"HOW-TO" GUIDES 2017

FULL TEXT

CHEO RESEARCH INSTITUTE
CLINICAL RESEARCH UNIT

Dedicated with love to my late mother Ivy Harrison

CHEO RESEARCH INSTITUTE
CLINICAL RESEARCH UNIT

CLINICAL RESEARCH UNIT

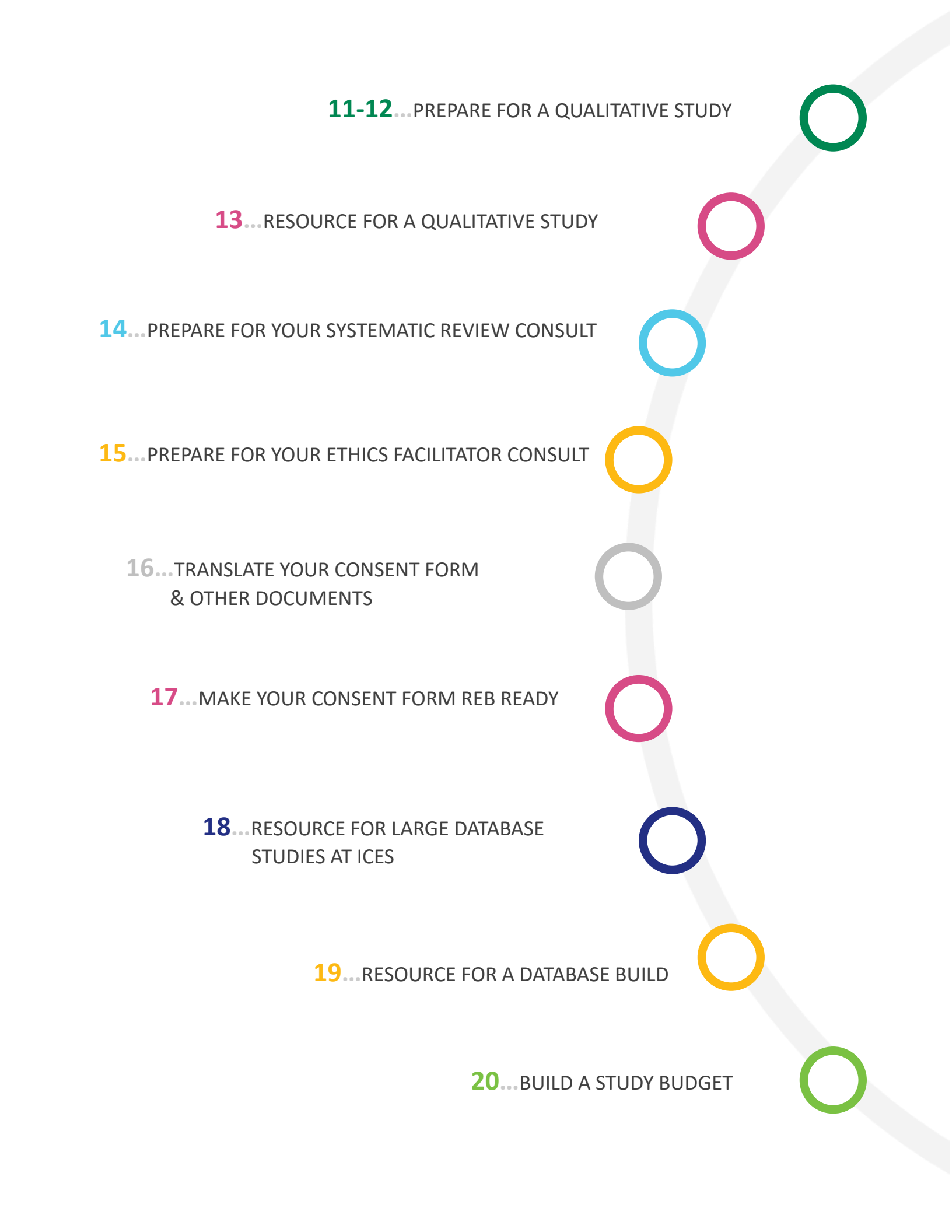
MISSION

To provide comprehensive research support in order to help clinicians and scientists achieve their academic research goals.

SERVICES

ABOUT US

Table of Contents


11-12...PREPARE FOR A QUALITATIVE STUDY
13...RESOURCE FOR A QUALITATIVE STUDY
14...PREPARE FOR YOUR SYSTEMATIC REVIEW CONSULT
15...PREPARE FOR YOUR ETHICS FACILITATOR CONSULT
16...TRANSLATE YOUR CONSENT FORM & OTHER DOCUMENTS
17...MAKE YOUR CONSENT FORM REB READY
18...RESOURCE FOR LARGE DATABASE STUDIES AT ICES
19...RESOURCE FOR A DATABASE BUILD
20...BUILD A STUDY BUDGET

