ANONYMIZED RESEARCH PROTOCOL TEMPLATE — PORTFOLIO SAMPLE

[FACULTY NAME]
[DEPARTMENT NAME] · [UNIVERSITY NAME]

RESEARCH PROTOCOL

[RESEARCH TITLE]

Version [VERSION NUMBER] – [MONTH YEAR]

[REVISION NOTE, IF APPLICABLE; E.G. "REVISED FOLLOWING PRELIMINARY SCREENING BY THE RELEVANT ETHICS COMMITTEE"]

Application reference: [REGISTRATION NUMBER / ETHICS APPLICATION REFERENCE, IF APPLICABLE]

Student Investigator
[RESEARCHER NAME], [ACADEMIC QUALIFICATIONS]
[DEGREE PROGRAM]

Principal Investigator and Supervisor
[SUPERVISOR NAME]

Co-Supervisor
[CO-SUPERVISOR NAME]

[CITY, COUNTRY] · [SUBMISSION DATE]

ABOUT THIS TEMPLATE

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- **Guidance lines.** Lines beginning with “Guidance:” are drafting notes. Delete them before submission.
- **Optional sections.** Sections that apply only to some designs (for example, Section 13 and Appendices B to E for two-group or multi-phase studies) may be deleted. Renumber headings and cross-references afterwards.
- **Table of contents.** The table of contents is an automatic Word field built from the heading styles. After editing, right-click it and choose Update Field, then Update entire table.
- **Tables and figures.** All tables are editable Word tables. Figure 1 is an editable placeholder diagram. Add or delete rows as needed and renumber captions.
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PROTOCOL SUMMARY

Item	Detail
Title	[RESEARCH TITLE]
Application reference	[REGISTRATION NUMBER / ETHICS APPLICATION REFERENCE, IF APPLICABLE]
Protocol version	Version [VERSION NUMBER] ([REVISION NOTE, IF APPLICABLE])
Principal Investigator	[PRINCIPAL INVESTIGATOR NAME]
Student investigator	[RESEARCHER NAME]
Institution	[FACULTY NAME], [UNIVERSITY NAME]
Design	[STUDY DESIGN]
Populations	[TARGET POPULATION]
Sample size	[CALCULATED SAMPLE SIZE]
Primary outcome	[PRIMARY OUTCOME]
Key secondary outcomes	[SECONDARY OUTCOMES]
Risk level	[RISK LEVEL AND RATIONALE]
Ethics committee and status	[ETHICS COMMITTEE NAME]; [ETHICS APPROVAL STATUS]
Planned duration	[PROPOSED STUDY PERIOD] (Section 20)

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1. BACKGROUND AND RATIONALE

1.1 Scientific Background

[INTRODUCTION AND BACKGROUND]

Guidance: Introduce the topic, define key concepts and describe the health or healthcare context in which the study sits. Keep the heading structure and paragraph formatting of this section.

[CURRENT EVIDENCE AND SCIENTIFIC CONTEXT]

[CLINICAL OR RESEARCH PROBLEM]

1.2 Statement of the Problem

[PROBLEM STATEMENT]

[IDENTIFIED RESEARCH GAP]

Guidance: State the gap only where it is supported by the evidence reviewed in Section 2. Do not carry over a gap from another project.

[BRIEF STATEMENT OF HOW THE PROPOSED STUDY RESPONDS TO THE IDENTIFIED GAP]

1.3 Rationale and Significance

[JUSTIFICATION FOR THE PROPOSED STUDY]

- **For clinical practice:** [EXPECTED CONTRIBUTION TO CLINICAL PRACTICE]
- **For professional or service practice:** [EXPECTED CONTRIBUTION TO PRACTICE, IF APPLICABLE]
- **For policy:** [EXPECTED CONTRIBUTION TO POLICY, IF APPLICABLE]
- **Methodologically:** [EXPECTED METHODOLOGICAL CONTRIBUTION, IF APPLICABLE]

2. LITERATURE REVIEW

2.1 Introduction

[INTRODUCTION TO THE LITERATURE REVIEW: SCOPE, ORGANISATION BY STUDY CONSTRUCT, AND LINK TO THE CONCEPTUAL FRAMEWORK IN SECTION 3]

2.2 [LITERATURE THEME 1]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

2.3 [LITERATURE THEME 2]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

2.4 [LITERATURE THEME 3]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

2.5 [LITERATURE THEME 4]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

2.6 [LITERATURE THEME 5]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

2.7 [LITERATURE THEME 6]

[RELEVANT LITERATURE]

[SUMMARY OF PREVIOUS STUDIES]

[CRITICAL APPRAISAL OF EXISTING EVIDENCE]

Guidance: Add or delete theme subsections to match the constructs of the proposed study; renumber subsequent headings. Cite using the reference style selected for the protocol (see References).

2.8 Summary of Gaps

[IDENTIFIED EVIDENCE GAP]

[METHODOLOGICAL LIMITATIONS OF THE EXISTING EVIDENCE, IF APPLICABLE]

3. CONCEPTUAL FRAMEWORK

[DESCRIPTION OF THE CONCEPTUAL FRAMEWORK: CONSTRUCTS, EXPECTED RELATIONSHIPS, AND THE ROLE OF THE FRAMEWORK IN THE STUDY]

Figure 1

Conceptual Framework of the Study

[INDIVIDUAL / BACKGROUND CHARACTERISTICS]	→	[EXPOSURE / INTERMEDIATE CONSTRUCTS]	→	[PRIMARY OUTCOME]

Note. [EXPLAIN THE ARROWS AND ANY CONDITIONAL OR MODERATING RELATIONSHIPS.] Replace this editable diagram with the framework drawn for the proposed study.

