

Guideline for Assignments

Resident Research Course

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Quality Improvement Guidelines provided by J. Thull-Freedman

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Submission of Assignments

All assignments (1, 2, 3 and Final Project) must be emailed to the following people by the date and time indicated.

- Course Coordinator (Jolene.haddad@ahs.ca)
- Small Group Leaders
- Project Supervisor

Your supervisor and Small Group Leaders should receive all assignments so that they can give you feedback. Please send in a **Word document** to allow feedback.

Timeline of Assignments

Assignment	Details*	Date Due
Assignment 1	Research Question, Hypothesis, and Objectives	Monday, October 31, 2022 by 17:00
Assignment 2	Background, Methods, and Outcome Measures	Monday, November 7, 2022 by 17:00
Assignment 3	Sample size considerations and Statistical Analyses/Analysis Methods	Monday, November 14, 2022 by 17:00
Digital Poster	Send <u>final</u> copy to only course coordinator	Wednesday, November 16, 2022 by 08:30
Final Project	Completed Research Proposal ready for submission to ethics board/scientific review	Friday, November 18, 2022 by 17:00

* See Quality Improvement and Qualitative Research sections for modifications according to project type.

Assignment 1: Research Questions, Hypothesis, and Objectives

Length: Approximately, but not constrained to, 1-2 pages double spaced.

Give a few introductory sentences that set the general (biological/health/social) stage (i.e., why is it important to conduct research in this area?), and then the research stage (why is your particular research an important area of inquiry, are there important gaps that you think you will address with your research, etc.).

Clearly state your research question: “Given that sex differences have been identified in fetal glucocorticoid synthesis, how do these sex differences affect fetal growth?” Remember to “reflect” your PICOD (population/patients/problem, intervention or exposure, comparison, outcome, design) in your question when appropriate for your study type.

Next, state your specific objective: “To answer the research question, we have three specific objectives ...”. You should have no more than four specific objectives. These objectives describe the activities that you will perform to answer your research question. Don’t forget to state what each objective accomplishes: “To identify molecular regulators of fetal glucocorticoid synthesis, we will...”.

Taken together, your objectives define an approach to the research question. State why you are using this approach: “Our approach will be to identify the role that sex differences in fetal glucocorticoid synthesis play in regulating fetal growth”.

Finally, state a hypothesis for each of the specific objectives. These hypotheses should be testable and describe the expected outcomes. If your work is not hypothesis driven, be sure to specify what you expect the research will achieve.

Quality Improvement Projects

For quality improvement projects, the assignment will be to answer questions 1 and 3-6 in the [SQUIRE 2.0 Guidelines](#). (Step 2 defines the abstract.)

1. **Title:** Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
3. **Problem description:** Nature and significance of the local problem. If you do not yet have data to describe the extent of the local problem precisely, suggest an estimate.
4. **Available knowledge:** Summary of what is currently known about the problem (locally and in published literature).
5. **Project rationale:** Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention, and reasons why the intervention is expected to work
6. **Specific SMART aim(s):** Specific, measurable, achievable, relevant, and time-based statement(s) of what is hoped to be achieved. The aim statement in QI takes the place of a research hypothesis. The aim should be described as an absolute improvement rather than a relative improvement compared to the current baseline. (An absolute aim will be necessary for displaying on a run chart or control chart and will be more clinically meaningful to frontline

staff.) In addition to a primary aim, you may have secondary aims. If you are planning a hybrid design and intend to add a hypothesis-testing analysis at the end of the quality improvement project (not a requirement), state the hypothesis and the expected outcomes.

If you are considering a project that has a primary purpose of describing a local problem in order to inform later improvement plans, but you are not planning to include improvement interventions in your project, the SQUIRE 2.0 guidelines will not fully apply. The project may share some design similarities with a research project but may be appropriate for ethics review through ARECCI and exemption from REB review. If you think your project falls in this category, please inform Dr. Thull-Freedman and discuss the classification as research versus quality assurance/quality improvement with your supervisor.

Qualitative Projects

Qualitative research is fundamentally different from quantitative research in many ways, and the sections of your proposal (and corresponding assignments) will look different.

Question - You should state the overarching question that your research aims to answer. Indicate your population of interest and provide the context for this question within your research goals. For example, “what is the lived experience of pregnant and parenting Albertans with accessing addiction recovery services in the perinatal period?”. This indicates that you will focus on sampling people from Alberta with specific characteristics.

Next, state your study goal or objective. What is the purpose of gathering the information for the study? For example this might be: to inform prenatal counselling and referral practices, or to inform the development of a new perinatal addictions program. Your objective should be within the scope of the project – for example, to inform recommendations, but not to decrease the prevalence of active addiction in pregnancy. The information may eventually be used for other projects, and have broader impact, but the objective should be specific and something you will fulfill with your project.

We do not typically generate hypotheses in qualitative research. Instead, the researcher should state their own roles in the project and their relationship to the study being conducted, including an explicit statement of any potential sources of personal bias. For example: as a healthcare provider, I recognize that my view on medication compliance is from the lens of clinical care and based in pharmacoepidemiologic evidence etc., and how this might influence their perspective or interpretation, as well as how they plan to mitigate any foreseeable issues.