How To…

Prepare for your CRU Consult

- **Know your question**
  - Perhaps a clinical observation has led to a question you would like to answer. Formulate the question as clearly as possible and ensure you understand exactly which patient population you want to include and what outcomes are most important.
  - State the research question in exact terms using the PICO acronym to ensure your question addresses all key elements:
    - P = Population
    - I = Intervention
    - C = Comparison
    - O = Outcome
  - Be very specific about your outcome measures and understand the clinical significance of possible results (e.g., What result would make you and your colleagues change your clinical practice?) Confirm with your clinical colleagues that your question meets the FINER criteria:
    - F = Feasible
    - I = Interesting
    - N = Novel
    - E = Ethical
    - R = Relevant
- **Bring your protocol**
  - If you haven't already attached your protocol to the Consult Request Form, email it to the consultant (even a rough draft) in advance of your meeting.
- **Bring relevant literature and supporting documents**
  - It is important to be thoroughly versed in the relevant literature on your topic. Exemplars from the literature (including the non-pediatric literature) can be extremely helpful during your methodology consult.
  - If there are previously published studies in the literature that you have identified as excellent (e.g., strong methods, similar outcome measures, etc.), please bring them in electronic or paper form to discuss with the consultant.
- **Know your timelines (and deadlines!)**
  - For grants, begin to prepare at minimum 3 months in advance of the deadline date. Give yourself 6 months if you are a novice and/or there are many people who will contribute to the proposal. Note that some CIHR applications require Registration or submission of a Letter of Intent in advance of the grant deadline.
  - Analysis of qualitative data requires at least one month.
  - If you are within the first 3 years of appointment there is a mandatory internal peer review process mandatory internal peer review process for grant applications:
- **Invite your supervisor**
  - If you are a trainee (e.g., resident, fellow, medical/graduate student), the principal investigator and/or research supervisor should attend your initial CRU consultation meeting to ensure that there is agreement regarding the scope of the project, costs, etc.
- **If relevant, bring draft case report forms**
  - This is especially important if you require consultation on database design and setup (e.g. REDCap)

To request a consult with CRU, click here

How to resource for a quantitative study

Please note: Time estimates are approximate only and can vary substantially on a case-by-case basis. Please consult your statistician to determine resource considerations for your study.

Two stages should be considered: (1) data preparation, and (2) statistical analysis.

Stage 1- Data preparation

Basic data preparation: 7.5 – 37.5 hours (typically 22.5 hours)

- Importing data from REDCap
- Importing data from Excel or a CSV file
  - Trimming spreadsheet and extraneous contents
  - Fixing variable names
- Recoding or collapsing factor levels (e.g. converting grade level into elementary, high school, …)
- Basic derived variable calculations (e.g. calculating age at surgery)
- Basic subsetting (e.g. selecting only patients under age 10)
- Basic statistical data validation to identify outliers, inconsistent entries, missing data

Intermediate data preparation: 37.5 – 75 hours (typically 60 hours)

- *Basic data preparation (as above)*
- Excel files
  - Combining multiple worksheets
  - Handling Excel formulas
- Importing data from other formats (e.g. SAS, SPSS, etc.)
- Simple data restructuring
- Intermediate derived variable calculations
- Intermediate subsetting (e.g. involving derived variables)
- Intermediate statistical data validation to identify outliers, inconsistent entries, missing data

Complex data preparation: 75+ hours (typically 150 or more hours)

- *Basic and intermediate data preparation (as above)*
- Merging data from more than one data file
- Restructuring longitudinal data and/or data with multiple events
- Extracting data from columns containing multiple items (e.g. SBP/DBP)
- Recoding free text
- Complex derived variable calculations
- Complex statistical data validation to identify outliers, inconsistent entries, missing data

Stage 2 - Statistical analysis

Includes review and revision of statistical analysis plan as well as report preparation.

Basic analyses: 37.5 – 75 hours (typically 60 hours)

- Descriptive statistics (frequencies, percentages, means, medians, standard deviations, etc.)
- A total of up to three basic tables or figures.

Intermediate analyses: 75 – 225 hour (typically 150 hours)

- *Basic analyses (as above)*
- Up to three additional basic tables or figures.
- Hypothesis tests (e.g. t-test, Mann-Whitney test, chi-square test, Fisher's exact test), p-values
- confidence intervals

Complex analyses: 225+ hours (typically 300 or more hours)

- *Basic and intermediate analyses (as above)*
- Additional tables and figures, and/or customized or complex tables and figures
- Additional analyses, e.g. regression (linear, logistic, etc.), meta-analysis, longitudinal analyses, mixed effects models*, c*omplex non-standard analyses

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Other things to consider

Many factors affect the resource requirements for a quantitative study.

- **Data size** (in terms of both number of **cases** and number of **variables**) can have an impact on the resources required for both data preparation and statistical analysis. For example basic data preparation and analysis for a big data set can easily require the same resources as intermediate or even complex data preparation and analysis of a smaller data set.

- When the statistical analysis plan in the study protocol lacks clarity, resource requirements increase.

To request a consult with CRU, click here

How To…

Prevent missing data in your study

Missing data can irrevocably harm the validity of your study, whether it is a small resident project or a multi-centre randomized trial. Some forms of missing data are unavoidable (e.g., you can´t force participants to attend follow-up sessions). Planning ahead is the best remedy. Even a little missing data can bias your results. Missing data statistical analyses, while sophisticated, are only Band-Aids.