[EXPLAIN HOW THE FRAMEWORK DETERMINES THE CONTENT OF THE INSTRUMENTS (SECTION 11) AND THE STRUCTURE OF THE ANALYSIS (SECTIONS 12 TO 14)]

4. AIMS, OBJECTIVES, AND RESEARCH QUESTIONS

4.1 Aim

[GENERAL AIM]

4.2 Research Questions

- [PRIMARY RESEARCH QUESTION]
- [SECONDARY RESEARCH QUESTIONS, IF APPLICABLE]
- [SECONDARY RESEARCH QUESTION 2, IF APPLICABLE]

4.3 Specific Objectives and Their Measures

[STATE THE PRIMARY OBJECTIVE, SECONDARY OBJECTIVES AND EXPLORATORY OBJECTIVES, IF APPLICABLE, AND EXPLAIN HOW EACH IS LINKED TO THE MEASURES IN TABLE 1]

Table 1
Specific Objectives, Measures, and Research Questions

Original objective	Operational objective	Measure (items)	RQ
[GENERAL OBJECTIVE 1]	[PRIMARY OBJECTIVE]	[MEASURE / ITEM CODES]	[RQ NO.]
	[SECONDARY OBJECTIVE]	[MEASURE / ITEM CODES]	[RQ NO.]
[GENERAL OBJECTIVE 2]	[SECONDARY OBJECTIVE]	[MEASURE / ITEM CODES]	[RQ NO.]
[GENERAL OBJECTIVE 3, IF APPLICABLE]	[EXPLORATORY OBJECTIVE, IF APPLICABLE]	[MEASURE / DATA SOURCE]	[RQ NO.]

4.4 Hypotheses

[STATE THE BASIS ON WHICH THE HYPOTHESES ARE DERIVED AND WHICH PHASES TEST THEM]

- **H0.** [NULL HYPOTHESIS, IF APPLICABLE]
- **H1.** [ALTERNATIVE HYPOTHESIS, IF APPLICABLE]
- **H2.** [ADDITIONAL HYPOTHESIS, IF APPLICABLE]

5. STUDY OUTCOMES

5.1 Primary Outcome

[PRIMARY OUTCOME: DEFINITION, MEASUREMENT INSTRUMENT, SCORING OR CLASSIFICATION RULE, AND HOW IT IS REPORTED]

5.2 Secondary Outcomes

Outcome	Measure	Scale and scoring
[SECONDARY OUTCOME 1]	[MEASURE / ITEM CODES]	[SCALE AND SCORING]
[SECONDARY OUTCOME 2]	[MEASURE / ITEM CODES]	[SCALE AND SCORING]
[SECONDARY OUTCOME 3]	[MEASURE / ITEM CODES]	[SCALE AND SCORING]
[QUALITATIVE OUTCOMES, IF APPLICABLE]	[DATA SOURCE]	[ANALYSIS APPROACH]

6. STUDY DESIGN

[STUDY DESIGN]

[JUSTIFICATION FOR THE CHOSEN DESIGN AND HOW IT FOLLOWS FROM THE RESEARCH QUESTIONS. IF A MULTI-PHASE DESIGN IS USED, STATE THE PRIORITY AND SEQUENCE OF THE PHASES AND REFER TO SECTION 13 FOR INTEGRATION]

Figure 2
Study Flow

Stage	Activity	Output
[STAGE 1: PREPARATION]	[ACTIVITIES]	[OUTPUT]
[STAGE 2: PHASE 1]	[ACTIVITIES, INCLUDING PARTICIPANT GROUPS AND TARGET NUMBERS]	[OUTPUT]
[STAGE 3: TRANSITION, IF APPLICABLE]	[ACTIVITIES]	[OUTPUT]
[STAGE 4: PHASE 2, IF APPLICABLE]	[ACTIVITIES]	[OUTPUT]
[STAGE 5: INTEGRATION / REPORTING]	[ACTIVITIES]	[OUTPUT]

7. STUDY SETTING

[STUDY SETTING]

[SITES, FACILITIES OR COMMUNITY LOCATIONS WHERE RECRUITMENT OR DATA COLLECTION WILL TAKE PLACE]

[SITE PERMISSIONS AND AUTHORISATIONS REQUIRED, AND THEIR STATUS (E.G., GRANTED / PENDING / NOT REQUIRED). DO NOT STATE THAT A PERMISSION HAS BEEN GRANTED UNLESS DOCUMENTARY EVIDENCE EXISTS]

8. STUDY POPULATION AND ELIGIBILITY

[TARGET POPULATION] / [STUDY POPULATION]

	[PARTICIPANT GROUP 1]	[PARTICIPANT GROUP 2, IF APPLICABLE]
Inclusion	[INCLUSION CRITERIA]	[INCLUSION CRITERIA]
Exclusion	[EXCLUSION CRITERIA]	[EXCLUSION CRITERIA]

[ELIGIBILITY SCREENING PROCEDURE AND ANY DEFINITIONS USED IN THE CRITERIA]

[HANDLING OF INELIGIBLE RESPONDENTS]

9. SAMPLING AND SAMPLE SIZE

9.1 Sampling Strategy

[SAMPLING METHOD]

[JUSTIFICATION FOR THE SAMPLING METHOD, FEASIBILITY CONSTRAINTS AND ANTICIPATED SELECTION BIAS]

[STEPS TAKEN TO LIMIT SAMPLING BIAS AND HOW THE ACHIEVED SAMPLE WILL BE REPORTED AND INTERPRETED (SEE SECTION 15)]

9.2 Sample Size

[SAMPLE SIZE JUSTIFICATION AND CALCULATION]

Guidance: State the software, assumptions (alpha, power, effect size, anticipated non-response) and reference for every calculation. Do not enter a sample size that has not been calculated for the proposed study.

