Building a Protocol

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I Want to Perform Human Subjects Research

01 Complete required training (e.g., CITI)

02 Develop a Hypothesis

03 Do a Literature Search
I Want to Perform Human Subjects Research

If you are a trainee, have you completed your eligibility determination request and selected a research mentor?

Choose a Study Design

Develop a Protocol
Hierarchy of Evidence for Questions About Interventions
Observational Studies

- Observational studies: exposure (e.g., treatment) not assigned by investigator
  
  - **Descriptive**: do not test a hypothesis; collect information of the distribution of disease patterns across demographics or clinical characteristics
  
  - **Analytic**: do test a causal hypothesis of the relationship between exposure and disease
Analytical Observational Studies

• TEST a causal hypothesis of the relationship between exposure and disease
  • Cohort studies
    • retrospective
    • prospective
  • Case-Control Studies
Cohort Study Design

Note the direction of inquiry:
starting with exposure and asking about the outcome
Can be retrospective or prospective
Cohort Study Example

• Retrospective
  • In people with exposure to known environmental toxins, was there an increased risk for developing ALS?
    • Take a known historical exposure and look forward in time to see who developed ALS and if there was a difference in risk based on exposure history.

• Prospective
  • In people who use e-cigarettes, will there be an increased risk in developing lung cancer compared to those who abstain from traditional cigarettes and e-cigarettes?
    • Take a current known exposure and follow people into the future to document whether they develop lung cancer.
Case-Control Study Design

Note the direction of inquiry: starting with outcome and asking about the frequency of exposure and non-exposure. Retrospective studies by nature.
Case Control Study Example

- If someone has valvular heart disease, what are the odds that they were treated with a dopamine agonist?
  
  - 8.78 times greater than if you do not have valvular heart disease

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Choose a Study Design

Develop a Protocol
Ready to Develop My Protocol

- Accessing Protocol Builder
  - Go to the HRPP website and click on eIRB
  - Click on Protocol Builder
  - Use your SSO to access
  - Click Start Document to begin a new protocol
  - All your projects are saved
I Just Need to Complete a Chart Review

### Residency Project Proposal

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Resident:</td>
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<tr>
<td>Project Advisor:</td>
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<tr>
<td>Project Committee:</td>
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#### Background

Briefly summarize scientific background and any related studies (provide citations) conducted previously. Identify gap(s) in the literature that your research project aims to address.

#### Purpose/Objectives

Most sentences start with “To characterize”, “To evaluate”, etc.

1.  
2.  

#### Research Question/Hypothesis

Final research question (from PICO/FHNR worksheet):

- Null Hypothesis (H₀):
- Alternative Hypothesis (H₁):

#### Methods

**Study Design**

1. Retrospective Cohort
2. Prospective Cohort
3. Case-Control
4. Other (please specify):

**Setting**

Single center vs multicenter? Inpatient vs outpatient?

**Participants**

- Inclusion Criteria:
- Exclusion Criteria:

**Intervention/Exposure**

What intervention/exposure will define your intervention/exposure cohort (for case-control studies, what outcome will define your outcome cohort)?

**Comparator**

If applicable

**Study Period and Follow-Up**

When will the study period begin and end? What criteria must be met for termination of follow-up? (Typically, follow-up should be terminated upon occurrence of the primary outcome, death, etc)

**Patient Identification**

How will patients be identified? (SlicerDicer vs other software, ICD-10 codes, medication exposures, etc)

**Anticipated Study Size**

How many patients will be targeted/anticipated?

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Try the Residency Research Protocol Form

2-page outline of the required components of a protocol for most chart reviews

Includes a data dictionary to help you identify exactly which data elements you need for your project

Reach out to your Directors; they can share a Word version of this form and provide feedback on your protocol before you submit it to the IRB
Create Data Collection Tools

• Questionnaires
• Excel spreadsheets
• REDCap data forms
  • Place a request through The Hub to receive access to REDCap (an ‘existing application’)
• Anything that a participant engages with must be included in your protocol and reviewed by the IRB, such as surveys, scales and questionnaires
• Other data collection tools should be described in your protocol, including your data security plan and data sharing plan (if applicable)
Other Considerations for Human Subjects Research

- Do I need a consent form?
  Prospective studies may require a consent form

- Should I register my study with clinicaltrials.gov?
  Generally, yes if using drug/device and/or an interventional trial

- Can I bill insurance for research activities?
  Work with Research Finance

- Can I share data with collaborators?
  If outside Ochsner, may need a data use agreement

- Should I consult with Biostats?
  Design phase is the perfect time to ask for help
I Have a Protocol – What’s Next?

Go to the Office of Epidemiology & Biostatistics and submit a request for help

Submit the protocol through eIRB

Register for an account if you are a first-time user

• Trainees and collaborators may register using their professional email address (does not have to be an Ochsner email)
You can access the Biostats site externally through the research.Ochsner.org site or through their Sharepoint site.
Submitting Your Protocol through eIRB

Go to the HRPP site and click the link for eIRB on the right.

On the next page, click Login at the top right and use your Ochsner SSO to login.

Go to the IRB tab and choose “Create New Study” on the left.
IRB Review is Complete & I’m Ready to Begin

- If your study meets the definition of Human Subjects research, you will need a **study binder** for keeping records of your study activities, including deviations from your protocol, adverse events, training and communication with your research team, enrollment, etc.

- If you need a **data pull**, go to the “Research Information Analytics” link on the Outcomes Research page on the research.Ochsner.org site.
  - Download a data request template and submit it via the REDCap survey form.

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**How to Request Research Data**

**STEP 1**
Complete a consult with Biostatistical Support to review your research questions, study variables and how they are measured.

**STEP 2**
Draft your clinical data request (variable + instructions) for IRB approved research work. Download sample data request.

Best Practice: Use the available Epic tools (e.g. Slicer Dicer) to find your target population by applying your inclusion and exclusion criteria. Verify that these patients and variables are IRB approved. Send us your MRNs and we’ll pull data for those patients.

**STEP 3**
Submit your “Research Information Analytics Request” via custom REDCap survey. Here you will find an example data request to download.
Data Collection is Complete: I Need Help with My Analysis

Go back to the Biostatistics site and submit a form for help with analysis and interpretation

How to Request a Consultation

Step 1 Submit a Request form
Step 2 A biostatistician will contact you for an initial consult
Step 3 Send your assigned biostatistician your summary sheet (consult template)

Things to know:

- During the initial consultation we will review your study design, research question(s) and hypothesis, variables and how these are measured, so please have these items finalized.
- Requests take at least 4 weeks from initial consultation and/or receipt of final data.
- Results will include statistical methods, statistical results, and basic interpretation.
- If you need further explanation of your results or additional analysis, you may contact your biostatistician directly.
- The magnitude of services provided by your biostatistician may merit co-authorship. Discuss this with your biostatistician prior to any abstract or manuscript submission.