- **Have a statistician on your research team, and include study coordinators in planning meetings**
  - A statistician and experienced research coordinator will provide invaluable insight into the likelihood of problems that could lead to missing data and into possible simple remedies
- **Dedicate time during planning to discussing how likely it is that:**
  - Individuals will drop out of follow-up in your study or miss appointments
  - Certain questions on surveys or questionnaires will not be answered
- **Your proposed statistical analysis section should include a missing data analysis plan**
  - This may require inflating your sample size and collecting auxiliary data to inform the reasons for missing data

Some considerations

- **… for avoiding missing data in studies with follow-up**
  - Ensure your recruiters, coordinators, and interviewers are personable, friendly, welcoming, and well-trained
  - Extra hospital visits by participants for research purposes should be avoided, but otherwise should not be a burden (e.g., cover parking costs, onsite diversions for siblings)
  - Keep appointments as short as possible and avoid unnecessary questions (e.g., use direct data capture from charts and electronic records when available)
  - While a participant in a randomized trial can be withdrawn from the investigational treatment that is not the same thing as withdrawal from study follow-up. This distinction is especially important when it comes to measuring the primary outcome.
  - Discuss different study designs with your statistician and team. There are often several options, even among randomized trials.
  - Keep contact information of participants up to date.
  - Multi-centre studies can include incentivization for completeness of information
  - Consider using methods to keep participants engaged (e.g., newsletters, study website)
- **… for avoiding missing data in surveys**
  - Avoid unnecessarily long surveys. Collect only what you need for your research objectives.
  - You can include branching logic in the survey to cut down on the number of questions participants need to read (make sure you test this branching logic carefully)
  - You must distinguish “don´t know”, “not applicable”, and “missing”
- **… before heading into fieldwork**
  - Discuss with your statistician the pros and cons of face-to-face interviews, paper formats, and more automated approaches (e.g., online REDCap surveys).
  - Always pilot your forms and surveys; download the data and inspect its structure with a statistician
- **… during fieldwork**
  - Set acceptable targets for missing data and monitor your study as it progresses.

To request a consult with CRU, click here

How To Expedite Your Statistical Analysis

Why statistical analysis can be time consuming

The statistical analysis stage of a research project may often require more time than anticipated. There are several reasons for this, including the following:

- During analysis, data anomalies are often detected and need to be corrected.
- Your statistician is typically working on more than one project at the same time. In order to meet their commitments on multiple projects, they need to divide their time.
- Sometimes analyses are performed that, at least in hindsight, were not necessary.

Steps you can take to expedite your statistical analysis

In order to expedite your statistical analysis, there are several steps you can take:

- Plan well in advance of key deadlines to ensure a statistician is available.
- An initial meeting between the principal investigator and the statistician should take place at least 4 to 6 weeks in advance of a key deadline (3 months for more complex studies).
- Before the actual data analysis begins, work with your statistician to develop a detailed Statistical Analysis Plan.
    - The analysis plan should focus on your main objectives and list the specific statistical methods that will be used to achieve those objectives.
    - Specific variables to be included should be listed.
    - Key derived variables should be explicitly defined using variable names from the database.
    - It is often helpful to include examples or templates of desired tables and figures.
- Keep the number of tables and figures to a minimum.

What to minimize

Time requirements can be reduced by *minimizing*:

- The number of outcomes examined
- Exploratory or hypothesis-generating analyses
- Repeating analyses as part of "fishing expeditions" to seek statistical significance
- Unplanned analyses (even when they address pre-specified objectives)
- Changes to the statistical analysis plan

All of the above can greatly increase the time required to complete your analysis. Additionally, they may adversely affect the scientific integrity of your results since they increase the chance of false positive results.

Exploratory science

Timely completion of statistical analyses is much more likely if a detailed analysis plan is in place, and what's more, this will reduce the chance of obtaining spurious results. Nevertheless, scientific research often has an iterative, exploratory aspect. Important serendipitous discoveries can take place in the course of an analysis focused on something else. However it is better to postpone further exploration of unexpected findings until after the initial analysis plan is complete, and the main paper is submitted for peer-review publication.

To request a consult, click here.

How To…

Organize the Data in your Excel spreadsheet before giving it to a Statistician

Your data has been collected using Excel and you are requesting the services of a CRU statistician to analyze your data. Note that the way that data is *organized* in an Excel spreadsheet can have an impact on how much time will be required to migrate it to a statistical software program. Here are some steps to follow to minimize this time.

