

Appendix J
Summary Table on Evaluation of 23 Design Options

Evaluation of NCS Study Design Options Relative to Givens, Scientific Merit, and Cost

Category	Criterion	A1: P1:0% P2:0% P3:100% 0 PSUs	A2: P1:0% P2:0% P3:50% 0 PSUs	B3: P1:0% P2:25% 0 PSUs	B4: P1:0% P2:50% 0 PSUs	B5: P1:0% P2:75% 0 PSUs	C6: P1:25% P2:25% 50 PSUs	C7: P1:25% P2:50% 50 PSUs	C8: P1:25% P2:75% 50 PSUs	D9: P1:50% P2:25% 50 PSUs	D10: P1:50% P2:50% 50 PSUs	D11: P1:50% P2:75% 50 PSUs	E12: P1:75% P2:25% 50 PSUs
GIVENS	1. Community Involvement	Exc	Exc	Exc	Exc	Exc	Good	Good	Good	Fair	Fair	Fair	Poor
	2. Specialized measures	Exc	Exc	Exc	Exc	Exc	Good	Good	Good	Fair	Fair	Fair	Poor
	3. Prenatal recruitment	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
SCIENTIFIC MERIT: External Validity	4. Probability basis	Poor	Poor	Poor	Fair	Fair	Fair	Fair	Good	Fair	Good	Exc	Good
SCIENTIFIC MERIT: Diversity	5. Range of exposure	Poor	Poor	Poor	Fair	Fair	Fair	Fair	Fair	Good	Good	Good	Exc
SCIENTIFIC MERIT: Internal Validity	6. Confounders and covariates	Exc	Exc	Exc	Good	Fair	Good	Good	Fair	Good	Fair	Poor	Fair
SCIENTIFIC MERIT: Power	7. Unweighted, fixed sample size	95% (>91% of other designs)	95% (>96% of other designs)	94% (>87% of other designs)	93% (>83% of other designs)	90% (>52% of other designs)	92% (>70% of other designs)	92% (>65% of other designs)	90% (>48% of other designs)	90% (>57% of other designs)	89% (>35% of other designs)	87% (>22% of other designs)	86% (>13% of other designs)
	8. Unweighted, fixed cost	89% (>91% of other designs)	90% (>96% of other designs)	89% (>83% of other designs)	89% (>87% of other designs)	87% (>78% of other designs)	86% (>52% of other designs)	86% (>57% of other designs)	84% (>39% of other designs)	87% (>70% of other designs)	87% (>74% of other designs)	85% (>43% of other designs)	86% (>65% of other designs)
	9. Weighted, fixed sample size	92%	74%	48%	67%	72%	59% (>17% of other designs)	63% (>28% of other designs)	61% (>22% of other designs)	71% (>33% of other designs)	76% (>61% of other designs)	77% (>72% of other designs)	73% (>39% of other designs)
	10. Weighted, fixed cost	86%	64%	42%	62%	69%	48% (>17% of other designs)	51% (>22% of other designs)	54% (>28% of other designs)	66% (>50% of other designs)	71% (>56% of other designs)	72% (>61% of other designs)	75% (>72% of other designs)
	11. Retention	76,956 (>91% of other designs)	79,400 (>96% of other designs)	66,928 (>87% of other designs)	56,848 (>74% of other designs)	46,768 (>52% of other designs)	56,871 (>83% of other designs)	49,311 (>70% of other designs)	41,751 (>39% of other designs)	46,814 (>61% of other designs)	41,774 (>48% of other designs)	36,734 (>22% of other designs)	36,757 (>30% of other designs)
SCIENTIFIC MERIT: Resource for the Future	12. Resource for future												
	13. Standardization	High Difficulty	High Difficulty	High Difficulty	High Difficulty	High Difficulty	High Difficulty	High Difficulty	High Difficulty	Medium Difficulty	Medium Difficulty	Medium Difficulty	Low Difficulty
	14. Access to data	Exc	Exc	Exc	Exc	Exc	Good	Good	Good	Fair	Fair	Fair	Poor
COSTS	15. Cost, assuming fixed sample size	\$3.5B (>87% of other designs)	\$3.4B (>78% of other designs)	\$3.3B (>70% of other designs)	\$3.2B (>52% of other designs)	\$3.0B (>39% of other designs)	\$3.3B (>74% of other designs)	\$3.2B (>57% of other designs)	\$3.1B (>43% of other designs)	\$3.0B (>30% of other designs)	\$2.9B (>17% of other designs)	\$2.8B (>13% of other designs)	\$2.6B (>9% of other designs)
	16. Initial sample size, with fixed cost	76,750 (>26% of other designs)	75,750 (>22% of other designs)	80,000 (>43% of other designs)	84,000 (>52% of other designs)	88,000 (>65% of other designs)	77,000 (>30% of other designs)	80,000 (>39% of other designs)	83,500 (>39% of other designs)	88,500 (>70% of other designs)	91,000 (>78% of other designs)	94,000 (>83% of other designs)	104,000 (>87% of other designs)

