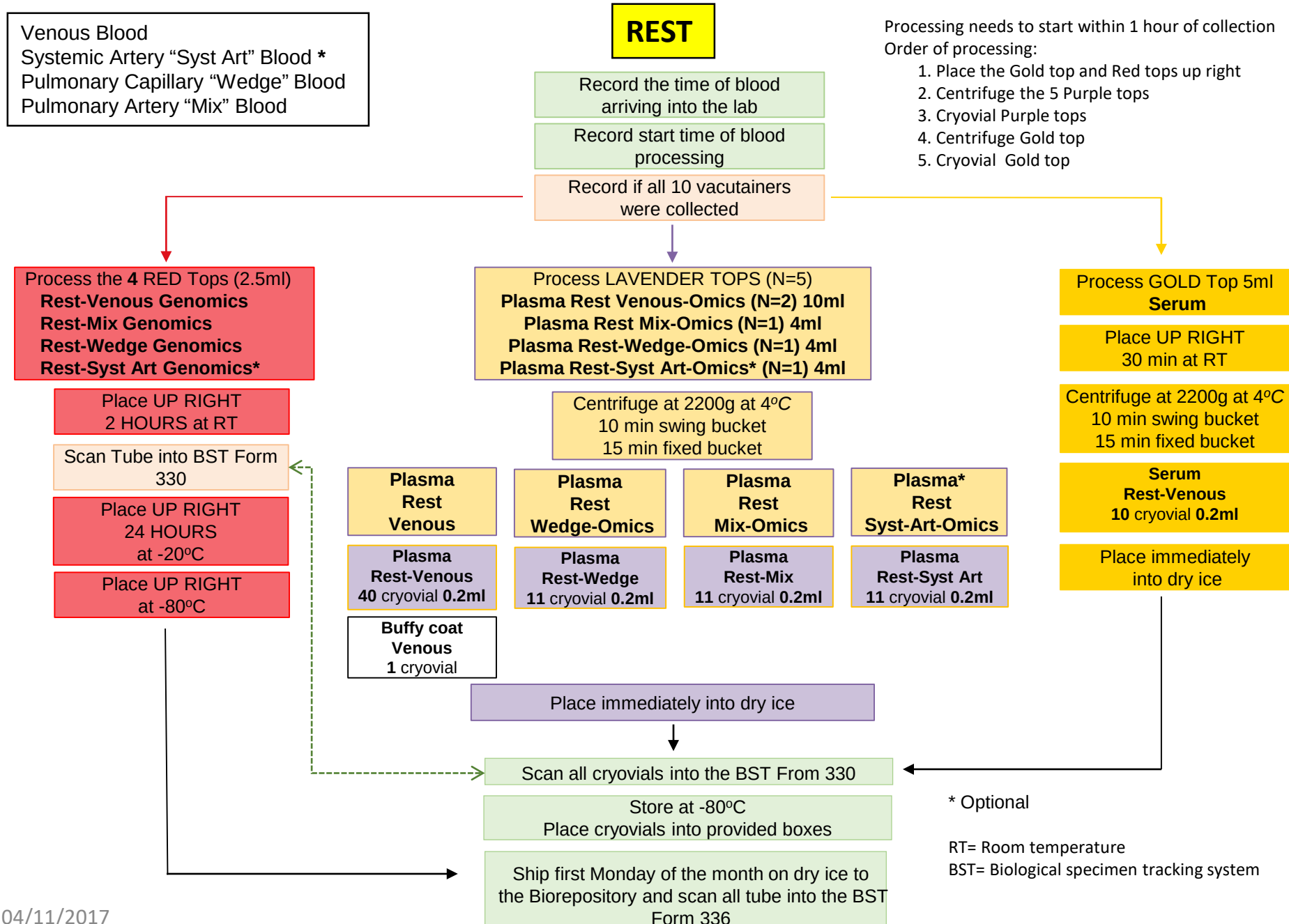
- OMICS 1 is a ***peripheral venous*** sample
 - Draw from antecubital
- OMICS 2 is from the ***SVC, mixed venous and PCWP***
 - Rest
 - Exercise
- **Right IJ** is the preferred site for RHC
 - Allows for drawing of OMICS 2 blood from the SVC via the side-port of the introducer (less shearing)

Appendix 34.1: PVDOMICS OMICS Blood and Urine Collection 1: Processing, Aliquoting, Recording and Storing of Biospecimens

