APPENDIX A: Sample Data Extraction Form

Part A - Study Characteristics		
Item		**Response Options**
A1	First author's last name or study group name (e.g. HEALTH Investigators).	Text
A2	Year of publication	Text
A3	Journal	Text
A4	Country where the study is taking place (check all that apply).	□ Canada □ USA □ Netherlands □ UK □ Australia □ Other (specify) □ Unclear/not reported
A5	Funding source (check all that apply)	□ Industry □ Government (e.g. CIHR, NIH) □ Academic □ Association/foundation/non-profit □ Other (specify) □ Unclear/not reported
A6	Clinical trial identification number (e.g. clinicaltrials.gov number). If not reported specify "NR".	Text
A7	Is this a single centre or multicentre trial?	□ Single centre □ Multicentre □ Unclear/not reported
A8	Surgical specialty (check all that apply)	□ General surgery □ Neurosurgery □ Obstetrics & gynaecology □ Oral & maxillofacial surgery □ Orthopaedic & trauma surgery □ Plastic surgery □ Thoracic/cardiac surgery □ Vascular surgery □ Other (specify) □ Unclear/not reported
A9	Patients' disease/condition of interest (e.g. rotator cuff tear, heart disease). If not reported specify "NR".	Text
A10	Type of surgical study.	□ Surgery A vs. surgery B □ Surgical vs. non-surgical □ Timing of surgery (early vs. delayed)
A11	Control condition(s) (e.g. standard of care,	Text

	sham device, delayed surgery)	
A12	Intervention condition(s)	Text
A13	Primary outcome. If not reported specify "NR".	Text
A14	Planned sample size. If not reported specify "NR".	Text
A15	Number of authors. If group authorship, how many investigators are reported?	###
Part B – Methodological Characteristics		
Item		**Response Options**
B1	Is the planned allocation sequence generation adequate?	□ Adequate □ Inadequate □ Unclear/not reported
B2	Does the planned allocation sequence generation allow for adequate allocation concealment?	□ Adequate □ Inadequate □ Unclear/not reported
B3	Will participants be adequately blinded?	□ Adequate □ Inadequate □ Unclear/not reported □ Not relevant/not possible
B4	Will treatment providers be adequately blinded?	□ Adequate □ Inadequate □ Unclear/not reported □ Not relevant/not possible
B5	Will outcome assessors be adequately blinded?	□ Adequate □ Inadequate □ Unclear/not reported □ Not relevant/not possible
B6	If there is a risk of differential expertise across groups, does the protocol adequately account for this?	□ Adequate □ Inadequate □ Unclear/not reported □ Not relevant
B7	Were outcomes selected to be objective, patient-important and assessed in a manner to limit bias?	□ Adequate □ Inadequate □ Unclear/not reported
B8	Is the planned sample size sufficiently large to assure a balance of prognosis and number of outcome events?	□ Adequate □ Inadequate □ Unclear/not reported
B9	Are the planned statistical analyses (including subgroup, sensitivity, and adjusted analyses) selected to minimize bias?	□ Adequate □ Inadequate □ Unclear/not reported
B10	Does the funding source pose a risk of bias, or are there relevant conflicts of interest?	□ Adequate □ Inadequate □ Unclear/not reported
Part C – Statistical Reporting		

Item		Response Options
C1 Primary analysis Does the protocol report:	a) which outcome the primary analysis is based on?	□ Yes □ No □ Unclear
	b) the planned statistical test for the primary outcome?	□ Yes (specify) □ No □ Unclear
	c) the intended effect measure (e.g. hazard ratio, relative risk)?	□ Yes □ No □ Unclear
	d) the significance level?	□ Yes □ No □ Unclear
	e) intended use of confidence intervals?	□ Yes □ No □ Unclear
C2 Secondary analyses Does the protocol report:	a) whether secondary analyses are planned?	□ Yes – secondary analyses planned □ Yes – secondary analyses not planned □ Not reported □ Unclear
	b) the planned statistical test for each secondary outcome?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no secondary analyses
	c) the intended effect measure(s) (e.g. hazard ratio, relative risk)?	□ Yes □ No □ Partially reported □ Unclear □ N/A– no secondary analyses
	d) the significance level?	□ Yes □ No □ Partially reported □ Unclear □ N/A– no secondary analyses
	e) intended use of confidence intervals?	□ Yes □ No □ Partially reported □ Unclear □ N/A– no secondary analyses
C3 Sample size Does the protocol report:	a) the planned number of participants to be included in the trial?	□ Yes □ No □ Unclear
	b) which outcome the calculation is based on?	□ Yes □ No □ Unclear
	c) which statistical test the calculation is based on?	□ Yes □ No