Category	Criterion	E13: P1:75% P2:50% 50 PSUs	E14: P1:75% P2:75% 50 PSUs	F15: P1:25% P2:25% 100 PSUs	F16: P1:25% P2:50% 100 PSUs	F17: P1:25% P2:75% 100 PSUs	G18: P1:50% P2:25% 100 PSUs	G19: P1:50% P2:50% 100 PSUs	G20: P1:50% P2:75% 100 PSUs	H21: P1:75% P2:25% 100 PSUs	H22: P1:75% P2:50% 100 PSUs	H23: P1:75% P2:75% 100 PSUs
GIVENS	1. Community Involvement	Poor	Poor	Good	Good	Good	Fair	Fair	Fair	Poor	Poor	Poor
	2. Specialized measures	Poor	Poor	Good	Good	Good	Fair	Fair	Fair	Poor	Poor	Poor
	3. Prenatal recruitment	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
SCIENTIFIC MERIT: External Validity	4. Probability basis	Exc	Exc	Fair	Fair	Good	Fair	Good	Exc	Good	Exc	Exc
SCIENTIFIC MERIT: Diversity	5. Range of exposure	Exc	Exc	Fair	Fair	Fair	Good	Good	Good	Exc	Exc	Exc
SCIENTIFIC MERIT: Internal Validity	6. Confounders and covariates	Poor	Poor	Good	Good	Fair	Good	Fair	Poor	Fair	Poor	Poor
SCIENTIFIC MERIT: Power	7. Unweighted, Fixed Sample size	85% (>9% of other designs)	84% (>0% of other designs)	93% (>78% of other designs)	92% (>74% of other designs)	89% (>43% of other designs)	91% (>61% of other designs)	89% (>39% of other designs)	88% (>30% of other designs)	88% (>26% of other designs)	87% (>17% of other designs)	85% (>4% of other designs)
	8. Unweighted, fixed cost	86% (>61% of other designs)	85% (>48% of other designs)	80% (>13% of other designs)	79% (>9% of other designs)	78% (>0% of other designs)	81% (>26% of other designs)	81% (>17% of other designs)	79% (>4% of other designs)	82% (>30% of other designs)	83% (>35% of other designs)	81% (>22% of other designs)
	9. Weighted, fixed sample size	77% (>67% of other designs)	79% (>83% of other designs)	59% (>11% of other designs)	59% (>6% of other designs)	59% (>0% of other designs)	74% (>44% of other designs)	76% (>56% of other designs)	76% (>50% of other designs)	78% (>78% of other designs)	81% (>94% of other designs)	80% (>89% of other designs)
	10. Weighted, fixed cost	80% (>89% of other designs)	81% (>94% of other designs)	37% (>0% of other designs)	40% (>6% of other designs)	42% (>11% of other designs)	61% (>33% of other designs)	64% (>44% of other designs)	63% (>39% of other designs)	74% (>67% of other designs)	77% (>83% of other designs)	76% (>78% of other designs)
	11. Retention	34,237 (>13% of other designs)	31,717 (>4% of other designs)	56,871 (>78% of other designs)	49,311 (>65% of other designs)	41,751 (>35% of other designs)	46,814 (>57% of other designs)	41,774 (>43% of other designs)	36,734 (>17% of other designs)	36,757 (>26% of other designs)	34,237 (>9% of other designs)	31,717 (>0% of other designs)
SCIENTIFIC MERIT: Resource for the Future	12. Resource for future											
	13. Standardization	Low Difficulty	Low Difficulty	High Difficulty	High Difficulty	High Difficulty	Medium Difficulty	Medium Difficulty	Medium Difficulty	Low Difficulty	Low Difficulty	Low Difficulty
	14. Access to data	Poor	Poor	Good	Good	Good	Fair	Fair	Fair	Poor	Poor	Poor
COSTS	15. Cost, assuming fixed sample size	\$2.6B (>4% of other designs)	\$2.6B (>0% of other designs)	\$3.7B (>96% of other designs)	\$3.6B (>91% of other designs)	\$3.5B (>83% of other designs)	\$3.3B (>65% of other designs)	\$3.3B (>61% of other designs)	\$3.2B (>48% of other designs)	\$3.0B (>35% of other designs)	\$3.0B (>26% of other designs)	\$2.9B (>22% of other designs)
	16. Initial sample size with fixed cost	106,000 (>91% of other designs)	107,500 (>96% of other designs)	63,000 (>0% of other designs)	66,000 (>4% of other designs)	69,000 (>9% of other designs)	73,000 (>13% of other designs)	75,000 (>17% of other designs)	77,500 (>35% of other designs)	85,500 (>57% of other designs)	87,000% (>61% of other designs)	89,000 (>74% of other designs)