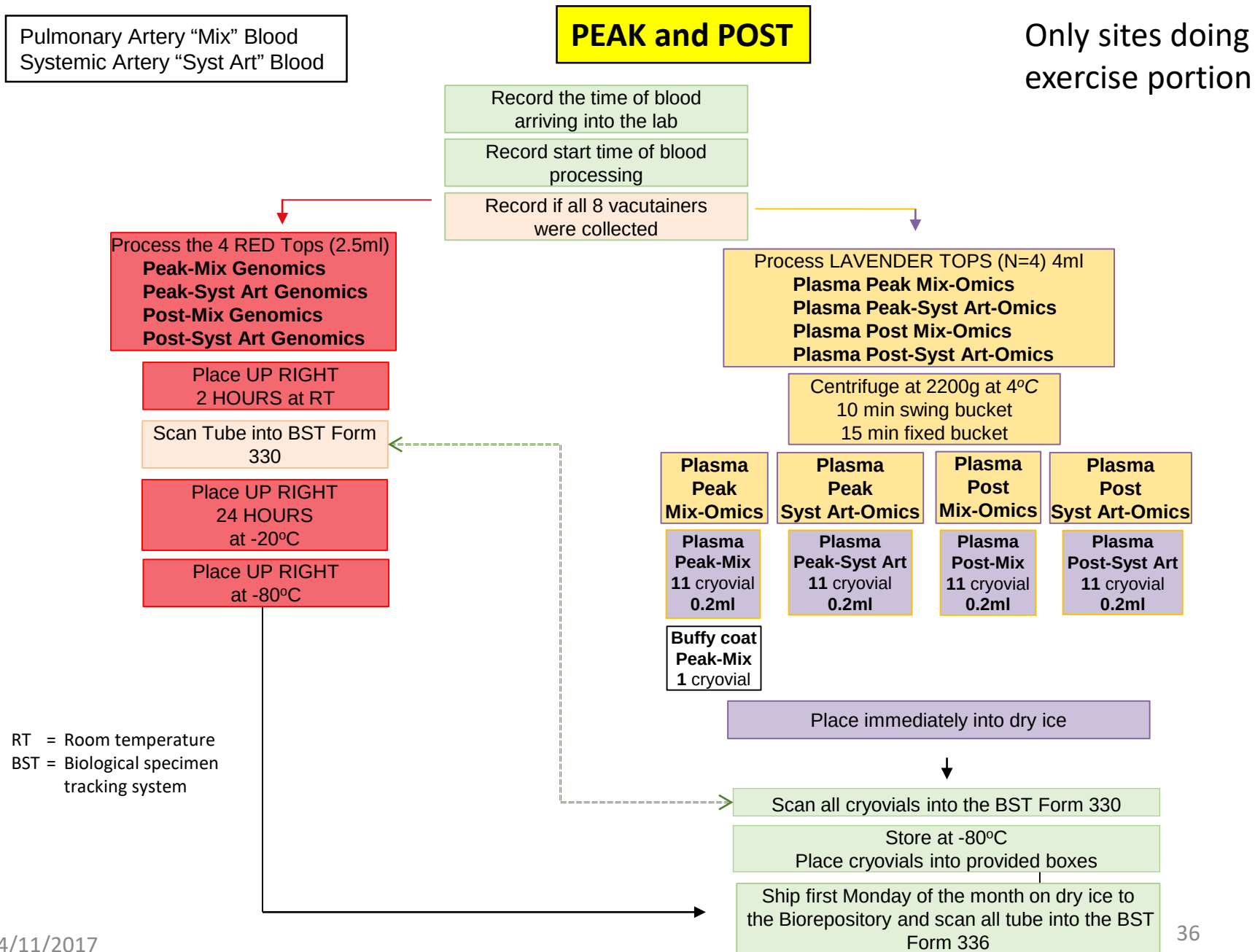
Processing needs to start
within 1 hour of collection



Appendix 34.2: PVDOMICS OMICS Blood Collection 2: Processing, Aliquoting, Recording and Storing of Biospecimens



Appendix 34.2: PVDOMICS OMICS Blood Collection 2: Processing, Aliquoting, Recording and Storing of Biospecimens



Form 290: Noninvasive CPET (as of 11/03/2017)

