ITEMS TO INCLUDE WHEN REPORTING CLINICAL RESEARCH

CHECKLIST I: CLINICAL TRIALS

Item		Description
Title	☐	Identify **study type** (randomised, observational, cohort, case-control, cross-sectional)
	☐	Identify **area of focus** (e.g. disease, exposure/intervention)
Authors	☐	Contact details for the corresponding author
Introduction		***Why did you start?***
	☐	Scientific/medical background
	☐	Rationale –why is this study needed?
	☐	Specific objectives, hypothesis
Trial design		***What is it?***
	☐	Description of the trial design (e.g. parallel, cluster, non-inferiority, cohort, case-control, cross-sectional)
	☐	State whether prospective or retrospective
	☐	State whether single-center or multi-center
Methods		***What did you do?***
Ethical approval	☐	**Give IRB oversight number**, and registration number (if applicable)
Participants	☐	Eligibility criteria for participants (inclusion/exclusion)
	☐	Settings where the data were collected
	☐	Relevant dates, time periods (recruitment, exposure, follow-up, data collection)
	☐	Describe sources and selection methods for participants;
	☐	If applicable: Describe methods of case ascertainment; control selection;matching criteria; number of exposed vs unexposed; etc.
Interventions (if applicable)	☐	Interventions intended for each group
Outcome	☐	Clearly defined **primary and secondary outcomes**
Bias	☐	Describe efforts to address potential sources of bias (e.g. randomization, blinding for RCTs, matching criteria for observational studies; controls)
Results		***What did you find?***
Participants	☐	Number of participants at each stage; reasons for non-participation
Descriptive data	☐	Characteristics of participants (demographic, clinical, etc.)
	☐	Information on interventions/exposures, potential confounders
Numbers analysed	☐	Number of participants analysed in each group
Outcome	☐	Outcome result for each group and the estimated effect size and its precision
Harms	☐	Important adverse events or side effects
Conclusions		***What does it mean?***
	☐	Summarise key results with reference to study objectives
	☐	Limitations (potential sources of bias, imprecision)
	☐	Generalizability (external validity, applicability) of trial findings
	☐	Interpretation consistent with results, balancing benefits and harms, considers other relevant evidence
Funding and Conflicts of interest	☐	Source of funding and other support (e.g. supply of device, drugs) if applicable
	☐	State any conflicts of interest

CHECKLIST II: CASE SERIES, CHART REVIEWS

Item	Description
Title	☐ Identify **study type** case series, chart review) ☐ Identify **area of focus** (e.g. disease, exposure/intervention, procedure)
Authors	Contact details for the corresponding author
Introduction	***Why did you start?***
	☐ Scientific/medical background, summary of what is currently known ☐ Rationale –why is this study needed? ☐ Unifying theme (e.g. common disease, exposure, intervention and outcome, etc.)
Methods	***What did you do?***
Ethical approval	☐ Was IRB approval required? If so give number. If not, provide justification
Study design	☐ State whether prospective or retrospective ☐ State whether cases are consecutive or non-consecutive ☐ State whether single-center or multi-center
Participants	☐ Settings, location where data were collected ☐ Eligibility criteria (inclusion/exclusion) ☐ Relevant dates, time periods ☐ Describe sources and selection methods for participants; ☐ Describe methods and duration of follow-up ☐ Relevant characteristics of participants (comorbidities, tumor staging, etc.) ☐ Describe pre-intervention considerations
Personnel	☐ Describe who performed the procedures (operator experience, prior training, specialization, etc)
Interventions	☐ Type of interventions and justification of treatment offered (pharmacological, surgical, physiotherapy, psychological, preventative etc.) ☐ Describe concurrent treatments (e.g. antibiotics, VTE prophylaxis, PO etc) ☐ For medical devices- specify manufacturer, model
Peri-interventions	☐ Administration protocol (what, when, where, how) e.g. surgery; anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc). ☐ Pharmaceutical therapies should include drug, formulation, dose, strength, route, duration
Post-interventions	☐ Post-operative instructions and place of care. ☐ Relevant follow-up procedures; diagnostic and other test results. Future surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair (EVAR), clinical exam; ultrasound, etc.)
Results	***What did you find?***
Participants	☐ Number of participants; characteristics, summary measures
Interventions	☐ Changes during the course of the case series (has it evolved, been tinkered with, learning etc.) ☐ Comment on learning curves for new methods, devices

