

Session 7 (PROTECT & WRITE): Exercise sheet

Foundations of Clinical Research · Level 1 · Neudata · #ClearDataClearImpact · Week 7 · Saturday 12 December 2026 · online, 19:30–22:30

Name: _____ Department: _____

This sheet is sent by email before the session, as a Word file and as a PDF. Keep it open on your screen and type your answers into the Word file (or print the PDF). In class the whole group works together: you answer in the chat or in polls, and the instructor writes the class answer on the shared screen. The writing you hand in is your own.

Part	Exercise	When	How
A	Integrity scenarios: green, amber or red?	20:25 (5 min)	Whole class, polls: 3 scenarios in class, 3 at home
B	Proposal builder 7: ethics, registration, feasibility, publication plan	20:30 (15 min)	The instructor models it on the running example; you write your own Part 4 at home
C	Manuscript workshop 1: Methods + Results of your FLUID-ICU paper	21:35 (45 min)	30 min whole class on Q1, then 15 min on your own question; finish at home

Files you need (all in the course folder and sent before the session): the results pack for the question you chose ([Course/Data/results_packs/Results_Pack_Q1 to Q5](#)); the manuscript template ([Course/Templates/Manuscript_Template_IMRaD](#)); Paper 1 (Boulet 2024, a randomised pilot trial of restrictive fluids in septic shock) and Paper 2 (Hyun 2023, a propensity-matched cohort of fluid balance and death in sepsis), both in [Course/Papers](#).

Part A: Integrity scenarios: green, amber or red? (5 minutes, 20:25)

In class we vote on scenarios 1, 3 and 4 in a poll; scenarios 2, 5 and 6 are homework. For each scenario choose:

- **GREEN:** acceptable as described.
- **AMBER:** acceptable **only if** something is fixed or disclosed (say what).
- **RED:** research misconduct or a serious breach. Do not do it.

Write one sentence explaining your colour.

#	Scenario	Colour	Why?
1	Three patients' day-3 fluid charts are lost. A resident "remembers roughly" what their balances were and enters values so the dataset is complete.		
2	After seeing the results, the team removes two patients with "strange" fluid values because they weaken the association. The paper does not mention it.		
3	The head of department did not take part in the study but asks to be last author "because it is my department".		
4	(a) A nurse uses an AI chatbot to improve the English of the Discussion she wrote, checks every sentence, and states this in the Acknowledgements. (b) A colleague uploads the study spreadsheet (names and hospital numbers included) to a free public chatbot and asks it to "run the statistics".	(a)	
		(b)	
5	A cohort of patients with sepsis like FLUID-ICU is published as three papers (mortality, acute kidney injury and ICU stay) in three journals, none mentioning the others.		
6	Two paragraphs of a published review are copied word for word into your Introduction. The review is cited at the end of the paragraph, but there are no quotation marks.		

Part B: Proposal builder 7: ethics, registration, feasibility and publication plan

In class (20:30, 15 minutes): the instructor fills in this worksheet live on the shared screen for the running example (a retrospective cohort of fluid balance and 28-day mortality in adults with septic shock in our ICU). You suggest answers in the chat.

At home this week: fill it in for **your own** proposal. It becomes Part 4 of your written proposal and slides 5 (ethics and feasibility) and 6 (publication plan) of your presentation. Everyone submits the written proposal and the 6 slides before 19:30 on the day of Session 8

([Course/Assignment/proposal_brief.md](#)).

B1. Ethics and consent

Question	Your answer
Which ethics committee will review the study? What type of review do you expect (exempt / expedited / full)? The committee decides.	
Who are the participants, and can they decide for themselves when they become eligible?	
Who gives consent (patient / legal representative / deferred consent / waiver requested)? Use the ICU consent flowchart (Session 7 slides).	
Who takes consent, when and where?	
What are the risks and burdens for participants, and how are they minimised?	
Does the study need registration (trials: yes, before the first patient, in ClinicalTrials.gov or another WHO registry; systematic reviews: PROSPERO; observational: recommended)?	

B2. Confidentiality

Question	Your answer
Which direct identifiers will you collect (if any), and why?	
How will each patient get a study code?	
Where is the key file (code to identity) kept, and who can open it?	
Where will the de-identified data be stored (institution-approved, password-protected)?	

B3. Feasibility check (tick and comment)

✓	Question	Comment
☐	Time: realistic timeline (ethics 1–3 months, recruitment, analysis, writing)?	
☐	Money: budget headings named (staff time, materials/tests, publication fee)?	
☐	People: who collects data (nights, weekends), who analyses, protected time?	
☐	Patients: how many eligible patients did your unit see last year? How many can you realistically enrol?	
☐	Data: are the key variables recorded routinely? How much is likely missing?	