Table 2

Minimum Sample Sizes for the Planned Tests ([ALPHA], [POWER], [EFFECT SIZE CONVENTION])

Planned test	Effect size	Minimum total sample
[PLANNED STATISTICAL TEST 1]	[EFFECT SIZE]	[CALCULATED MINIMUM]
[PLANNED STATISTICAL TEST 2]	[EFFECT SIZE]	[CALCULATED MINIMUM]
[PLANNED STATISTICAL TEST 3]	[EFFECT SIZE]	[CALCULATED MINIMUM]

[PARTICIPANT GROUP 1]. [CALCULATED SAMPLE SIZE AND JUSTIFICATION]

[PARTICIPANT GROUP 2, IF APPLICABLE]. [CALCULATED SAMPLE SIZE, POWER FOR PLANNED COMPARISONS AND INTERPRETIVE CAUTIONS]

[QUALITATIVE PHASE, IF APPLICABLE]. [RATIONALE FOR QUALITATIVE SAMPLE SIZE AND STOPPING RULE]

10. RECRUITMENT PROCEDURES

[PARTICIPANT RECRUITMENT PROCEDURE] [RECRUITMENT PERIOD]

10.1 [PARTICIPANT GROUP 1] Survey

- **[RECRUITMENT CHANNEL 1].** [DESCRIPTION OF THE PROCEDURE AND ANY SUPPORTING MATERIALS (APPENDIX E)]
- **[RECRUITMENT CHANNEL 2].** [DESCRIPTION OF THE PROCEDURE]
- **[RECRUITMENT CHANNEL 3, IF APPLICABLE].** [DESCRIPTION OF THE PROCEDURE, INCLUDING SAFEGUARDS FOR POTENTIALLY DEPENDENT PARTICIPANTS]

10.2 [PARTICIPANT GROUP 2] Survey

- [INVITATION AND DISTRIBUTION PROCEDURE]
- [REFERRAL OR SNOWBALL PROCEDURE, IF APPLICABLE]
- [REMINDER SCHEDULE, IF APPLICABLE]

10.3 Phase 2

[PROCEDURE FOR IDENTIFYING AND CONTACTING VOLUNTEERS FOR THE FOLLOW-UP PHASE, INCLUDING HOW CONTACT DETAILS ARE KEPT SEPARATE FROM STUDY DATA (SECTION 17; APPENDIX E.4)]

10.4 Duplicate and Ineligible Responses

[PROCEDURE FOR PREVENTING AND DETECTING DUPLICATE OR INELIGIBLE RESPONSES]

11. STUDY INSTRUMENTS: DEVELOPMENT, ADAPTATION, AND VALIDATION

11.1 Questionnaire Content

[DESCRIPTION OF THE INSTRUMENTS, CORRESPONDING APPENDICES, AND WHICH ARE ESTABLISHED OR NEWLY DEVELOPED (TABLE 3)]

Table 3

Questionnaire Components and Sources

Component	Items	Source	Status
[INSTRUMENT FOR PARTICIPANT GROUP 1]			
[COMPONENT NAME]	[NO.]	[SOURCE CITATION OR "DEVELOPED FOR THE STUDY"]	[ESTABLISHED / ADAPTED / NEW; PERMISSION STATUS]
[COMPONENT NAME]	[NO.]	[SOURCE CITATION OR "DEVELOPED FOR THE STUDY"]	[ESTABLISHED / ADAPTED / NEW; PERMISSION STATUS]
[INSTRUMENT FOR PARTICIPANT GROUP 2, IF APPLICABLE]			
[COMPONENT NAME]	[NO.]	[SOURCE CITATION OR "DEVELOPED FOR THE STUDY"]	[ESTABLISHED / ADAPTED / NEW; PERMISSION STATUS]

[EVIDENCE OF RELIABILITY AND VALIDITY OF THE ESTABLISHED INSTRUMENTS, AND RATIONALE FOR ANY NEWLY DEVELOPED ITEMS]

11.2 Permissions

[PERMISSIONS OR LICENCES REQUIRED FOR COPYRIGHTED INSTRUMENTS AND THEIR STATUS. DO NOT REPRODUCE COPYRIGHTED ITEMS WITHOUT PERMISSION]

11.3 Content Validity of New Items

[EXPERT PANEL COMPOSITION, RATING PROCEDURE, INDICES AND ACCEPTANCE THRESHOLDS WITH REFERENCES]

11.4 Translation and Cultural Adaptation

[TRANSLATION AND CULTURAL ADAPTATION GUIDANCE FOLLOWED, IF APPLICABLE]

- **[STEP 1].** [DESCRIPTION]
- **[STEP 2].** [DESCRIPTION]
- **[STEP 3].** [DESCRIPTION]

[LANGUAGE VARIETY USED AND CULTURAL APPROPRIATENESS CONSIDERATIONS]

11.5 Cognitive Interviews and Pilot Study

[COGNITIVE INTERVIEW PROCEDURE AND PARTICIPANT NUMBERS]

[PILOT STUDY PROCEDURE, PARTICIPANT NUMBERS, ASSESSED PARAMETERS AND TREATMENT OF PILOT DATA]

11.6 Psychometric Evaluation in the Main Sample

[RELIABILITY AND VALIDITY ANALYSES, THRESHOLDS AND DECISION RULES FOR COMPOSITE SCORES]

12. DATA COLLECTION PROCEDURES

12.1 Phase 1: Surveys

[DATA COLLECTION TOOLS] [PLATFORM AND HOSTING, CONSENT PROCEDURE ON THE FIRST PAGE, LANGUAGE OPTIONS]

[PAPER-BASED DATA COLLECTION, DATA ENTRY AND VERIFICATION PROCEDURE, IF APPLICABLE]

[DATA COLLECTION PERIOD AND STOPPING CRITERIA (SECTION 20)]

12.2 Phase 2: Interviews and Focus Groups

Participant selection. [PURPOSIVE OR OTHER SELECTION CRITERIA FOR THE FOLLOW-UP PHASE, IF APPLICABLE]

Procedures. [DETAILED STUDY PROCEDURES: FORMAT, DURATION, LANGUAGE, LOCATION OR PLATFORM, INTERVIEW GUIDES (APPENDIX C), FIELD NOTES]

Recording and transcription. [RECORDING, TRANSCRIPTION, ANONYMISATION AND TRANSLATION PROCEDURES]

12.3 Qualitative Analysis and Rigour

[QUALITATIVE ANALYTIC APPROACH, SOFTWARE, CODING PROCEDURE, TRUSTWORTHINESS CRITERIA, REFLEXIVITY STATEMENT AND REPORTING CHECKLIST, WITH REFERENCES]

13. INTEGRATION OF QUANTITATIVE AND QUALITATIVE COMPONENTS

Guidance: Retain this section only if the study combines more than one component or method; otherwise delete it and renumber.