1. Data should be stored in one sheet. Do not split data across multiple sheets (or files).
   - An additional sheet may be used to specify variable meanings and codes (a "code book").
2. Ensure that there are no patient identifiers in the file (i.e. MRN, name, phone no., etc).
3. Ensure that there are no merged cells.
4. Avoid computed values (calculations should be done by the statistician to avoid errors).
5. Remove any blank columns between data.
6. **Missing Values:** Be consistent with how missing values are identified (e.g. leave the cells blank).
7. **Color coding:** Avoid color-coding your data (i.e. representing information by highlighting cells in different colors, using different colored fonts, etc.).
   - If cells are color-coded, re-specify the coding as another variable. For example, if coding is used to specify context (e.g. high, medium, low), this should be a separate variable. The code book should specify what the codes represent (i.e. 1="low", 2="medium", 3="high").
8. **Dates and time:** Ensure that times and dates are formatted consistently.
   - Ensure that time durations are consistent within a column (i.e. always specify in seconds, minutes, hours, days or weeks). Do not write the unit in each cell.
   - For dates, it is often best to use separate columns for year, month and day.
9. **Variable names:** Variable names should start with a letter, never with a number and must not contain spaces or symbols.
   - Keep the number of characters to a minimum and non-capitalized (e.g. dob (date of birth), los (length of stay), age_cat (age category).
10. **Variable coding**:
    - Work with numerical values when possible as they are easily analyzed. Avoid text. Variables should be coded numerically (also known as 'dummy-coding'). For example, rather than entering the words "no" or "yes", use numbers to represent words (e.g. 0="no" and 1="yes"). The same applies for male/female, etc.). When dummy coding, include a code book (see tip #1).
    - Avoid flagging special cases or values with symbols (e.g. asterisks, indentation, italics, etc.). If there are cases you want to bring to the attention of the statistician, create a separate column with a numeric code to flag these cases.
    - Never use numbers with hyphens (Excel automatically converts these to dates).
    - Each column should contain just one value (e.g. for blood pressure one column for SBP and one for DBP).
11. **Numbers as text:** Sometimes when you import data from text files or external databases, numbers get stored as text. Ensure that your numbers are stored as numbers by using Excel's 'format cells' feature.

Tip: The CRU *recommends* using REDCap for all data collection. Please visit http://www.cheori.org/en/redcap for REDCap information, resources, and training videos!

All REDCap related enquiries (including new account requests, password resets, and troubleshooting questions) should be directed to redcap@cheo.on.ca.

To request a consult, click here

Integrate Automated University of Ottawa Library Access with Google Scholar

Did you know…
All CHEO RI employees are eligible for online access to the University of Ottawa library? Contact Jeanette Alexander: jealexander@cheo.on.ca

Once you have your access to the library….

1. Go to the Google Scholar home page: https://scholar.google.ca Click on the upper right tab 'settings'

2. 2. Click the tab "Library links" and then select libraries that you have access to. At CHEO we can select: CHEO – CHEO Full Text; Ottawa Hospital – Civic Campus – Available online; Ottawa University – Get It Full Text; University of Ottawa Library/Bibliothéque uOttawa – afficher/get it! Uottawa

3. Now search for your articles in google scholar. A series of hyperlinks are now retrieved alongside the official journal links

4. If the article is not freely available via the publishers link click the "afficher/get it! Uottawa" link which will take you to the University page

5. Once there, click on the hyperlink

6. If this is the first time in your current session that you have gone through the library, enter you username and password (note: if you search for multiple articles in a single session, you will only need to log in once)

7. Click 'sign in' to be taken to the article: **Voila!**

To request a consult with CRU, click here

How To…

Build a Great Database

To request a consult with CRU, **click here**

CODING

Follow the first rule of coding	
1, Yes 0, No	If you select the "Yes/No" field type in REDCap, these codes will be automatically assigned. But if you need/want to code the response options yourself, always follow this rule. "Yes", "No" and any other response options can be in any order – just make sure these are the codes you assign.

"Match" response options and codes	
Example: What year of residency are you in?	
GOOD	BAD
1, PGY 1	0, PGY 1
2, PGY 2	1, PGY 2
3, PGY 3	2, PGY 3
4, PGY 4	3, PGY 4

Assign codes consistently (if possible)	
Example:	
I feel confident.	*I feel happy*
1, Strongly Disagree	1, Strongly Disagree
2, Disagree	2, Disagree
3, Agree	3, Agree
4, Strongly Agree	4, Strongly Agree

VARIABLE NAMING

Keep it short and simple: In most cases, variable names should not exceed 20 characters. Consider using accepted abbreviation (e.g. dx, hx, dob).

Field label	BAD Variable Names	GOOD Variable Names
Was there visual acuity impairment?	visual_acuity_impairment_yn	visual_impair
Have you had any previous clinic visits?	prevclinicvisits_yesno	prev_visit

Make it meaningful: Variable names should be clear enough that your statistician will be able to understand which question you are referring to. In general, better to have a long variable name that's clear than an overly short one that is incomprehensible.

Field label	BAD Variable Names	GOOD Variable Names
Level of sadness regarding surgery	health_feelings	surg_sad
Has the parent received a flu shot?	flushot1	par_flushot
Has the child received a flu shot?	flushot2	child_flushot

Keep it consistent: Avoid inconsistencies by noting how you named previous variables.

Field label	BAD Variable Names	GOOD Variable Names
Record medications the child is taking.	med1 medication_2 drug3	med1 med2 med3
Heart rate before exam	hr_before	hr_pre
Blood pressure before exam	bp_pre	bp_pre
Heart rate after exam	hr_after	hr_post
Blood pressure after exam	bp_post	bp_post

PRIVACY

CHEO RI Policy on Identifiers

Entering any identifying information* into REDCap is strongly discouraged. When possible, identifiers that are required for administrative purposes (names and addresses) should not be stored in the research database. Recruitment logs or other means (which may be electronic) should be kept in a separate location and used to link contact information with subject IDs and unique study codes. Some studies require the collection of identifiers. Where this is the case, ethics applications must detail what identifiers are collected and how they are stored in the database. Only the minimum number of identifiers required should be entered into REDCap. Furthermore, any identifying information should be flagged as an "Identifier" through the Online Designer or Data Dictionary. Contact redcap@cheo.on.ca if you are unsure about storing identifying information for your project.