Conclusions		***What does it mean?***
	□	Summarise key results with reference to study objectives
	□	Interpretation consistent with results
	□	Discussion of the relevant literature – how do outcomes compare with established therapies, current gold standard (if it exists)?
	□	Implications for clinical practice
	□	Limitations (potential sources of bias)
Funding and conflicts of interest	□	Source of funding and other support (e.g. supply of device, drugs) if applicable
	□	State any conflicts of interest

CHECKLIST III: QUALITY IMPROVEMENT

Item		Description
Title	□	Identify as a **quality improvement initiative**
	□	Identify **area of focus** (quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, equity)
Authors	□	Contact details for the corresponding author
Introduction		***Why did you start?***
	□	Problem description
	□	Summary of what is currently known
	□	Rationale for problem (frameworks, models, concepts, theories), development of intervention, reasons why intervention is expected to work
	□	Specific aims
Methods		***What did you do?***
Ethical oversight	□	Was IRB approval required? If so give number. If not, provide justification
Context	□	Describe contextual elements judged important at onset
Interventions	□	Describe interventions in enough detail to allow replication
	□	How was the impact of the intervention assessed?
	□	How was it determined that observed outcomes resulted from the intervention?
Personnel	□	Specifics of team involved in the work
Process measures	□	What factors were used to measure intervention and outcomes? Include operational definitions, validity, reliability
	□	What factors were measured to assess success/failure/efficiency/ cost
	□	What qualitative and quantitative methods were used to make inferences from the data?
Results		***What did you find?***
Intervention process	□	Time-line diagram, flow chart etc. describing initial steps of intervention and modification over time
Process measures	□	Describe measures and outcomes, summary statistics if applicable
Contextual elements	□	Describe elements interacting with intervention
Associations	□	Describe associations between outcomes, interventions and relevant contextual elements
Unintended consequences	□	Important unexpected events, benefits, problems, failures, costs, associated with the intervention
Conclusions		***What does it mean?***
	□	Summarise key findings and how they relate to rationale and specific aims
	□	Discussion of the relevant literature, comparison of findings
	□	Impact on people and systems, costs and strategic trade-offs
	□	Limitations (potential sources of bias, imprecision)
	□	Generalisability (external validity, applicability, sustainability potential to be replicated elsewhere)
	□	Implications for practice
	□	Suggested next steps
Funding and conflicts of interest	□	Source of funding and other support if applicable
	□	State any conflicts of interest