[OVERVIEW OF THE INTEGRATION FRAMEWORK AND LEVELS OF INTEGRATION, WITH REFERENCES]

- **Design level.** [DESCRIPTION]
- **Methods level.** [DESCRIPTION OF HOW THE COMPONENTS ARE CONNECTED OR BUILT ON EACH OTHER]
- **Interpretation and reporting level.** [DESCRIPTION OF JOINT DISPLAYS AND HOW CONFIRMATION, EXPANSION OR CONTRADICTION WILL BE JUDGED AND REPORTED (TABLE 4)]

Table 4
Planned Joint Display Structure

Quantitative finding (Phase 1)	Related qualitative themes (Phase 2)	Fit	Meta-inference
[QUANTITATIVE FINDING / OBJECTIVE]	[RELATED QUALITATIVE THEMES]	[CONFIRM / EXPAND / DISCORD]	[INTEGRATED INTERPRETATION]
[QUANTITATIVE FINDING / OBJECTIVE]	[RELATED QUALITATIVE THEMES]		
[QUANTITATIVE FINDING / OBJECTIVE]	[RELATED QUALITATIVE THEMES]		

14. DATA ANALYSIS PLAN

14.1 General Approach

[DATA MANAGEMENT PLAN SUMMARY] [STATISTICAL ANALYSIS PLAN: SOFTWARE, DATA SCREENING, HANDLING OF MISSING DATA, SIGNIFICANCE LEVEL, EFFECT SIZES AND CODING RULES (APPENDIX F)]

14.2 Analysis by Objective

Table 5
Analysis Plan Aligned With Objectives and Hypotheses

Objective / hypothesis	Variables	Analysis
[OBJECTIVE / HYPOTHESIS 1]	[INDEPENDENT, DEPENDENT AND COVARIATE VARIABLES]	[STATISTICAL ANALYSIS]
[OBJECTIVE / HYPOTHESIS 2]	[VARIABLES]	[STATISTICAL ANALYSIS]
[OBJECTIVE / HYPOTHESIS 3]	[VARIABLES]	[STATISTICAL ANALYSIS]
[QUALITATIVE OBJECTIVE, IF APPLICABLE]	[DATA SOURCE]	[QUALITATIVE ANALYSIS AND INTEGRATION (SECTIONS 12.3 AND 13)]

14.3 Reliability

[CROSS-REFERENCE TO RELIABILITY AND VALIDITY ANALYSES (SECTION 11.6)]

15. POTENTIAL SOURCES OF BIAS, LIMITATIONS, AND MITIGATION

Table 6

Potential Sources of Bias and Mitigation Measures

Source of bias	How it may arise	Mitigation
[SOURCE OF BIAS 1]	[HOW IT MAY ARISE IN THIS STUDY]	[MITIGATION MEASURES]
[SOURCE OF BIAS 2]	[HOW IT MAY ARISE IN THIS STUDY]	[MITIGATION MEASURES]
[SOURCE OF BIAS 3]	[HOW IT MAY ARISE IN THIS STUDY]	[MITIGATION MEASURES]
[CONFOUNDING, IF APPLICABLE]	[HOW IT MAY ARISE IN THIS STUDY]	[MITIGATION MEASURES]
[RESEARCHER BIAS (QUALITATIVE), IF APPLICABLE]	[HOW IT MAY ARISE IN THIS STUDY]	[MITIGATION MEASURES]

Limitations. [ANTICIPATED STUDY LIMITATIONS]

16. ETHICAL CONSIDERATIONS AND RISK ASSESSMENT

16.1 Ethical Approval

Ethics committee: [ETHICS COMMITTEE NAME]

Ethics approval status: [ETHICS APPROVAL STATUS]

Approval reference: [APPROVAL REFERENCE, IF APPLICABLE]

[PROPOSED ETHICS AND PERMISSION PROCEDURE. DISTINGUISH CLEARLY BETWEEN PROCEDURES THAT ARE PROPOSED AND PROCEDURES THAT HAVE BEEN APPROVED, AND DESCRIBE HOW AMENDMENTS WILL BE SUBMITTED] [ETHICAL CONSIDERATIONS]

16.2 Risk Assessment

[OVERALL RISK CLASSIFICATION AND RATIONALE; SUMMARY OF FORESEEABLE RISKS IN TABLE 7]

Table 7
Risk Assessment

Risk	Likelihood	Impact	Mitigation
[FORESEEABLE RISK 1]	[LOW / MODERATE / HIGH]	[LOW / MODERATE / HIGH]	[MITIGATION]
[FORESEEABLE RISK 2]	[LOW / MODERATE / HIGH]	[LOW / MODERATE / HIGH]	[MITIGATION]
[FORESEEABLE RISK 3]	[LOW / MODERATE / HIGH]	[LOW / MODERATE / HIGH]	[MITIGATION]

Benefits. [EXPECTED BENEFITS TO PARTICIPANTS AND TO SOCIETY]

Vulnerable groups. [VULNERABLE OR POTENTIALLY DEPENDENT GROUPS AND SAFEGUARDS]

Incentives. [INCENTIVES OR PAYMENTS, IF ANY]

Conflicts of interest. [DECLARATION OF CONFLICTS OF INTEREST]

16.3 Informed Consent Procedures

[INFORMED CONSENT PROCEDURE]

Table 8

Consent Procedures by Study Component

Component	Information provided	How consent is obtained and documented	Withdrawal
[STUDY COMPONENT 1]	[INFORMATION SHEET (APPENDIX D)]	[CONSENT METHOD AND DOCUMENTATION]	[WITHDRAWAL CONDITIONS]
[STUDY COMPONENT 2]	[INFORMATION SHEET (APPENDIX D)]	[CONSENT METHOD AND DOCUMENTATION]	[WITHDRAWAL CONDITIONS]
[AUDIO RECORDING, IF APPLICABLE]	[INFORMATION PROVIDED]	[CONSENT METHOD]	[WITHDRAWAL CONDITIONS]
[USE OF QUOTATIONS, IF APPLICABLE]	[INFORMATION PROVIDED]	[CONSENT METHOD]	[WITHDRAWAL CONDITIONS]