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns: Forms= 6 w/ CPET=1	N m i s s	Ns: Forms=11 w/ CPET=10	N m i s s	Ns: Forms= 50 w/ CPET=43	N m i s s	Ns: Forms= 20 w/ CPET=18	N m i s s	Ns: Forms= 1 w/ CPET=1	N m i s s	Ns: Forms= 1 w/ CPET=0	N m i s s	Ns: Forms= 30 w/ CPET=19
Noninvasive CPET? 1=Yes, cpet was completed 2=Physically unable to cycle 3=Known exercise contraindication 4=Other contraind. or physician judgement	0	1 (17%) 0 1 (17%) 4 (67%)	0	10 (91%) 1 (9%) 0 0	0	43 (86%) 1 (2%) 0 6 (12%)	0	18 (90%) 0 0 2 (10%)	0	1 (100%) 0 0 0	0	0 1 (100%) 0 0	0	19 (63%) 1 (3%) 4 (13%) 6 (20%)
Exercise: time 0: Dyspnea (Borg scale) 0=Nothing at all 0.5=Very, very 1=Very mild 2=Mild 3=Moderate	.		0	. 5 (50%) 2 (20%) 2 (20%) 0 1 (10%)	18	. 16 (62%) 3 (12%) 4 (15%) 1 (4%) 1 (4%)	4	. 9 (64%) 2 (14%) 3 (21%) 0 0	0	. 1 (100%) 0 0 0 0	.		0	. 11 (58%) 2 (11%) 3 (16%) 1 (5%) 2 (11%)
Exercise: time 0: RPE (Borg scale) 0=Nothing at all 0.5=Very, very 1=Very mild 2=Mild 3=Moderate 5=Strong or hard breathing 6=--	.		0	. 4 (40%) 1 (10%) 4 (40%) 0 1 (10%) 0 0	2	. 26 (63%) 8 (20%) 5 (12%) 1 (2%) 1 (2%) 0 0	5	. 8 (62%) 0 3 (23%) 1 (8%) 1 (8%) 0 0	0	. 0 1 (100%) 0 0 0 0 0	.		0	. 3 (16%) 7 (37%) 5 (26%) 2 (11%) 0 1 (5%) 1 (5%)
Did RER reach or exceed 1.10? 0=No 1=Yes	0	. 1 (100%) 0	1	. 4 (44%) 5 (56%)	30	. 4 (31%) 9 (69%)	0	. 4 (22%) 14 (78%)	0	. 0 1 (100%)	.		7	. 7 (58%) 5 (42%)

CPET Key points

- Data only required every **2 minutes** with exercise (Borg, HR, BP)
- Data required every **1 minute** during recovery x 5 minutes (Borg, HR, BP)
 - 2 minutes free-wheel
 - 3 minutes rest
- Consider using manual blood pressure cuff
- Respiratory Exchange Ratio (RER) should reach or exceed 1.1 to indicate “adequate stress”
- PI or qualified person (fellow) ***required to review/ sign-off form***

Form 131: Hip/Waist Ratio (as of 11/03/2017)

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns Forms=8	N m i s s	Ns Forms=9	N m i s s	Ns Forms=36	N m i s s	Ns Forms=36	N m i s s	Ns Forms=83	N m i s s	Ns Forms=68	N m i s s	Ns Forms=68
Waist/hip completed? 1=Yes, test was completed 2=No, wheelchair use only 3=No, logistics problem – pt 4=No, medical contraindication 5=No, logistic problem - site 6=No, participant refused	0	. 4 (50%) 0 1 (13%) 0 0 3 (38%)	0	. 8 (89%) 1 (11%) 0 0 0 0	0	. 36 (100%) 0 0 0 0 0	0	. 36 (100%) 0 0 0 0 0	0	. 83 (100%) 0 0 0 0 0	0	. 66 (97%) 1 (1%) 0 1 (1%) 0 0	0	. 31 (100%) 0 0 0 0 0
Waist circumference (cm)	0	77.5 ± 18.9 [60.0, 104]	0	103 ± 31 [35.3, 132]	0	94.3 ± 18.5 [70.0, 152]	0	97.1 ± 16.2 [69.5, 134]	0	100 ± 20 [41.0, 152]	0	109 ± 17 [72.0, 144]	0	98.9 ± 18.0 [72.0, 155]
Hip circumference (cm)	0	87.1 ± 16.9 [71.0, 111]	0	115 ± 36 [43.7, 170]	0	104 ± 17 [80.0, 154]	0	110 ± 14 [79.1, 154]	0	110 ± 16 [43.0, 149]	0	118 ± 18 [85.0, 163]	0	109 ± 16 [90.9, 159]
Waist-hip ratio	0	0.88 ± 0.05 [0.85, 0.94]	0	0.89 ± 0.16 [0.71, 1.20]	0	0.91 ± 0.08 [0.77, 1.06]	0	0.88 ± 0.13 [0.70, 1.26]	0	0.91 ± 0.11 [0.57, 1.23]	0	0.93 ± 0.10 [0.77, 1.19]	0	0.90 ± 0.08 [0.76, 1.04]