Assignment 2: Background, Methods, and Outcome Measures

Length: Approximately 5-6 pages double spaced.

Your background (approximately 2-3 pages) should state how both (i) current knowledge, and (ii) your (or your supervisor’s) preliminary/previous work has led you to your research question. The background for a quality improvement project should state what is known in the literature as well as locally about the problem, and it may include rationale for planned tests of change. Your summary of the literature should state what is currently known and identify an important gap in our current knowledge, or

limitations of already published data. It may be important to note how this gap in knowledge or limitations in previous studies impacts research or practice and how your research will move the field forward. The background should be more than a summary of previous studies. It should critically analyze and synthesize the existing research. Take care that your critique accurately depicts previous studies. For example, avoid terms such as “failed” etc., as in “Nettel-Aguirre et al. failed to take into account that x....”

Your methods (approximately 3-4 pages) should be composed of the following elements:

Study design – a description of the basic approach (randomized controlled trial, prospective cohort, case-control, etc.). If you are confused about the “name” do explain how it will be done.

Study participants - a description of the population from which you will draw your sample, how the sample will be obtained, and any inclusion and exclusion criteria.

Outcomes – what you will obtain from each participant. Be careful not to confuse outcome with outcome measure. Be sure to provide an operational definition of your outcome (i.e., specifically how your outcome will be measured) and make the description of your study consistent with it.

Measures – a description of each measure you are proposing, its validity and reliability (if required) for the purpose you are proposing or with the sample you are using, and its use within your study (primary outcome measure, primary exposure, predictor variable, covariate for statistical analyses, etc.). You should justify the methods and measures you use, especially if there are equally valid alternatives or risks associated with your measures.

Procedures – a description of how the study is conducted, the time points at which measures are obtained, how samples are stored, what analytic techniques are used with samples, etc. If relevant, this section should include who is doing the measurements/intervention and a timeline that details when the work will be done from ethics application through to disseminating results. Think of potential biases incurred and how you expect to mitigate them.

Anticipated difficulties – your methods will describe the research approach that you think is best for your study, but you may wish to describe alternate strategies that you will employ if problems are encountered. This should be brief and is mainly a way to show that you are aware that problems may arise and that you’ve thought of how to address them.

Ethics – what ethical considerations do you need to make for your approach? Will your project require full board review, or will it be expedited or exempted? How will you obtain consent/assent (if required)?

Quality Improvement Projects

Your methods section will cover steps 7-12 of the [SQUIRE 2.0 Guidelines](#):

7. **Context** – elements of the local setting that are important in influencing response to tests of change.
8. **Interventions** – what are the key tests of change that are being planned, described in sufficient detail to be reproducible to other teams, and who will be part of the improvement team.
9. **Study of the interventions** – what will be the measurement approach to verify that the observed outcomes are due to the interventions.

10. Measures – Measures chosen for studying processes and outcomes, including rationale for choosing them, their operational definitions, what is known about their reliability and validity, and methods to assess completeness and accuracy of data. Also describe the approach to assess contextual elements that contribute to the success of interventions, and/or efficiency and cost.
11. Analysis – Methods used to draw inferences from the data and for understanding variation. Typically, a quality improvement project will involve assessing change over time using a run chart or statistical process control chart.
12. Ethics – Will the project be exempted from research ethics review, and if so, what will be your alternative plan to assess project ethics (typically this will be [ARECCI](#) for a QI project, followed by communication with the REB to confirm exemption).

Qualitative Projects

Your background section will explore the literature that has led you to your research question. This can include both quantitative and qualitative literature. Your background section should frame the knowledge gap that your study will fill and should include a theoretical framework that will guide your research. Examples of this might be the social-ecological theory, or feminism, but can include many others. When writing your background, it's important to keep in mind that qualitative projects answer different types of research questions (i.e. the why, and how) than quantitative. For example, there may be quantitative research showing poor medication compliance for psychiatric patients with condition X. A qualitative study could fill the knowledge gap of why these patients are non-compliant, through an exploration of their experiences. Your background should describe why your project is important, and why a qualitative methodology is appropriate.

Methods - *It is recommended that if conducting a qualitative project, that you download the Consolidated criteria for REporting Qualitative research (COREQ) checklist as a guide for what to include in your methods section: http://cdn.elsevier.com/promis_misc/ISSM_COREQ_Checklist.pdf*

You will first need to identify what qualitative methodology you will use. This is the parallel concept to “study design” in quantitative studies. Some common examples are thematic analysis, grounded theory, interpretive description, or phenomenology, but there are many.

Next you should detail the study population (this is the population from which you will take your sample of participants. Or in other words, the population that your study sample will represent. Then you should detail how you will sample and recruit the participants for your study, detailing inclusion and exclusion criteria, and providing justification for these. Include descriptions of interactions with participants, how relationships or trust will be established if applicable.