[STATEMENT ON RECONFIRMATION OF CONSENT AND LANGUAGES OF THE INFORMATION SHEETS AND CONSENT FORMS]

17. CONFIDENTIALITY

[CONFIDENTIALITY AND DATA PROTECTION PLAN: ANONYMITY OF RESPONSES, SEPARATION OF CONTACT DETAILS, CODING OF PARTICIPANTS, REMOVAL OF IDENTIFYING DETAILS]

18. DATA MANAGEMENT AND SECURITY

[APPLICABLE DATA PROTECTION LAW, REGULATION AND INSTITUTIONAL POLICY] [DATA MANAGEMENT PLAN]

Table 9
Data Management Plan

Data	Storage	Access	Retention and disposal
[DATA TYPE 1]	[STORAGE LOCATION AND PROTECTION]	[AUTHORISED PERSONS]	[RETENTION PERIOD AND DISPOSAL METHOD]
[DATA TYPE 2]	[STORAGE LOCATION AND PROTECTION]	[AUTHORISED PERSONS]	[RETENTION PERIOD AND DISPOSAL METHOD]
[DATA TYPE 3]	[STORAGE LOCATION AND PROTECTION]	[AUTHORISED PERSONS]	[RETENTION PERIOD AND DISPOSAL METHOD]

Security measures. [SECURITY MEASURES, ACCESS CONTROL, DATA SHARING POLICY AND PROCEDURE FOR REPORTING A SUSPECTED DATA BREACH]

19. RESEARCH TEAM: ROLES, RESPONSIBILITIES, TRAINING, AND OVERSIGHT

Table 10
Research Team

Name	Role in the study	Responsibilities
[PRINCIPAL INVESTIGATOR NAME]	[PRINCIPAL INVESTIGATOR / SUPERVISOR]	[RESPONSIBILITIES]
[CO-SUPERVISOR NAME]	[CO-SUPERVISOR]	[RESPONSIBILITIES]
[RESEARCHER NAME]	[STUDENT INVESTIGATOR]	[RESPONSIBILITIES]

Training. [TRAINING AND CERTIFICATION OF TEAM MEMBERS]

Oversight. [SUPERVISION MEETINGS, MONITORING OF RECRUITMENT, REPORTING OF PROTOCOL DEVIATIONS, COMPLAINTS AND ADVERSE EVENTS, AND PROGRESS REPORTING]

20. TIMELINE

Table 11
Study Timeline

Stage	Planned period
[STAGE 1: ETHICS SUBMISSION AND APPROVAL]	[PLANNED PERIOD]
[STAGE 2: INSTRUMENT PREPARATION]	[PLANNED PERIOD]
[STAGE 3: PILOT STUDY]	[PLANNED PERIOD]
[STAGE 4: DATA COLLECTION]	[PROPOSED STUDY PERIOD / RECRUITMENT PERIOD]
[STAGE 5: ANALYSIS]	[PLANNED PERIOD]
[STAGE 6: REPORTING AND SUBMISSION]	[PLANNED PERIOD]

[PROJECT TIMELINE]

21. DISSEMINATION

[DISSEMINATION PLAN: THESIS, PUBLICATIONS, PRESENTATIONS, FEEDBACK TO PARTICIPANTS AND SITES]

22. FUNDING

[FUNDING SOURCE AND ROLE OF THE FUNDER, IF APPLICABLE] [BUDGET, IF APPLICABLE]

REFERENCES

[REFERENCES RELEVANT TO THE PROPOSED RESEARCH QUESTION]

Guidance: The reference style of the source protocol was a Vancouver-type numbered style, with numerals in square brackets in the text. Retain the style required by the institution. The entries below are formatting patterns only; they are not real references and do not support any research project.

Formatting examples (patterns only):

- *Journal article.* [AUTHOR SURNAME INITIALS], [AUTHOR SURNAME INITIALS]. [ARTICLE TITLE]. [JOURNAL ABBREVIATION]. [YEAR];[VOLUME]([ISSUE]): [PAGES]. doi:[DOI]
- *Book.* [AUTHOR SURNAME INITIALS]. [BOOK TITLE]. [EDITION]. [PLACE OF PUBLICATION]: [PUBLISHER]; [YEAR].
- *Legislation or official document.* [JURISDICTION]. [TITLE OF LEGISLATION OR DOCUMENT] [Internet]. [YEAR] [cited [DATE ACCESSED]]. Available from: [URL]
- *Web page.* [AUTHOR OR ORGANISATION]. [PAGE TITLE] [Internet]. [PLACE]: [PUBLISHER]; [DATE PUBLISHED] [cited [DATE ACCESSED]]. Available from: [URL]

[REFERENCE 1]

[REFERENCE 2]

[REFERENCE 3]

APPENDICES

[LIST THE APPENDICES INCLUDED IN THIS PROTOCOL AND THE LANGUAGES IN WHICH EACH IS PROVIDED]

- Appendix A: [PARTICIPANT GROUP 1] questionnaire ([LANGUAGE 1] and [LANGUAGE 2])
- Appendix B: [PARTICIPANT GROUP 2] questionnaire ([LANGUAGE 1] and [LANGUAGE 2])
- Appendix C: Semi-structured interview guides ([LANGUAGE 1] and [LANGUAGE 2])
- Appendix D: Participant information sheets and consent forms ([LANGUAGE 1] and [LANGUAGE 2])
- Appendix E: Recruitment materials ([LANGUAGE 1] and [LANGUAGE 2])
- Appendix F: Data codebook and scoring rules

Reference numbers in square brackets refer to the reference list of the main protocol.

APPENDIX A: [PARTICIPANT GROUP 1] QUESTIONNAIRE ([LANGUAGE 1])

Study title: [RESEARCH TITLE]

Ethics reference: [ETHICS APPROVAL REFERENCE, IF APPLICABLE]

The questionnaire is preceded by the participant information sheet and consent statement (Appendix D). Item codes are shown for data entry and may be hidden in the online version. Items marked † are newly developed for this study and are reviewed by the expert panel (Section 11.3) before piloting.