CHECKLIST IV: EDUCATIONAL INITIATIVES

Item	Description
Title	☐ Identify **type of study** (educational, teaching) ☐ Identify **area of focus**
Authors	☐ Contact details for the corresponding author
Introduction	***Why did you start?*** ☐ Background, explanation of rationale ☐ Describe educational theory, concept or approach used in the intervention ☐ Specific learning objectives, hypothesis
Methods	***What did you do?***
Ethical oversight	☐ Was IRB approval required? If so give number. If not, provide justification
Materials (WHAT)	☐ Describe the specific educational materials: (a) used in training the intervention providers; (b) provided to learners
Study design	☐ Trial type (randomised controlled trial, cohort, before-after, qualitative, etc.)
Content	☐ Describe teaching/learning strategies (e.g. tutorials, lectures, online, etc.) ☐ Describe learning objectives, outcomes ☐ Content of evidence-based practice included in intervention (if applicable)
Personnel (WHO)	☐ Participants: Describe ☐ relevant demographics, how recruited ☐ any incentives or reimbursements provided to learners ☐ how participants were assessed and by whom ☐ Instructors: Describe ☐ professional standing, ☐ teaching experience/expertise/ ☐ study-specific training
Delivery (HOW)	☐ **Delivery** (face-to-face, classroom, self-directed, web-based etc.) ☐ **Individually-based or group** (if group, describe ratio of learners:instructors) ☐ **Delivery assessment:** Processes used to determine if materials and educational strategies were delivered as planned
Environment (WHERE)	☐ **Physical learning space** (conference, lecture theatre, hospital ward, bedside, community, etc.)
Schedule (WHEN, HOW MUCH)	☐ **Schedule:** Describe **number of sessions, frequency, timing, duration**
Evaluation (How did you know it worked?)	☐ Methods of assessment used for the learners (test, questionnaire, etc) ☐ Outcome measures (qualitative, quantitative, score, Likert scale, etc.) ☐ Methods of analysis ☐ Cost assessment
Results	***What did you find?***
Participants	☐ Describe learner attendance, number of participants recruited, completing, dropouts
Outcomes	☐ Summarise outcomes with measures of precision
Changes	☐ Planned and unplanned changes to implementation of intervention
Conclusions	***What does it mean?*** ☐ Summarize key results with reference to study and learning objectives

	□ Limitations (potential sources of bias, imprecision, barriers to implementation) □ Generalizability (external validity, applicability) of study findings □ Interpretation consistent with results, consider other relevant evidence □ Potential cost:benefit
Funding, conflicts of interest	□ Source of funding and other support (e.g. supply of device, materials, etc.) if applicable □ State any conflicts of interest

ITEMS TO INCLUDE WHEN REPORTING ANIMAL RESEARCH

Modified from ARRIVE guidelines *https://www.nc3rs.org.uk/sites/default/files/documents/Guidelines/*

Item	Description
Title	Identify study as **animal-based research** and **area of focus** (e.g. disease, exposure/intervention)
Authors	Contact details for the corresponding author
Introduction	*Why did you start?* Scientific background, explanation of rationale Justify choice of animal model and species (relationship to study objectives, relevance to clinical problems) Specific objectives, hypothesis
Methods	*What did you do?*
Ethical oversight	Give IACUC reference number
Study design	Number of intervention and control groups Methods used to minimise bias (randomisation, blinding) Sample size: Give number of animals used, justification (e.g power calculations), number of animals lost from the protocol (deaths).
Animals	"Demographics': Species, strain, source, vendor, sex, age ,weight Husbandry: housing, light:dark cycle, temperature, feeding regime, enrichment Relevant physiological measures
Procedures	Describe **pre-intervention** procedures e.g. surgical instrumentation, special diets, etc. **Intervention**: what was the experimental intervention tested (e.g. drug, device)? What was done? How was it assessed? What was used for control? **Post-intervention**: palliative care, health & welfare monitoring **Welfare-related**: Describe methods of anesthesia, analgesia, humane endpoints, euthanasia
Outcomes	Clearly defined **primary and secondary outcomes**
Results	*What did you find?*
Baseline data	Summarise relevant characteristics and health status prior to treatment or testing
Numbers analysed	Report absolute number of animals analysed in each group (e.g .10/20 not 50%) Justify any animals not included in analyses,
Outcomes	Summarise results for each group, give estimated effect size and precision (95% confidence intervals)
Adverse events	Describe unexpected events or harms occurring during the experiments
Conclusions	*What does it mean?* Summarise key findings relative to hypothesis, study objectives relevant literature Limitations (potential sources of bias, imprecision, limitations of animal model) Generalisability of findings (external validity, applicability, potential for translation) Interpretation consistent with results, balancing benefits and harms, consider other relevant evidence
Funding	Source of funding and other support (e.g. supply of device, drugs) if applicable
Conflict of interest	Report any conflicts of interest