Form 132: BIA (as of 11/03/2017)

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns Forms=8 w/ Ampu- tations=0 w/ BIA=2	N m i s s	Ns Forms=6 w/ Ampu- tations=1 w/ BIA=1	N m i s s	Ns Forms=50 w/ Ampu- tations=0 w/ BIA=46	N m i s s	Ns Forms=32 w/ Ampu- tations=0 w/ BIA=30	N m i s s	Ns Forms=83 w/ Ampu- tations=0 w/ BIA=69	N m i s s	Ns Forms=73 w/ Ampu- tations=0 w/ BIA=67	N m i s s	Ns Forms=31 w/ Ampu- tations=0 w/ BIA=30
Standing measured height (cm)	0	165 ± 6 [152, 170]	1	168 ± 14 [155, 184]	4	166 ± 9 [152, 183]	2	168 ± 12 [148, 195]	3	170 ± 10 [152, 195]	1	165 ± 9 [144, 196]	1	166 ± 10 [152, 190]
Current measured weight (kg)	0	79.6 ± 26.0 [53.1, 118]	1	82.3 ± 25.6 [58.5, 113]	4	77.8 ± 22.9 [47.0, 136]	2	88.9 ± 23.9 [51.5, 150]	3	86.6 ± 22.5 [44.7, 138]	1	87.8 ± 22.0 [48.4, 143]	1	83.3 ± 24.5 [52.5, 168]
Was a barefoot standing BIA measurement performed? 1=Yes, test was completed 2=No, wheelchair use only 3=No, logistics problem - participant 4=No, medical contraindication/safety 5=No, logistic problem - clinical site 6=No, participant refused	0	. . 2 (25%) 0 2 (25%) 1 (13%) 0 3 (38%)	0	. . 1 (17%) 1 (17%) 0 4 (67%) 0 0	0	. . 46 (92%) 0 0 2 (4%) 2 (4%) 0	0	. . 30 (94%) 0 0 0 2 (6%) 0	0	. . 69 (83%) 0 0 10 (12%) 3 (4%) 1 (1%)	0	. . 67 (92%) 0 1 (1%) 3 (4%) 0 2 (3%)	0	. . 30 (97%) 0 0 0 0 1 (3%)
Measured body fat (%)	0	31.5 [31.0, 32.0]	0	18.2	0	30.7 ± 11.2 [10.3, 54.2]	0	35.5 ± 10.3 [12.6, 52.0]	0	32.4 ± 11.0 [10.0, 54.0]	0	37.6 ± 9.2 [18.4, 53.7]	0	36.9 ± 11.0 [7.30, 59.4]
BMI (BIA)	0	28.4 [25.9, 30.9]	0	32.1	0	27.8 ± 8.2 [17.8, 55.9]	0	31.5 ± 7.8 [17.4, 48.1]	0	29.8 ± 7.5 [16.6, 50.3]	0	32.2 ± 7.9 [18.9, 54.2]	0	30.3 ± 7.4 [19.5, 53.5]
Total body water (%)	0	48.4 [48.1, 48.7]	0	57.7	0	48.2 ± 7.1 [34.3, 62.4]	0	48.5 ± 8.0 [36.0, 65.7]	0	46.9 ± 7.7 [22.4, 65.3]	1	44.1 ± 5.7 [33.6, 56.5]	2	46.9 ± 9.1 [29.8, 67.9]
Impedance (50 kHz)	0	483 [464, 501]	0	10.0	3	495 ± 126 [266, 977]	0	574 ± 88 [445, 867]	0	446 ± 122 [10.1, 721]	0	472 ± 105 [187, 723]	0	633 ± 109 [429, 833]