Biggest feasibility risk: _____ One fix: _____

B4. Publication plan (slide 6 of your presentation)

Item	Your answer
Working title (from your PICO: design, I vs C, P, O; 10–16 words)	
Target journal (and a back-up), checked in DOAJ / NLM Catalog, with fees and licence known	
Reporting guideline (CONSORT / STROBE / STARD / PRISMA / SPIRIT / CARE)	
Registration needed? Where? (from B1)	
Authors (all four ICMJE criteria) and their roles (CRediT)	
Conflicts of interest and funding to declare	
Data-sharing statement (what, where, under which conditions)	
Conference where you would present an abstract first	

Structured-abstract skeleton. One line each. Results are the results you *expect to report* (format, not numbers).

Section	One line
Background	
Methods	
Results (expected)	e.g. "28-day mortality: n/N per group, RR (95% CI)"
Conclusion	Write the sentence you would use if the result is positive, and the one you would use if it is not.

Part C: Manuscript workshop 1: Methods and Results (45 minutes, 21:35)

What you are doing

Each participant writes the **Methods** and **Results** of their own short STROBE-guided paper on **one FLUID-ICU question**, using **only** the results pack for that question. We give you the results; you write the paper. Nobody calculates anything.

Question	Topic	Results pack
Q1	Positive fluid balance by day 3 and 28-day mortality	Course/Data/results_packs/Results_Pack_Q1
Q2	Cumulative fluid balance and acute kidney injury (AKI)	Results_Pack_Q2
Q3	Cumulative fluid balance and ventilator-free days	Results_Pack_Q3
Q4	Initial lactate and 28-day mortality; complete-case vs multiple imputation	Results_Pack_Q4
Q5	Fluid balance and ICU length of stay among survivors	Results_Pack_Q5

FLUID-ICU is a **simulated teaching dataset**. In your ethics sentence write: *"This analysis used a simulated teaching dataset; no ethics approval or consent was required."*

How the 45 minutes are used

Clock	Who	Task
21:35–21:50	Whole class, on Q1	The instructor shares the template and results pack Q1. You suggest each Methods sentence in the chat; the instructor types the best one.
21:50–22:02	Whole class, on Q1	Results: participants first, the Table 1 sentence, outcome numbers, crude and adjusted estimates.
22:02–22:05	Whole class	A volunteer reads every number in the class draft against the pack.
22:05–22:20	You, alone	Open the results pack for YOUR question. Follow the structure of the class draft and start your Methods. Ask questions in the chat.
At home	You	Finish the Methods and Results (~600 words), Table 1 and one figure or table. If you chose Q1, write it in your own words; do not copy the class draft.

The class draft is shared as a PDF after the session.

Methods: headings and checklist (STROBE items in brackets)

- **Study design and setting** (4, 5): prospective multicentre cohort; 4 ICUs; dates as given in the pack.
- **Participants** (6): who was included and excluded; how many.

- **Variables** (7): exposure (how fluid balance was calculated and over which days), outcome (definition and time point), confounders adjusted for.
- **Data sources** (8): routine ICU charts / study case report form.
- **Bias** (9): how confounding by indication was addressed (adjustment for severity).
- **Study size** (10): "all eligible patients in the cohort were included" (no new sample size for a fixed dataset).
- **Statistical analysis** (12): summary statistics; the test for each comparison; the regression model(s) and which variables; how missing data were handled; software (R, version from the pack); reporting of 95% CIs.

Results checklist

- ☐ Participants first: number analysed (and excluded, with reasons) (13)
- ☐ Table 1 summarised in one or two sentences: how the groups differed at baseline (14)
- ☐ Outcome numbers per group (15)
- ☐ Main result: **crude AND adjusted** estimate with 95% CI (16)
- ☐ One further analysis (secondary outcome, sensitivity, imputation) (17)
- ☐ No interpretation ("because", "suggests", "important"). Move it to the Discussion
- ☐ No number without its unit and, for effects, its 95% CI

Question-specific reminders

- **Q3:** ventilator-free days are skewed and count death as zero; choose the summary accordingly.
- **Q4:** report BOTH the complete-case and the multiple-imputation estimates.
- **Q5:** survivors only; use medians and IQR.

Deliverable

Your own Methods + Results (~600 words) + Table 1 + one figure or table, saved as `Surname_Manuscript_QN_draft1` in the course folder (or sent by email) **before Session 8**. In Session 8 you add the Introduction, Discussion, Abstract and Title, and submit the complete draft by 23:59 that day (`Course/Assignment/manuscript_brief.md`).