**not sure what constitutes an identifier? Check out the CHEO REDCap Best Practice Guidelines link available in every project.*

REDCap Research Electronic Data Capture

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Conduct Preliminary Data Cleaning of your REDCap Database

You have finished entering data into your REDCap project! Before data analysis can begin, it's important to clean your data. Data cleaning involves checking for errors, outliers, inconsistencies, and other problems. This will ensure that the findings from your study are as reliable as possible.

We recommend the following process:

1. Perform preliminary data cleaning within REDCap.
2. Perform more intensive data cleaning using a statistics package.

During each of these steps, you will likely identify discrepancies in the data which will need to be corrected in REDCap.

1. Preliminary data cleaning in REDCap

- Go into your project on REDCap
- In the menu on the left hand side of the screen, select **Data Exports, Reports, and Stats**.
- Under **My Reports & Exports**, click **Stats & Charts**.
- Under **DISPLAY OPTIONS**, if you have more than one data collection instrument, select the one you want to review.
- A report will be produced summarizing the values for each of the fields.
    - For numeric fields, you will see the min, max, percentiles, etc. If the minimum or maximum is unrealistic for a given variable, there may be an error. There will also be a dot plot showing each value. If you click on a dot it will take you to the data collection instrument with that value entered for that field. If it is in error, you should correct it. This is an especially useful feature as it can be used to identify outliers and fix errors.
    - For categorical fields, bar charts are displayed. Review these to check that they appear reasonable.

2. Intensive data cleaning in a statistics package

- While the Stats & Charts feature in REDCap provides a good first step for data cleaning, it does not have the full features for data manipulation and examination that are available in a separate statistics package.
- If you know how to use a statistics package, you can perform these steps yourself. Ensure that you make any corrections that are required *directly in REDCap*.
- If you require assistance, the CRU can help. To request a consult, click here

How To…

Work with an editor on your research paper

1. **In order to apply to work with our pilot project editor on your manuscript, you are required to first:**
   - Have completed the study data collection and the analysis.
   - Know the journal — or journals — you are considering, the type of paper you are planning (e.g. **original research, literature review, clinical trial, etc.), your audience, and your main message.**
   - **Write an outline or a draft of the article (this can be in point form or more fully formed).**
   - Only **one** paper per research team is permitted to be in the queue at any time.

2. **If you are approved, you will:**
   - Be added to the queue and contacted once the editor is available.
   - Identify the lead researcher. In the event that a project is trainee-led, the supervisor is required to be the primary contact with the editor throughout the process.
   - Send your draft/outline and preferred journals to the editor, who will read the article (and some background pieces for context) and research what's needed for submission to the journals (length, form, focus, style, etc.)
   - Meet (in person or online) with the editor for an in-depth discussion about the focus, content and process. This usually takes about an hour and establishes a mutual understanding of where the project is going, the next step and the timing.
   - Write a draft piece based on the discussion and send it to the editor or, if you have already sent a solid draft, wait until the next draft comes back to you.

3. **The editor uses up to three steps to move a paper from draft to submission:**
   - **First hard edit/rewrite:** The editor produces a first rough draft, based on your draft, the interview and the requirements for the articles as posted on the journal's website. This will include (via the 'Track Changes' process) all the editor's changes, suggestions and questions as well as proposals for possible charts, illustrations and references.

     The editor sends the draft to you, the lead researcher, who will accept or reject all changes, answer questions posed, add your own changes and comments and send it through to all the authors for their changes/comments. You will then approve or reject your co-authors' changes and send the updated draft back to the editor. It is absolutely essential that you and your co-authors all work on the same draft, so there's no confusion about the content when it returns to the editor.

   - **Second (fine) edit:** The editor incorporates changes/ideas sent by the lead researcher, provides additional tightening/revamping as needed and does a close style edit before sending the second draft to you, the same process applies as above, with substantially fewer changes.

   - **Third and final edit:** This is the step that you may choose to omit. If you prefer a last outside read before submission, the editor will put final touches on the final draft, which should then be ready for submission. However, you may feel the manuscript doesn't need another outside read before you submit it. Your call.

IMPORTANT NOTE: It is your responsibility to submit the article. Once submitted, the manuscript will go through a series of editors at the journal. This is not a promise of publication but it is a way to help get an article in good enough shape for submission and give it a leg up for consideration, if the journal likes your research.

To request a consult with CRU, click here

Prepare for a Qualitative Study

Things to know…

In qualitative research, the researcher is considered the instrument. Researchers are intimately involved in all steps of the research process, including data collection, analysis, and interpretation. It is best practice for data to be collected, analyzed, and interpreted by the same individual(s). We therefore recommend identifying the individual(s) early on, prior to study commencement. These individuals are typically the Principal Investigator and a second individual also with experience with qualitative methodologies. This ensures a strong understanding of the study, from the research aim to the analysis and interpretation of data. In qualitative research, a lack of understanding of any aspects of the research process can impact the quality, depth, and breadth of the data collected and how they are analyzed and interpreted.