Screening

S1. [SCREENING QUESTION 1] ☐ Yes ☐ No *([SKIP OR END-OF-SURVEY RULE])*

S2. [SCREENING QUESTION 2] ☐ Yes ☐ No *([SKIP OR END-OF-SURVEY RULE])*

S3. [SCREENING QUESTION 3] ☐ Yes ☐ No *([SKIP OR END-OF-SURVEY RULE])*

Section A: [DEMOGRAPHIC AND BACKGROUND PROFILE]

A1. [ITEM TEXT, NUMERIC RESPONSE]: _____

A2. [ITEM TEXT]: ☐ [OPTION 1] ☐ [OPTION 2] ☐ [OPTION 3]

A3. [ITEM TEXT]: ☐ [OPTION 1] ☐ [OPTION 2] ☐ Other (please specify): _____

A4. *([CONDITIONAL ITEM, IF APPLICABLE])* [ITEM TEXT]: ☐ [OPTION 1] ☐ [OPTION 2]

Section B: [ESTABLISHED INSTRUMENT 1]

[INSTRUCTIONS TO RESPONDENTS]

B1–B[N]. [INSTRUMENT NAME AND CITATION] [NUMBER OF ITEMS], [RESPONSE SCALE]

[STATEMENT ON COPYRIGHT AND PERMISSION. DO NOT REPRODUCE LICENSED ITEMS WITHOUT WRITTEN PERMISSION.]

Section C: [MATRIX-FORMAT SECTION] †

[INSTRUCTIONS AND RESPONSE SCALE ANCHORS, E.G. 1 = ..., 5 = ...]

Statement	1	2	3	4	5
C1. [ITEM STATEMENT]	☐	☐	☐	☐	☐
C2. [ITEM STATEMENT]	☐	☐	☐	☐	☐
C3. [ITEM STATEMENT]	☐	☐	☐	☐	☐
C4. [ITEM STATEMENT]	☐	☐	☐	☐	☐

Section D: [CATEGORICAL RATING SECTION]

D1. [ITEM STEM]

Source	[ANCHOR 1]	[ANCHOR 2]	[ANCHOR 3]	[ANCHOR 4]
a. [ROW LABEL]	☐	☐	☐	☐
b. [ROW LABEL]	☐	☐	☐	☐
c. [ROW LABEL]	☐	☐	☐	☐

Section E: [SCENARIO OR VIGNETTE SECTION, IF APPLICABLE] †

[SCENARIO TEXT. THE SCENARIO MUST BE REVIEWED BY THE EXPERT PANEL AND IN COGNITIVE INTERVIEWS BEFORE USE.]

E1. [PRIMARY OUTCOME ITEM] ☐ [ANCHOR 1] ☐ [ANCHOR 2] ☐ [ANCHOR 3] ☐ [ANCHOR 4] ☐ [ANCHOR 5]

E2. [ITEM STEM]

Condition	[ANCHOR 1]	[ANCHOR 2]	[ANCHOR 3]	[ANCHOR 4]	[ANCHOR 5]
a. [ROW LABEL]	☐	☐	☐	☐	☐
b. [ROW LABEL]	☐	☐	☐	☐	☐
c. [ROW LABEL]	☐	☐	☐	☐	☐

Follow-up Interview

F1. [FOLLOW-UP INTERVIEW INVITATION] ☐ Yes ☐ No

[STATEMENT THAT CONTACT DETAILS ARE COLLECTED SEPARATELY AND ARE NOT LINKED TO SURVEY ANSWERS.]

Thank you for your time.

APPENDIX A (continued): [PARTICIPANT GROUP 1] QUESTIONNAIRE ([LANGUAGE 2] – DRAFT FORWARD TRANSLATION)

[STATUS OF THE TRANSLATION AND REFERENCE TO THE TRANSLATION PROCESS IN SECTION 11.4]

[أدخل النسخة المترجمة هنا]

[INSERT SECOND-LANGUAGE VERSION HERE, KEEPING THE SAME SECTION ORDER AND ITEM CODES AS THE SOURCE-LANGUAGE VERSION. RIGHT-TO-LEFT TEXT IS SUPPORTED BY THE PARAGRAPH DIRECTION SETTING IN WORD]

APPENDIX B: [PARTICIPANT GROUP 2] QUESTIONNAIRE ([LANGUAGE 1])

Preceded by the participant information sheet and consent statement (Appendix D). Items marked † are newly developed for this study and are reviewed by the expert panel (Section 11.3) before piloting. [NOTE ON ITEMS THAT MIRROR ITEMS IN APPENDIX A, IF APPLICABLE.]

Screening

S1. [SCREENING QUESTION 1] ☐ Yes ☐ No *([SKIP OR END-OF-SURVEY RULE])*

S2. [SCREENING QUESTION 2] ☐ Yes ☐ No *([SKIP OR END-OF-SURVEY RULE])*

Section A: [PROFESSIONAL OR BACKGROUND PROFILE]

A1. [ITEM TEXT]: ☐ [OPTION 1] ☐ [OPTION 2] ☐ Other (please specify): _____

A2. [ITEM TEXT, FREE-TEXT RESPONSE]: _____

A3. [ITEM TEXT] *(tick all that apply)*: ☐ [OPTION 1] ☐ [OPTION 2] ☐ [OPTION 3]

Section B: [ATTITUDE SECTION] †

[RESPONSE SCALE ANCHORS]

Statement	1	2	3	4	5
B1. [ITEM STATEMENT]	☐	☐	☐	☐	☐
B2. [ITEM STATEMENT]	☐	☐	☐	☐	☐
B3. [ITEM STATEMENT]	☐	☐	☐	☐	☐

Section C: [RATING SECTION] †

C1. [ITEM STEM]

Source	[ANCHOR 1]	[ANCHOR 2]	[ANCHOR 3]	[ANCHOR 4]
a. [ROW LABEL]	☐	☐	☐	☐
b. [ROW LABEL]	☐	☐	☐	☐
c. [ROW LABEL]	☐	☐	☐	☐

Section D: [ADDITIONAL SECTIONS AS REQUIRED] †

D1. [ITEM TEXT] ☐ [OPTION 1] ☐ [OPTION 2] ☐ [OPTION 3] ☐ [OPTION 4]

Follow-up Interview

E1. [FOLLOW-UP INTERVIEW INVITATION] ☐ Yes ☐ No

Thank you for your time.