Evaluation of NCS Study Design Options Relative to Givens, Scientific Merit, and Cost (With Alternative Retention Rates)

Category	Criterion	A1: P1:0% P2:0% P3:100% 0 PSUs	A2: P1:0% P2:0% P3:50% 0 PSUs	B3: P1:0% P2:25% 0 PSUs	B4: P1:0% P2:50% 0 PSUs	B5: P1:0% P2:75% 0 PSUs	C6: P1:25% P2:25% 50 PSUs	C7: P1:25% P2:50% 50 PSUs	C8: P1:25% P2:75% 50 PSUs	D9: P1:50% P2:25% 50 PSUs	D10: P1:50% P2:50% 50 PSUs	D11: P1:50% P2:75% 50 PSUs	E12: P1:75% P2:25% 50 PSUs
SCIENTIFIC MERIT: Power	7. Unweighted, fixed sample size	95% (>39% of other designs)	95% (>57% of other designs)	95% (>30% of other designs)	95% (>48% of other designs)	95% (>17% of other designs)	95% (>52% of other designs)	96% (>87% of other designs)	96% (>74% of other designs)	95% (>13% of other designs)	95% (>22% of other designs)	95% (>26% of other designs)	94% (>9% of other designs)
	8. Unweighted, fixed cost	90% (>65% of other designs)	89% (>57% of other designs)	91% (>83% of other designs)	91% (>96% of other designs)	90% (>70% of other designs)	89% (>48% of other designs)	89% (>43% of other designs)	88% (>35% of other designs)	89% (>52% of other designs)	90% (>74% of other designs)	90% (>61% of other designs)	90% (>78% of other designs)
	9. Weighted, fixed sample size	92%	74%	51%	72%	79%	71% (>6% of other designs)	74% (>17% of other designs)	75% (>28% of other designs)	85% (>33% of other designs)	88% (>50% of other designs)	89% (>56% of other designs)	87% (>39% of other designs)
	10. Weighted, fixed cost	86%	64%	44%	67%	73%	56% (>17% of other designs)	60% (>22% of other designs)	61% (>28% of other designs)	77% (>50% of other designs)	79% (>56% of other designs)	80% (>61% of other designs)	84% (>72% of other designs)
	11. Retention	76,936 (>91% of other designs)	79,401 (>96% of other designs)	75,348 (>87% of other designs)	73,707 (>83% of other designs)	72,067 (>70% of other designs)	72,943 (>78% of other designs)	71,712 (>65% of other designs)	70,482 (>48% of other designs)	70,538 (>57% of other designs)	69,717 (>39% of other designs)	68,897 (>30% of other designs)	68,132 (>22% of other designs)
COSTS	15. Cost, assuming fixed sample size	\$3.5B (>57% of other designs)	\$3.4B (>52% of other designs)	\$3.4B (>48% of other designs)	\$3.4B (>35% of other designs)	\$3.4B (>26% of other designs)	\$3.6B (>70% of other designs)	\$3.5B (>65% of other designs)	\$3.5B (>61% of other designs)	\$3.3B (>22% of other designs)	\$3.3B (>17% of other designs)	\$3.3B (>13% of other designs)	\$3.1B (>9% of other designs)
	16. Initial sample size, with fixed cost	76,750 (>57% of other designs)	75,750 (>52% of other designs)	77,000 (>70% of other designs)	77,000 (>65% of other designs)	78,000 (>83% of other designs)	71,000 (>43% of other designs)	71,000 (>39% of other designs)	71,500 (>48% of other designs)	77,000 (>61% of other designs)	77,500 (>74% of other designs)	77,750 (>78% of other designs)	84,000 (>87% of other designs)