Things to consider…

Philosophical assumptions and theoretical frameworks
Start by reflecting on the philosophical assumptions (i.e., ontology, epistemology, axiology, methodology) and theoretical frameworks that influence qualitative research. Each theoretical framework has specific ontological, epistemological, axiological, and methodological beliefs that frame and inform each step of a qualitative study. It is important to reflect on and consider the perspective from which you are approaching your study.

- Theoretical frameworks include, for example, constructivism, transformative/post-modern, and pragmatism (Note: these represent a few theoretical frameworks commonly seen in health and social research, a number of others exist)

Research aim and question(s)
Ensure that the aim of your study and the research question(s) are well defined and best addressed by using a qualitative approach.

- For example, if you seek to explore, better understand, or describe a phenomenon, a qualitative approach may be suitable to fulfill the aim of your study.
- Qualitative research questions often begin with “How” or “What”.

How we can help…

Once you have established your research aim and question(s) and believe that a qualitative approach is most appropriate for your study, we can guide you through the design of your qualitative study.

Qualitative approach
We can help you choose the most appropriate qualitative approach as many approaches exist; each with unique characteristics and goals.

- This will ensure alignment with the research aim and research question(s).
- The qualitative approach will guide research processes, including data collection and analysis methods used.
- Common qualitative approaches include narrative, phenomenology, grounded theory, ethnography, and case study (Note: many more approaches exist in addition to these).

Sampling
We can help you choose the most appropriate sampling strategy as many strategies exist; each with unique purposes.

- This will ensure alignment with the research aim, research question(s), and qualitative approach chosen.

Data collection methods
We can help you choose the most appropriate and feasible data collection method(s).

- This will ensure alignment with the research aim, research question(s), qualitative approach, and participant population(s).
- Qualitative data collection methods include: Focus groups, interviews, observations, various types of documents (e.g., field notes, journal entries, public documents, etc.), and various types of audio visual materials (e.g., videos, photos, music).

Data collection instruments

Once you have decided on your data collection method(s), we can guide you in designing the appropriate data collection instrument(s).

- Data collection instruments should be informed by the literature, the research aim, and the research question(s).
- Data collection instruments should also be reviewed by experts (e.g., content experts, stakeholders) and piloted prior to use.

Data analysis methods

We can help you choose the most appropriate data analysis method(s) as many methods exist; each with unique purposes.

- This will ensure alignment with the research aim, research question(s), qualitative approach, and data collection method(s) used.
- Qualitative data analysis methods can range from simple content analysis, to the identification of categories or themes, to more complex analysis for theory generation.

Quality

We can help you choose the most appropriate strategies to assess the quality of your work. Many strategies exist, and while not all need to be implemented, multiple strategies should be implemented to ensure quality work.

- For example, comparison of analysis conducted individually by two investigators, peer checking of research processes, participant checking of findings, collection of rich data, detailed and rich description of research processes in reports and manuscripts, audit trails, etc.

Transcription of focus group and interview audio recordings

The research institute has recently secured transcription services through Capital Transcription. Please consult the following on CHEOnet: https://cheonet.cheo.on.ca/research-learning/research-institute/transcription

To request a consult, click here

Resource for a Qualitative Study

Level 1

Time Required 5-15 hours

- Thematic analysis of open-ended survey responses
- Content analysis of simple data set
- Deductive approaches to analysis
    - Analysis results in summative counts +/- a report with representative quotes
    - Includes assistance with methods writing

Level 2

Time Required: 15-60 hours

- Data collection by interview or focus group (estimate: 1 hour/interview; 2 hours/focus group with debrief notes)
- Inductive or deductive analysis of transcripts (estimate: 8 hours of analysis *per* transcript for in depth interviews that require line-by-line analysis)
- Content analysis of larger text-based data sets (e.g. social media feeds, discussion board forums)
- Data management with qualitative software (NVivo)—team training available.
- Team meetings to establish trustworthiness of findings or interrater agreement.
    - Analysis of results organized in a report by theme with representative quotes
    - Visual representations of data
    - Includes grant writing support and assistance with methods/results for manuscript

Level 3

Time Required: 60 hours +

- Complex qualitative designs (e.g., ethonography, grounded theory, narrative, phenomenology, case study). Guidance regarding design and application of methodology.
- Larger data sets with interview or focus group collection methods (estimate: 1 hour/interview; 2 hours/focus group with debrief notes)
- Data analysis methods that align with selected qualitative research approach and theoretical framework (estimate: 8 hours of analysis *per* transcript for in depth interviews that require line-by-line analysis)
- Analysis involving multiple methods (e.g. combining interviews with naturalistic observation, visual or video data, historical data or some other data point)
- Data management with qualitative software (NVivo)—team training available.
- Team meetings to establish trustworthiness of findings or interrater agreement.
    - Analysis results organized in a report with representative quotes from the data
    - Data visualizations
    - Includes grant writing support and assistance with methods/results for manuscript