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
Form 133: 6MWT	N m i s s		N m i s s		N m i s s		N m i s s		N m i s s		N m i s s		N m i s s	
N All Form 133s	.	8	.	8	.	32	.	30	.	82	.	59	.	29
Rested for 10 minutes prior to testing?	0	7 (100%)	0	8 (100%)	1	30 (100%)	0	30 (100%)	13	69 (84%)	4	49 (92%)	1	27 (100%)
Pre-test systolic blood pressure (mmHg)	0	129 ± 21 [102, 164]	0	104 ± 10 [86.0, 116]	1	108 ± 12 [79.0, 132]	0	129 ± 15 [102, 165]	11	120 ± 18 [90.0, 169]	3	110 ± 12 [86.0, 132]	1	120 ± 16 [97.0, 170]
Pre-test Borg Dyspnea Score	0	.	0	.	1	.	0	.	11	.	3	.	1	.
Pre-test baseline SpO2 (%) (resting/sitting, on O2)	0	95.6 ± 1.7 [93.0, 98.0]	0	95.8 ± 3.7 [89.0, 99.0]	1	96.6 ± 2.3 [92.0, 100]	0	97.5 ± 1.5 [93.0, 99.0]	11	95.6 ± 3.0 [85.0, 100]	2	95.2 ± 2.8 [88.0, 100]	1	95.0 ± 3.3 [85.0, 99.0]
Total distance walked (meters)	0	294 ± 99 [146, 439]	0	456 ± 92 [294, 568]	1	402 ± 112 [37.5, 677]	0	416 ± 144 [73.0, 678]	11	378 ± 126 [74.7, 655]	2	397 ± 133 [120, 716]	1	387 ± 94 [198, 519]
SpO2 at end of walk (%)	0	87.6 ± 3.8 [84.0, 94.0]	0	90.4 ± 9.3 [70.0, 99.0]	0	94.1 ± 4.7 [81.0, 100]	0	94.2 ± 6.4 [77.0, 99.0]	0	92.6 ± 7.1 [71.0, 100]	0	90.0 ± 5.7 [79.0, 100]	0	91.5 ± 7.1 [70.0, 99.0]
SpO2 at 1 minute recovery (%)	0	91.7 ± 4.2 [88.0, 98.0]	0	93.1 ± 7.3 [78.0, 98.0]	0	96.6 ± 2.9 [84.0, 100]	0	97.0 ± 2.8 [87.0, 99.0]	0	94.7 ± 4.7 [81.0, 100]	0	92.2 ± 5.1 [75.0, 100]	0	94.0 ± 6.0 [76.0, 100]
SpO2 at 2 minutes recovery (%)	0	94.4 ± 2.8 [91.0, 98.0]	0	94.3 ± 5.7 [82.0, 99.0]	0	97.5 ± 1.6 [94.0, 100]	0	97.7 ± 1.8 [92.0, 99.0]	0	95.7 ± 3.7 [82.0, 100]	0	94.3 ± 4.5 [74.0, 100]	0	95.8 ± 3.8 [84.0, 100]
Heart rate at end of walk (beats/minute)	0	104 ± 10 [90.0, 122]	0	106 ± 15 [92.0, 130]	0	99.5 ± 19.1 [64.0, 132]	0	91.1 ± 16.9 [60.0, 124]	0	93.1 ± 20.0 [50.0, 139]	0	115 ± 19 [80.0, 156]	0	107 ± 17 [73.0, 136]
Heart rate at 1 minute recovery (beats/minute)	0	92.4 ± 7.5 [81.0, 104]	0	97.6 ± 13.1 [82.0, 119]	0	86.7 ± 15.8 [52.0, 117]	0	79.9 ± 14.0 [54.0, 109]	0	86.9 ± 18.1 [50.0, 126]	0	99.7 ± 15.8 [74.0, 128]	0	92.4 ± 16.1 [63.0, 120]
Heart rate at 2 minutes recovery (beats/minute)	0	86.6 ± 7.5 [74.0, 98.0]	0	93.1 ± 13.7 [76.0, 114]	0	82.4 ± 15.6 [51.0, 116]	0	76.9 ± 13.1 [50.0, 109]	0	83.1 ± 16.4 [50.0, 117]	0	91.5 ± 14.4 [63.0, 125]	0	85.3 ± 15.6 [50.0, 112]