		□ Unclear
	d) the values assumed for the outcome in each study group (eg, proportion with event, or mean and standard deviation)?	□ Yes □ No □ Unclear
	e) alpha level?	□ Yes □ No □ Unclear
	f) power (or beta)?	□ Yes □ No □ Unclear
	g) a description of how the SS was calculated (e.g. provide a reference to a formula or name a statistical program)?	□ Yes □ No □ Unclear
	h) whether they plan to inflate the sample size for missing data or crossovers?	□ Yes □ No □ Unclear
	i) additional explanations for sample size based on special designs, if applicable (e.g. intracluster correlation coefficient for cluster RCTs)?	□ Yes □ No □ Unclear □ N/A – not a special design
C4 Subgroup analyses Does the protocol report:	a) whether subgroup analyses are planned?	□ Yes – subgroups planned □ Yes – subgroups not planned □ Not reported □ Unclear
	b) the number of planned subgroup analyses?	□ Yes (specify) □ No □ Unclear □ N/A – no subgroups planned
	c) which baseline variable(s) will be analysed?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no subgroups planned
	d) rationale for each subgroup analysis?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no subgroups planned
	e) definition of subgroup categories?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no subgroups planned
	f) planned test(s) of interaction?	□ Yes □ No □ Unclear □ N/A – no subgroups planned
C5 Adjusted analyses	a) whether adjusted analyses are planned?	□ Yes – adjusted analysis planned □ Yes – adjusted analysis not planned

Does the protocol report:		□ Not reported □ Unclear
	b) which variables will be used in the analysis, or how they will select the included variables?	□ Yes □ No □ Unclear □ N/A – no adjusted analyses planned
	c) how continuous variables will be handled, if applicable?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no adjusted analyses planned □ N/A – no continuous variables
C6 Sensitivity analyses Does the protocol report:	a) whether sensitivity analyses are planned?	□ Yes – sensitivity analysis planned □ Yes – sensitivity analysis not planned □ Not reported □ Unclear
	b) methods of the planned sensitivity analysis?	□ Yes □ No □ Partially reported □ Unclear □ N/A – no sensitivity analyses planned
C7 Interim analyses Does the protocol report:	a) whether interim analyses are planned?	□ Yes – interim analysis planned □ Yes – interim analysis not planned □ Not reported □ Unclear
	b) number of interim analyses planned?	□ Yes (specify) □ No □ Unclear □ N/A – no interim analyses planned
	c) timing of the planned interim analyses?	□ Yes □ No □ Unclear □ N/A – no interim analyses planned
	d) whether any adaptations will be made based on interim analysis results (e.g. sample size recalculation)?	□ Yes □ No □ Unclear □ N/A – no interim analyses planned
C8 Stopping guidelines Does the	a) who has final authority over deciding whether/when to stop the trial early?	□ Yes (specify) □ No □ Unclear
	b) objective statistical or other criteria for	□ Yes

protocol report:	determining whether/when to stop for futility?	□ No □ Unclear
	c) objective statistical or other criteria for determining whether/when to stop for harm/benefit?	□ Yes □ No □ Unclear
C9 Analysis population Does the protocol report:	a) the intended analysis population (e.g. all randomized participants regardless of protocol adherence, intent-to-treat)?	□ Yes – provides full description/definition □ Yes – but uses ambiguous descriptor like "intent-to-treat" or "per protocol" □ No □ Unclear
C10 Missing data Does the protocol report:	a) method planned to account for missing data (e.g. multiple imputation)?	□ Yes □ No □ Unclear
C11 Multiplicity Does the protocol report:	a) method planned to account for multiple testing, if applicable?	□ Yes □ No □ Unclear □ N/A - no risk of multiple testing
C12 Other	a) Does this study have a special design that would affect the statistical methods?	□ No, two group parallel superiority design □ Equivalence or non-inferiority □ Cluster □ Factorial (2x2) □ Factorial (3x2) □ Factorial (bigger than 3x2) □ More than two groups (not factorial) □ Crossover □ Unclear □ Other (specify)
	b) What type of variable is the primary outcome?	□ Continuous - Interval □ Continuous - Ratio □ Categorical - Ordinal □ Categorical - Nominal □ Categorical - Binary □ Unclear □ Not reported
	c) Please add any comments here for further discussion	Text (optional)