Type your text

To request a consult with the CRU, click here

Version 1.0; 31-12-2016

How To…

Prepare for your Systematic review consult

Start with finding your resources

- Search for systematic reviews related to your topic that have been previously registered in the international prospective register of systematic reviews called PROSPERO
- Search for reviews that have been previously published in PubMed/Medline. Apply the systematic review filter (under the subjects filter) to look for published reviews
- Guidelines to develop a systematic review protocol are available through the PRISMA-P statement and checklist
- Another useful guide for preparing your review is the Cochrane Handbook of Systematic Reviews

Before your consult please sent via email

- Your questions. What do you need help with?
- Find the PubMed IDs (PMIDS) for five articles that you would like to be included in the results of your review
- Protocol (if available)

After your consult

- Relevant resources will be emailed to you within 1-2 business days after the consult meeting and additional meetings will be arranged with Dr. Sampson (if required) regarding the search for articles
- Contact the Systematic Review Facilitator for any clarification or questions

To request a consult with CRU, click here

Prepare for your Ethcis Facilitator Consult

Being prepared for your meeting with the Ethics Facilitator will help to ensure that your submission is as complete as possible. Be sure to:

Before your consult:

- Prepare your questions to ask the Ethics Facilitator (make a list)
    - What do you need help with?
        - Forms on Romeo?
        - Questions with the forms?
        - Standard phrases
        - Consent form content
- Send your questions in advance of the meeting to the Ethics Facilitator
- Email your **documents** to the Ethics Facilitator for a pre-review prior to your meeting

After your consult:

- A summary of discussion points with resources, templates, standardized wording**,** etc. attached will be emailed to you with 1-2 business days after the consult has occurred
- Review materials to ensure you have what you need to move forward
- Contact the Ethics Facilitator for any clarification or questions

For further questions or comments about the role and services provided by the Ethics Facilitator contact the Clinical Research Unit at 613-737-7600 ext 3931.

To Request a consult, click here

Translate your informed consent form &/or other documents

Start by reading the Bilingualism Policy

- Read the REB Bilingualism Policy with respect to Informed Consent documents

- English version(s) of the informed consent, and any other documents to be translated (patient handouts, flyer, etc.), should be submitted first to the REB for review and approval. After approval of English versions the translation process may begin.

- Under limited circumstances, the REB can waive the translation requirement. In order to obtain such a waiver, the Investigator must demonstrate that it is either inappropriate or impracticable to require both French and English consent forms. When to request a waiver?
    - With your initial application ask for a waiver, if applicable. State and justify your request in your cover letter.
    - If you request a waiver after your study has been submitted/approved use the Acknowledgement form in ROMEO. Upload a letter in the attachment section, including justification.

Who to contact for Translation Services

- To request translation services contact Rose Gorrie at New Avenues Linguistic Services Inc. Send an email to: rgorrie@cheo.on.ca and attach Request Form accessible on My CHEOnet

- As per the REB website, if the option to use New Avenues Linguistic Services is not feasible, the documents can be translated by an employee who has a level of A+ from translation services for writing. Contact the CHEO REB for more information on this option for translation.

Documents are translated, now what?

- Submit translated documents to the REB for review and approval using ROMEO utilizing the "Translated Study Documents Form"

- Final written REB approval is required for all translated study documents prior to implementation

For further questions or comments about the role and services provided by the Ethics Facilitator, contact the Clinical Research Unit (CRU) at 613-737-7600 ex 3931 or to submit a consult, click here

Make your consent for REB review ready

Start with the resources that are available (Delegated Review)

- REB has an SOP on **Informed Consent Form Requirements and Documentation.** Check out this SOP (**701.002**) prior to writing your consent form. Click here to access.
- The **prospective minimal risk consent form template** is available. Adapt this template to suit your study. Click here to access.
- Add any applicable **standard phrases** to your minimal risk consent form, found here, for **English** click here and for **French**, click here

Double check your consent form

- Does your consent form include all the essential items? Consult the Informed Consent Form (ICF) Checklist to make sure your consent form is REB Review Ready. To access the checklist, click here

Add the Final touches

- Insert a footer on your consent form
  - **Consent Form Version: DD-MMM-YYYY_____Page X of X**
- Proof read your consent form for spelling and grammar
  - Check your consent form for readability level
  - Click the Microsoft Office File Tab
  - Click the Word Options button
  - Click the Proofing tab on the left side.
  - Select the Show Readability Statistics box.
  - Click OK.
  - Run the spell check. Once the spelling and grammar have been checked, a pop-screen showing the readability stats will appear.
  - Read the results.