APPENDIX B (continued): [PARTICIPANT GROUP 2] QUESTIONNAIRE ([LANGUAGE 2] – DRAFT FORWARD TRANSLATION)

[STATUS OF THE TRANSLATION AND REFERENCE TO SECTION 11.4]

[أدخل النسخة المترجمة هنا]

[INSERT SECOND-LANGUAGE VERSION HERE, KEEPING THE SAME SECTION ORDER AND ITEM CODES AS THE SOURCE-LANGUAGE VERSION. RIGHT-TO-LEFT TEXT IS SUPPORTED BY THE PARAGRAPH DIRECTION SETTING IN WORD]

APPENDIX C: SEMI-STRUCTURED INTERVIEW GUIDES

[NOTE ON HOW AND WHEN THE GUIDES ARE REFINED (SECTION 12.2), THE FLEXIBLE QUESTION ORDER AND USE OF PROBES.]

C.1 Interview Guide: [PARTICIPANT GROUP 1] ([LANGUAGE 1])

Opening (about [N] minutes). [OPENING SCRIPT: THANKS, CONFIRMATION OF CONSENT AND PERMISSION TO RECORD, NO RIGHT OR WRONG ANSWERS, RIGHT TO SKIP OR STOP]

1. [TOPIC AREA 1]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

2. [TOPIC AREA 2]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

3. [TOPIC AREA 3]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

4. [TOPIC AREA 4]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

5. Explaining the survey findings *[Questions added after Phase 1.]*

Closing (about [N] minutes). [CLOSING SCRIPT: FINAL OPEN QUESTION, THANKS, AND EXPLANATION OF WHAT HAPPENS TO THE DATA]

C.2 Interview Guide: [PARTICIPANT GROUP 2] ([LANGUAGE 1])

Opening (about [N] minutes). [OPENING SCRIPT: THANKS, CONFIRMATION OF CONSENT AND PERMISSION TO RECORD, NO RIGHT OR WRONG ANSWERS, RIGHT TO SKIP OR STOP]

1. [TOPIC AREA 1]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

2. [TOPIC AREA 2]

- [INTERVIEW QUESTION]

- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

3. [TOPIC AREA 3]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

4. [TOPIC AREA 4]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

5. [TOPIC AREA 5]

- [INTERVIEW QUESTION]
- [INTERVIEW QUESTION]
- *Probe:* [PROBE]

6. Explaining the survey findings *[Questions added after Phase 1.]*

Closing (about [N] minutes). [CLOSING SCRIPT: FINAL OPEN QUESTION, THANKS, AND EXPLANATION OF WHAT HAPPENS TO THE DATA]

C.3 [LANGUAGE 2] versions of the interview guides (draft translation)

[أدخل النسخة المترجمة هنا]

[INSERT SECOND-LANGUAGE VERSIONS OF GUIDES C.1 AND C.2]

APPENDIX D: INFORMATION SHEETS AND CONSENT FORMS

[STATEMENT ON WHEN PARTICIPANT DOCUMENTS MAY BE USED, E.G. ONLY AFTER ETHICS APPROVAL IS GRANTED, AND HOW THE ETHICS COMMITTEE CONTACT DETAILS WILL BE ADDED.]

D.1 Survey: Participant Information Sheet and Consent ([LANGUAGE 1])

[WHERE AND HOW THE SHEET IS USED (ONLINE FIRST PAGE, ATTACHED TO PAPER QUESTIONNAIRES), AND FOR WHICH PARTICIPANT GROUPS.]

Study title: [RESEARCH TITLE]

Ethics reference: [ETHICS COMMITTEE NAME], [APPROVAL REFERENCE, IF APPLICABLE]

Why is this study being done? [PLAIN-LANGUAGE ANSWER]

Who can take part? [PLAIN-LANGUAGE ANSWER]

What will I be asked to do? [PLAIN-LANGUAGE ANSWER]

Do I have to take part? [PLAIN-LANGUAGE ANSWER]

Are there any risks or benefits? [PLAIN-LANGUAGE ANSWER]

What happens to my answers? [PLAIN-LANGUAGE ANSWER]

Follow-up interview. [PLAIN-LANGUAGE ANSWER]

Who can I contact? Researcher: [RESEARCHER NAME], [CONTACT INFORMATION] · Principal Investigator and Supervisor: [SUPERVISOR NAME], [CONTACT INFORMATION] · Co-supervisor: [CO-SUPERVISOR NAME], [CONTACT INFORMATION] · [ETHICS COMMITTEE NAME]: Email: _____ Phone: _____

Consent

☐ [CONSENT STATEMENT]

([ONLINE VERSION RULE, E.G. THE QUESTIONNAIRE DOES NOT OPEN UNLESS THIS BOX IS TICKED.])

D.2 Interview and Focus Group: Participant Information Sheet ([LANGUAGE 1])

[WHEN THE SHEET IS SENT AND WHICH ACTIVITIES IT COVERS.]

Study title and ethics approval: as in D.1.

Why have I been invited? [PLAIN-LANGUAGE ANSWER]

What will I be asked to do? [PLAIN-LANGUAGE ANSWER]

Do I have to take part? [PLAIN-LANGUAGE ANSWER]

Recording. [PLAIN-LANGUAGE ANSWER]

Online interviews. [PLAIN-LANGUAGE ANSWER]

Group discussions. [PLAIN-LANGUAGE ANSWER]

Quotations. [PLAIN-LANGUAGE ANSWER]

Withdrawal. [PLAIN-LANGUAGE ANSWER]

Risks and benefits. [PLAIN-LANGUAGE ANSWER]

Confidentiality and data. [PLAIN-LANGUAGE ANSWER]

Who can I contact? as in D.1.