The next step will be to detail your data collection methods. Some examples are individual interviews, focus groups, or journal entries, but can include video, photos, artwork and other data types. The method should be justified (why is this the best/most feasible approach?). You can (and it is often recommended to) include different methods of data collection to address the same question. For example, this could include individual interviews with patients and with care providers, to get both perspectives on the medication compliance issue, or interviews and photos taken by participants to show their experiences. You should detail who will be conducting data collection, if it will be recorded or

transcribed and how, and how it will be stored. Describe ethical considerations, how you will obtain consent, and how and where the data collection will take place (i.e. in person vs. virtual etc.)

The parallel to exposure, outcome and outcome measures for a qualitative project are the qualitative interview guide, semi-structured interview questions, or other tools you will use to gather your data. Detail the questions you will ask your participants during data collection. Add prompts, or additional questions that can be used to follow-up or dig deeper into ideas that the participants introduce. Questions should be open-ended, and free from underlying assumptions tied to the researcher's role, perspective or implicit biases. For example: "Can you tell me about your experience with accessing addictions treatment services when you were pregnant? Were there things that stand out to you as challenging within this experience?" rather than "what made it difficult for you to access addictions services while pregnant?". See interview guide section of COREQ.

Assignment 3: Sample size considerations and Statistical Analyses

Length: Approximately 1-2 pages double spaced.

State how the sample size that is available (for projects where data has already been collected) or will be obtained (for projects that will be recruiting participants) is sufficient to address the objectives of your research project. Sample size is a function of many factors, but is always specific to the type of analysis that you intend to conduct. Provide adequate justification for the assumption you make and the specific values that you use in your sample size/power calculation so that they can be reproduced by anyone who reads your proposal. For a quality improvement project, describe the size of the data sample that will be obtained during each unit of time. Will you obtain data from the full population, or will a sampling strategy be utilized? Provide justification that the amount of data collected will be sufficient to determine whether changes are leading to improvement.

Describe the analyses that will be used. Be sure to match the analytical approach to the objectives, measures, and sample size in your project. It is important to match your statistical analyses to each of your research objective. You may need to propose a different analytic approach for each of your objectives, depending on the nature of your objectives. Ultimately your analytic strategy must address your hypothesis or question. For qualitative projects, be sure to describe your analytic process, what knowledge it produces, and how you will ensure the quality of your findings.

Quality Improvement Projects

For this assignment, you will further develop Step 11 of the [SQUIRE 2.0 Guidelines](#).

Describe your measurement strategy and how you will determine that sufficient data has been collected to assess the impact of your project. For a QI project, the sample size is based on pragmatic considerations rather than achieving sufficient power for hypothesis testing. What is the amount of data that will balance the importance of accurate measurement with resources available to the project team? Will you collect data on all members of the population of interest, or will a sampling strategy be utilized? When possible, a run chart should have 10-20 baseline data points prior to and after tests of change. Describe the estimated time required to achieve the project aims and whether the project

timeline will be extended if needed to achieve aims. Describe how you will determine whether change is significant or due to chance (e.g. whether you will use run charts to identify special cause variation).

The [Health Care Data Guide](#) is a highly useful resource for planning a quality improvement analysis.

Qualitative Projects

There are no sample size calculations, and your final sample is often determined after you start collecting and analyzing data. You should, however, discuss sample size considerations. What is a rough estimate of the number of people you will include? Different methodologies require different sample sizes. For example, with phenomenology, you might aim for very in-depth interviews with 8-10 people, whereas a thematic analysis might have 3-5 focus groups of 8-10 people each, and a grounded theory project might include shorter interviews with 50 people. In discussing your sample size, you should also consider how broad your research question is. More specific questions, in a smaller or more homogeneous population may require fewer people than a broad question or population. Finally, you will need to state how you will determine that you've reached your full sample. In qualitative studies this is often determined when you reach theoretical saturation, which implies that no substantial new knowledge would be gained by further increasing your sample. For example: "We will cease recruiting new participants when no new themes emerge from 3 sequential interviews."

Qualitative analysis: There are a number of different qualitative analysis methods. Some of the most common for health research are thematic analysis and narrative analysis. Discuss with your supervisor and course instructors to identify the best method for your study. The analysis methods should include a complete description of who is analyzing the data and how. Refer to the [COREQ reporting guideline](#) checklist for the details that you should include.

Digital Poster and Research Day Presentation

Poster: A good poster focuses on visuals that are clear and compelling and limits text to a minimum. We use digital posters for Research Day for ease of presentation, as each session is combined into one larger presentation. Both PowerPoint and PDF versions are accepted, but the preference is PPT.

Resources:

- [Poster Example](#)
- [Poster Tips from MITACS Conference](#)
- [Digital Poster PPT template](#)

Presentation: Each resident will have 7 minutes to present a poster with 3 minutes allowed for questions (10 minutes total). These presentations will be peer-reviewed, therefore attendance of each session is required even if you are not presenting.

Final Project

Your final project is an accumulation of the 3 assignments previously submitted with revisions made from the feedback given. This culmination should be a proposal ready for submission to ethics board/scientific review/ARECCI.