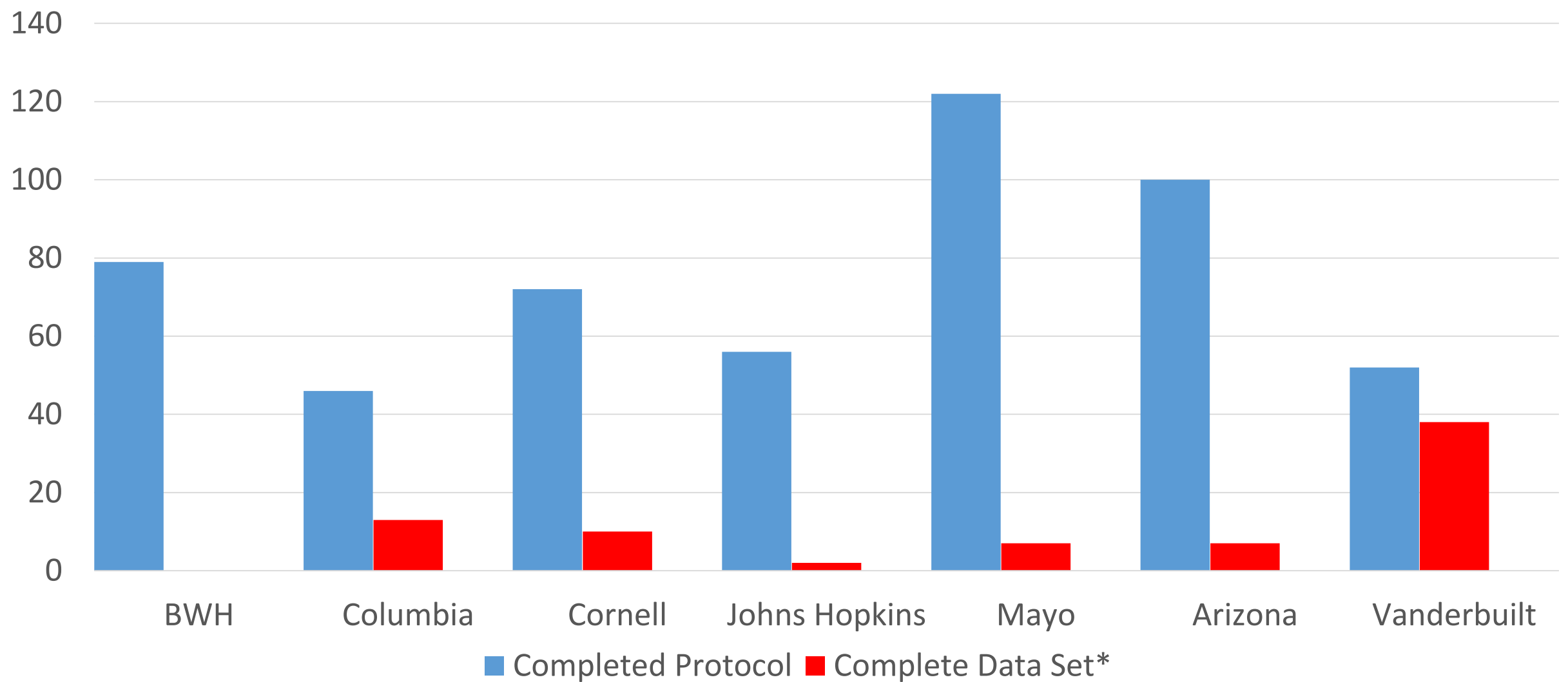
Form 270: PFTs (as of 11/03/2017)