Category	Criterion	E13: P1:75% P2:50% 50 PSUs	E14: P1:75% P2:75% 50 PSUs	F15: P1:25% P2:25% 100 PSUs	F16: P1:25% P2:50% 100 PSUs	F17: P1:25% P2:75% 100 PSUs	G18: P1:50% P2:25% 100 PSUs	G19: P1:50% P2:50% 100 PSUs	G20: P1:50% P2:75% 100 PSUs	H21: P1:75% P2:25% 100 PSUs	H22: P1:75% P2:50% 100 PSUs	H23: P1:75% P2:75% 100 PSUs
SCIENTIFIC MERIT: Power	7. Unweighted, Fixed Sample size	94% (>4% of other designs)	94% (>0% of other designs)	96% (>78% of other designs)	96% (>96% of other designs)	95% (>43% of other designs)	96% (>91% of other designs)	96% (>83% of other designs)	96% (>65% of other designs)	96% (>61% of other designs)	96% (>70% of other designs)	95% (>35% of other designs)
	8. Unweighted, fixed cost	91% (>91% of other designs)	91% (>87% of other designs)	83% (>4% of other designs)	83% (>9% of other designs)	82% (>0% of other designs)	86% (>17% of other designs)	86% (>22% of other designs)	85% (>13% of other designs)	88% (>30% of other designs)	88% (>39% of other designs)	87% (>26% of other designs)
	9. Weighted, fixed sample size	89% (>61% of other designs)	91% (>78% of other designs)	71% (>0% of other designs)	73% (>11% of other designs)	74% (>22% of other designs)	87% (>44% of other designs)	90% (>72% of other designs)	90% (>67% of other designs)	91% (>83% of other designs)	93% (>94% of other designs)	93% (>89% of other designs)
	10. Weighted, fixed cost	86% (>89% of other designs)	88% (>94% of other designs)	47% (>0% of other designs)	47% (>6% of other designs)	48% (>11% of other designs)	70% (>33% of other designs)	72% (>39% of other designs)	72% (>44% of other designs)	82% (>67% of other designs)	84% (>78% of other designs)	84% (>83% of other designs)
	11. Retention	67,722 (>13% of other designs)	67,312 (>4% of other designs)	72,943 (>74% of other designs)	71,712 (>61% of other designs)	70,482 (>43% of other designs)	70,538 (>52% of other designs)	69,717 (>35% of other designs)	68,897 (>26% of other designs)	68,132 (>17% of other designs)	67,722 (>9% of other designs)	67,312 (>0% of other designs)
COSTS	15. Cost, assuming fixed sample size	\$3.1B (>4% of other designs)	\$3.1B (>0% of other designs)	\$3.9B (>96% of other designs)	\$3.9B (>91% of other designs)	\$3.9B (>87% of other designs)	\$3.7B (>83% of other designs)	\$3.6B (>78% of other designs)	\$3.6B (>74% of other designs)	\$3.4B (>43% of other designs)	\$3.4B (>39% of other designs)	\$3.4B (>30% of other designs)
	16. Initial sample size with fixed cost	84,500 (>96% of other designs)	84,500 (>91% of other designs)	58,500 (>4% of other designs)	58,500 (>0% of other designs)	59,000 (>9% of other designs)	63,500 (>13% of other designs)	64,000 (>22% of other designs)	64,000 (>17% of other designs)	69,500 (>30% of other designs)	69,500% (>26% of other designs)	70,000 (>35% of other designs)