For further questions or comments about the role and services provided by the Ethics Facilitator contact the Clinical Research Unit (CRU) at 613-737-3931. To submit a consult to the CRU, click here

Resource for Large Database Studies at ICES

Small Project:

- 60+ hours
- Student project
- Analyst creates dataset for student and provides occasional support

Medium Project:

- 300+ hours
- Cohort creation requires a few different types of exclusions
- Looking at a decade's worth of data
- Datasets: RPDB DAD OHIP OCR
- Survival analysis
- Some sensitivity analysis to assess the robustness of the results

Large Project:

- 1000+ hours
- Some senior analyst time
- Cohort creation requires a few different types of exclusions
- Looking at a decade's worth of data
- Linkage of external datasets, probabilistic matching, datasets include derived cohorts
- Advanced analytic methods
- Some sensitivity analysis to assess the robustness of the results

To request a consult with CRU, click here

Resource for Database Build

Level 1 (Budget 1 to 10 hours)

- Less than 100 fields
- Simple setup
- Single or few short instruments
- Minimal branching
- Repetition

Level 2 (Budget 10-37.5 hours)

- 100-750 fields
- Advanced branching logic
- Multiple instruments
- Adverse Events and Con Meds
- Combination of forms and surveys
- Built in data quality rules

Level 3 (Budget 37.5 – 75+ hours)

- 750+ fields
- All of Level 2 characteristics
- Complex setup of both data entry forms and surveys
- Automated survey invitation setup and testing
- Bilingual
- Unique questions; not a lot of repetition

To request a consult with CRU, click here

Sample Study Budget 2016

	Range	Year 1	Year 2 onward			
PERSONNEL SERVICES						
Note: Please contact CHEO RI HR for current rates. Employee benefits - add 26% to hourly rates.						
Study Coordinator						
Research Coordinator	$27.75-$44.40/hr	Hourly rate + benefits	add 3% cost of living			
Research Assistants						
Site Research Assistants	$21-$31/hr	Hourly rate + benefits	add 3% cost of living			
Site Clinical Research Nurse (RN)	up to $44/hr	Hourly rate + benefits	add 3% cost of living			
Research Administrative Assistant	$19-$27/hr	Hourly rate + benefits	add 3% cost of living			
Post Doctoral Fellow						
Post Doctoral Fellow	$20-$31/hr	Hourly rate + benefits	add 3% cost of living			
CRU Services						
Data entry & validation	$25-$30/hr	Hourly rate + benefits	add 3% cost of living			
Database design, management, cleaning	$40-$55/hr	Hourly rate + benefits	add 3% cost of living			
Case Report Form development	$40-$48/hr	Hourly rate + benefits	add 3% cost of living			
Statistician - grant funded project	$44.50 ($55)-$65.50 (79.40)	Hourly rate + benefits	add 3% cost of living			
Statistician - industry funded project	$150-$300/hr					
Other Charges						
Overhead charges (CHEO RI)	add 35 % to overall budget when applicable					
Equipment funding	add 4% to basic science projects					
SUPPLIES AND SERVICES						
Laboratory Costs - lab supplies	Cost vary depending on tests required					
- lab services/labour	Contact Angel Hamilton ext. 2069 (AHamilton@cheo.on.ca) and Aleksandra Tasovac ext. 2261 (atasovac@cheo.on.ca)					
Pharmacy Costs - medications	Cost vary depending on service required - contact Danielle Garceau ext. 3860 (dgarceau@cheo.on.ca)					
- services/labour						
Photocopying - regular black & white	$0.05/page					
- colour copies	$1.00/page					
Self Addressed Pre-stamped Envelopes	500/box at $27.80/box					
Large 12 x 9 Envelopes	500/box at $50.00/box					
Address Labels	3000/box at $89.99/box					
Return Labels	8000/box at $89.99/box					
Office Supplies	$20/month					
Study Participant Incentives	Cost vary per project (i.e., coffee cards, Chapters gift cards)					
Soft ware	SPSS - $100; SAS $65.00; NVIVO $750 yearly or $1500 for a one time buy					
Medical Records - chart pulls	$3/chart					
Printing costs (i.e., study pamphlet)	vary depending on project					
Translation (consent forms/parent info. etc)	$0.25/word if the documents are not overly technical and $0.27/word if they are technical or urgent. Rose Gorrie (rgorrie@cheo.on.ca)					
Transcription	$2.00 per minute					
Study Parking Passes	$14.00 per day					
Data hosting costs (REDCap)	No cost at CHEO					
COMMUNICATION						
Telephone/Fax (long distance)	$10/month depending on usage					
Pager(s)	$8/month numeric, $20/month alpha-numeric					
Storage of Study Documents	$3/box/year					
CHEO teleconferencing Service (Arkadin)	$0.07/minute/person					
Courier	Cost vary depending on location and size					
Postage/Envelopes/labels	Costs vary					
Study PR (posters, handouts, newsletters)	Costs vary					
REB Costs						
Industry Grant - full board review	$3,000					
Industry Grant -major amendment	$500					
Industry grants - yearly renewal	$500					
KTE COSTS						
Conference registration	$500-$1,000 depending on conference					
Audio Visual Materials (slides or posters)	$400					
Reprints	$200					
Open access journal publication	$3,000					
Poster Printing	min $300/poster					
TRAVEL						
Site Visits/Audits	Cost vary depending on project					
Ongoing Monitoring of Sites	Cost vary depending on project					
Scientific Meetings	Cost vary depending on location					
Investigator meetings	Cost vary depending on number of participants and location					
Start up meeting	Cost vary depending on number of participants and location					
NOTE: You may call ext. 3931 to book a budget consultation with Clinical Research Unit staff or to request a consult, follow this link https://redcap.cheori.org/surveys/?s=62CfDv						