Factor	11. BWH		21. Columbia		22. Cornell		31. John Hopkins		41. Mayo		51. Arizona		61. Vanderbilt	
	N m i s s	Ns: Forms= 3 w/ PFT=3	N m i s s	Ns: Forms=3 w/ PFT=3	N m i s s	Ns: Forms= 38 w/ PFT=38	N m i s s	Ns: Forms= 14 w/ PFT=14	N m i s s	Ns: Forms= 46 w/ PFT=46	N m i s s	Ns: Forms= 42 w/ PFT=42	N m i s s	Ns: Forms= 23 w/ PFT=22
Conversion factor (ATPS to BTPS)	0	[1.06, 1.10]	3	[-., .]	33	[1.01, 1.02]	0	[1.05, 1.10]	45	[0, 0]	0	[1.07, 1.12]	1	[1.07, 1.11]
Was spirometry done? 0=No 1=Yes, pre-bronchodilator (bd) only 2=Yes, post-bronchodilator only 3=Yes, both pre-bd and post-bd done	0	. 0 2 (67%) 0 1 (33%)	0	. 3 (100%) 0 0 0	0	. 0 5 (13%) 0 33 (87%)	0	. 0 10 (71%) 0 4 (29%)	0	. 0 11 (24%) 0 35 (76%)	0	. 0 4 (10%) 0 38 (90%)	0	. 0 6 (27%) 0 16 (73%)
Resting (sitting) heart rate: (bpm)	1	[78.0, 98.0]	.	--	38	[-., .]	2	[51.0, 95.0]	0	[45.0, 110]	0	[59.0, 108]	0	[61.0, 105]
Pre BD Test 1: FVC (L) (BTPS)	0	[1.94, 2.87]	.	--	0	[1.37, 4.80]	0	[1.42, 7.76]	0	[1.57, 6.44]	0	[1.21, 5.84]	0	[1.43, 5.28]
Pre BD Test 1: FEV1 (BTPS)	0	[1.77, 2.07]	.	--	0	[1.10, 3.64]	0	[1.0, 6.69]	0	[0.810, 4.56]	0	[0.790, 4.41]	0	[0.840, 4.25]
Pre BD Test 1: FEV1/FVC (%)	0	[71.0, 91.0]	.	--	0	[60.0, 92.0]	0	[70.0, 86.0]	0	[39.0, 88.0]	0	[34.0, 87.0]	0	[31.0, 85.0]
Are flow volume-loop tracings x 3 attached? 0=No 1=Yes	0	. . 0 3 (100%)	.	--	0	. . 0 38 (100%)	0	. . 0 14 (100%)	0	. . 0 46 (100%)	0	. . 0 42 (100%)	0	. . 0 22 (100%)
Number of minutes spirometry done post-bronchodilator treatment	2	[15.0, 15.0]	.	--	38	[-., .]	11	[3.0, 30]	11	[15.0, 15.0]	4	[10.0, 15.0]	6	[15.0, 15.0]
Were Single Breath DLCO tests done? 0=No 1=Yes	0	. 0 3 (100%)	0	. 0 3 (100%)	0	. 0 38 (100%)	0	. 3 (21%) 11 (79%)	0	. 0 46 (100%)	0	. 1 (2%) 41 (98%)	0	. 0 22 (100%)
Hemoglobin (g/dl)	1	[13.4, 13.4]	1	[13.4, 13.4]	14	[8.90, 19.2]	1	[8.0, 17.1]	9	[6.0, 20.1]	3	[9.50, 18.2]	1	[11.0, 16.9]
Average: Vin (inspired volume) or IVC or VCmax	2	[0.90, 0.90]	1	[1.0, 1.0]	5	[1.48, 6.34]	11	[-., .]	34	[1.53, 6.26]	38	[1.24, 4.20]	22	[-., .]

PFTs: Key Points

- **Bronchodilator** testing is required
- **Body box** (pleth) is required for lung volumes and needs to be *linked*
- **Hemoglobin** within 2 weeks of PFTs
- **Vin (inspired volume) or IVC or Vcmax** required to QC diffusion
- Submit **screen shots** in addition to PFT data

Subjects with Complete Data Sets (02/27/2018)



* Excludes F207: ABG

80 of 80 Data Entry Completion Metric (as of 02/27/2018)

Clinic Center	Subjects Completed 6-week Study Protocol Period ⁽¹⁾ N	Subjects with 100% of Forms Entered ⁽²⁾ (% of subjects completed study)	Subjects with 80+% of Forms Entered ⁽³⁾ (% of subjects completed study)
11. Brigham and Women's	79	12 (15.2%)	31 (39.2%)
21. Columbia	45	21 (46.7%)	38 (84.4%)
22. Cornell	72	33 (45.8%)	67 (93.1%)
31. Johns Hopkins	55	3 (5.5%)	33 (60.0%)
41. Mayo Clinic	121	14 (11.6%)	119 (98.3%)
51. U. of Arizona	100	1 (1.0%)	97 (97.0%)
61. Vanderbilt	52	39 (75.0%)	51 (98.1%)
Total	524	123 (23.5%)	436 (83.2%)

⁽¹⁾ Completed study subjects: enrolled for 6 or more weeks (prior to 01/16/18) or past extension date (if granted)
Forms depend on gender and main/comparator vs. control status. Form 207: ABG is currently excluded from these summaries.

⁽²⁾ Forms that include option 'This test / procedure would not be completed' :

F131: Waist/Hip	F150: Sleep
F245: ECG	F250: ECHO
F251: MRI	F252/F253: CT
F254: V/Q	F270/F271: PFT
F280: RHC	F290/F291: CPET
F300: Biorep C1	F304/F307: Biorep C2
F320: Biorep Urine	

⁽³⁾ All other forms included here

Deviations

- No signed consent
- Inclusions & Exclusions criteria not met
- Procedure not done, unless exception granted
 - Exceptions will not be granted for items on minimal data set
- Procedure done “out of window”, unless extension granted
- Procedure done, but information is poor quality/not usable
- Procedure not de-identified (PHI present)