D.3 Interview and Focus Group: Consent Form ([LANGUAGE 1])

Please tick Yes or No for each statement.

Statement	Yes	No
1. [CONSENT STATEMENT, INCLUDING INFORMATION SHEET VERSION AND DATE]	☐	☐
2. [VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT]	☐	☐
3. [AUDIO RECORDING STATEMENT] *(Optional.)*	☐	☐
4. [QUOTATION STATEMENT] *(Optional.)*	☐	☐
5. *For group discussions only:* [GROUP CONFIDENTIALITY STATEMENT]	☐	☐
6. [AGREEMENT TO TAKE PART]	☐	☐

Participant name: _____ Signature: _____ Date: _____

Researcher name: _____ Signature: _____ Date: _____

Record of verbal consent (online interviews only). [STATEMENT BY THE RESEARCHER CONFIRMING THAT THE CONSENT STATEMENTS WERE READ AND RECORDED SEPARATELY]

Participant code: _____ Date and time: _____ Researcher signature: _____

D.4 [LANGUAGE 2] Information sheets and consent forms (draft translation)

[أدخل النسخة المترجمة هنا]

[INSERT SECOND-LANGUAGE VERSIONS OF D.1 TO D.3]

APPENDIX E: RECRUITMENT MATERIALS

[STATEMENT ON WHEN RECRUITMENT MATERIALS MAY BE USED, E.G. ONLY AFTER ETHICS APPROVAL IS GRANTED.]

E.1 Online Invitation: [PARTICIPANT GROUP 1] ([LANGUAGE 1] and [LANGUAGE 2])

[INVITATION HEADLINE]

[INVITATION TEXT: WHO IS INVITED, WHAT IS ASKED, DURATION, VOLUNTARY PARTICIPATION, NO PAYMENT, WHERE FULL INFORMATION IS GIVEN]

Link: [SURVEY LINK] · QR code: [QR CODE]

Ethics reference: [ETHICS COMMITTEE NAME], [APPROVAL REFERENCE, IF APPLICABLE]. Contact: [CONTACT INFORMATION]

E.2 Online Invitation: [PARTICIPANT GROUP 2] ([LANGUAGE 1] and [LANGUAGE 2])

[INVITATION HEADLINE]

[INVITATION TEXT, INCLUDING EMPLOYER CONFIDENTIALITY AND REMINDER SCHEDULE, IF APPLICABLE]

Link: [SURVEY LINK] · Ethics reference: [APPROVAL REFERENCE, IF APPLICABLE] · Contact: [CONTACT INFORMATION]

E.3 Poster Text for [RECRUITMENT SITES] ([LANGUAGE 1] and [LANGUAGE 2])

[LANGUAGE 1]	[LANGUAGE 2]
[POSTER HEADLINE]	**[POSTER HEADLINE]**
[WHO CAN TAKE PART]	[WHO CAN TAKE PART]
[WHAT IS INVOLVED]	[WHAT IS INVOLVED]
[HOW TO PARTICIPATE]	[HOW TO PARTICIPATE]
[VOLUNTARY PARTICIPATION STATEMENT]	[VOLUNTARY PARTICIPATION STATEMENT]
[INSTITUTION] · Ethics reference [APPROVAL REFERENCE, IF APPLICABLE] · [CONTACT INFORMATION]	[INSTITUTION] · Ethics reference [APPROVAL REFERENCE, IF APPLICABLE] · [CONTACT INFORMATION]

E.4 Phase 2 Volunteer Contact Form

[DESCRIPTION OF THE SEPARATE FORM AND CONFIRMATION THAT IT IS NOT LINKED TO QUESTIONNAIRE RESPONSES.]

Field	Purpose
[FIELD NAME]	[PURPOSE OF COLLECTING THE FIELD]

Field	Purpose
[FIELD NAME]	[PURPOSE OF COLLECTING THE FIELD]
[FIELD NAME]	[PURPOSE OF COLLECTING THE FIELD]
[CONSENT-TO-CONTACT STATEMENT] ☐	Consent to contact

[EXPLANATION OF HOW SELECTION CRITERIA THAT DEPEND ON SURVEY ANSWERS WILL BE APPLIED WITHOUT LINKING THE CONTACT FORM TO THE QUESTIONNAIRE]

APPENDIX F: DATA CODEBOOK AND SCORING RULES

[SOFTWARE AND FILE NAMING CONVENTION; MISSING-VALUE CODES; REVERSE-SCORING CONVENTION.]

F.1 [PARTICIPANT GROUP 1] Questionnaire

Variable	Item	Coding
id	Respondent identifier	[CODING RULE]
[VARIABLE NAME]	[ITEM CODE AND LABEL]	[VALUE LABELS OR UNITS]
[VARIABLE NAME]	[ITEM CODE AND LABEL]	[VALUE LABELS OR UNITS]
[VARIABLE NAME RANGE]	[ITEM CODE RANGE AND SCALE NAME]	[VALUE LABELS; REVERSE-SCORED ITEMS]

F.2 [PARTICIPANT GROUP 2] Questionnaire

Variable	Item	Coding
hid	Respondent identifier	[CODING RULE]
[VARIABLE NAME]	[ITEM CODE AND LABEL]	[VALUE LABELS OR UNITS]
[VARIABLE NAME RANGE]	[ITEM CODE RANGE]	[VALUE LABELS]

F.3 Derived Scores

Score	Calculation	Range	Interpretation
[DERIVED SCORE 1]	[CALCULATION]	[RANGE]	[INTERPRETATION]
[DERIVED SCORE 2]	[CALCULATION]	[RANGE]	[INTERPRETATION]
[BINARY OUTCOME CLASSIFICATION]	[CUT-OFF RULE]	0/1	[INTERPRETATION]

Note. [NOTE ON THE USE OF COMPOSITE SCORES FOR NEWLY DEVELOPED ITEMS, SUBJECT TO ACCEPTABLE INTERNAL CONSISTENCY.]