Minimal Data Set

- Signed consent
- Inclusion & exclusion (100)
- Medical history (103-107, 110, 121)
- Vital signs (120)
- Waist to hip circumference (131)
- BIA (132)
- HRQoL (170, 171, 172)
- Clinical blood tests (200-205)
- Omics blood and urine (300-303, 320-321)
- Electrocardiogram (245)
- Right heart catheterization (except controls)
- OMIC blood from RHC (280, 304-309)
- Cardiac MRI (251)
- Echocardiogram (250)
- Pulmonary function (270,271)
- Six minute walk (133)

The intent should be to complete ALL of the procedures in the protocol

Possible Exceptions (case by case basis)

- Ventilation perfusion scan
 - Overnight sleep monitoring
 - CPET
 - Chest CT
-
- Exception form required

Site Visits

- Protocol adherence
- Face-to-face questions/answers re study procedures
- Improve communication between sites and DCC
- Ensure quality of data collection
- Site Visit Team
 - Chair QCC
 - DCC representative(s)
 - NIH representative
 - Study coordinator from another clinical center
 - Investigator from another clinical center (as needed)

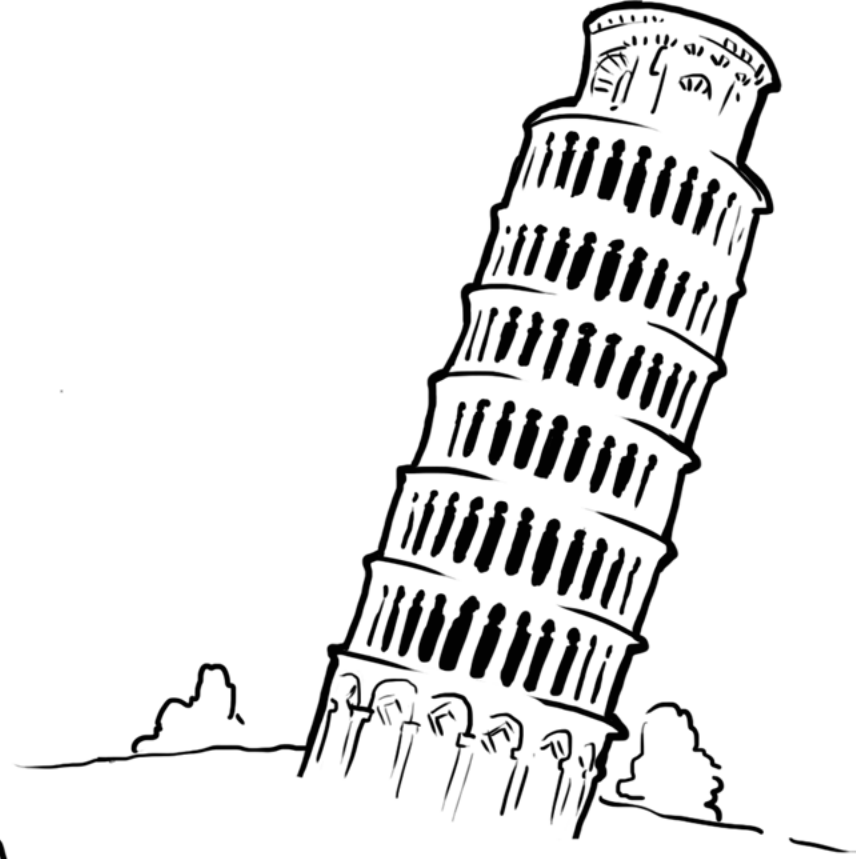
In person site visits: *tentative schedule*

- | | |
|----------------------|------------------------------------|
| • Brigham and Womens | December 2017, January 2018 (done) |
| • Johns Hopkins | March 2018 (scheduled) |
| • Columbia | January 2018 (done) |
| • Cornell | July 2018 |
| • Mayo | June 2018 |
| • Vanderbilt | April 2018 (scheduled) |
| • Arizona | May 2018 |

Site Visit Agenda

- Welcome and introductions
- Protocol walk-through
- Summaries from the weekly reports
- Quality control and review of data from the weekly QC report
- Enrollment goals
 - Promoting recruitment
 - Enrollment process
- Review of individual participants who have enrolled
- Promoting adherence to the protocol
 - Participant flow
 - Methods to promote adherence
- Data storage
- Logistics
 - Team meetings
 - Team communication
 - Back-up for PI
 - Back-up for study coordinator
 - Institutional support and resources
- Issues with DCC and study cores
- Payments
- Contract/budget issues
- Institutional support
- Final comments from site visit team

THAT'S GOOD ENOUGH.



QUALITY CONTROL