From Documentation Project to IRB

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What I'll cover today

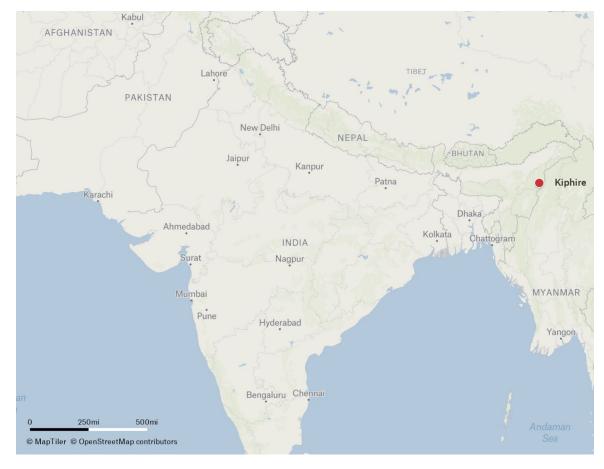
- ➤ How I went through the process of putting together an IRB for an international documentation projects
- > What the exact steps are, and what may differ for you
- What is NOT covered here: what makes a successful IRB, since I don't know how successful mine will be (it succeeded! With revisions once)

Roadmap

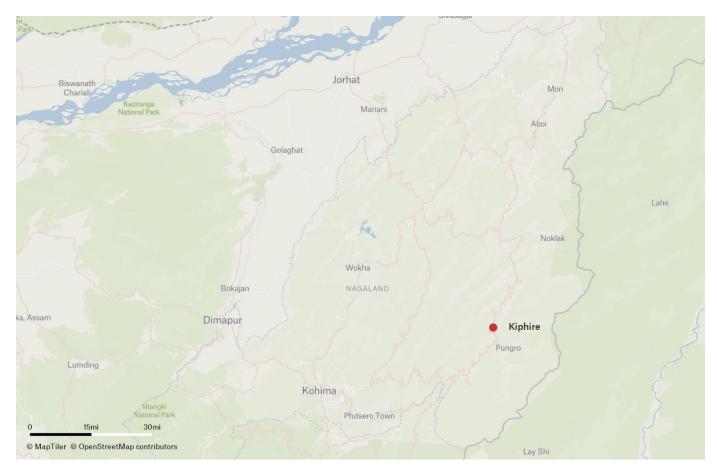
- The context of my project
- ➤ Why an IRB?
- What steps you need to take to put together an IRB
- Extra conditions your project may face
- Difficulties I faced in putting together materials
- > Time for questions/chat

My project: Documenting Tikhir, A Minority Naga Language

- An undescribed Tibeto-Burman language spoken in North-East India in the state of Nagaland
- Speakers typically speak 3-4 other languages: English (language of religion), Nagamese (local lingua franca/creole), and one of Yimchungru, Sangtam or Khiamniungan
- Mainly spoken in the Kiphire district, which is about 10-12 hours from Kohima (the capital) by unpaved roads, or by chopper from Dimapur (main city which is connected to the rest of India).
 Very close to Myanmar border!
- About 11,000 speakers, but that is based on census data
- Still being transmitted!:)



On a map: https://felt.com/map/Tikhir-map-0v7aXOYUSuq4Ji5Sz1o7gB?loc=26.12,-272.45,6z&share=1



Zoomed in



Photo from the Morung Express: https://morungexpress.com/nagaland-churches-to-reopen-in-kiphire-after-september-21





Some pictures:) - left to right, Apong Tikhir, Kiusumong Tikhir, me, Vichimshi T. Tikhir, Mimi Kevichüsa Ezüng



With Tsangli sir, far left in left pic, and N. Yutzü sir, middle in right pic

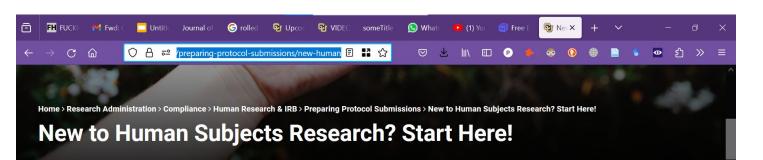
How I got in touch with the community

- Stephen, then Kellen
- Introduced to local academics
- Who then introduced me to the Tikhir community
- Main collaborators: Vichimshi and Kius sir

Return to Boulder: and starting up the IRB process

The absolute first place you should go is this link!:

https://www.colorado.edu/researchinnovation/research-administration/compliance/human-research-ir b/preparing-protocol-submissions/new-human



If you are new to human subjects research, the IRB process can be overwhelming. This checklist will help you get started and keep you on track for submitting an Initial Application to the IRB and what to do after approval.

✓ Are you a student? You will need a Faculty Advisor.

Faculty Advisors are responsible for ensuring that student research is appropriately designed; fully, clearly, and accurately described in the documents submitted for review; and conducted in accordance with the documentation Approved by the IRB. For Initial Application Submissions, Faculty Advisors are required to complete and sign the Faculty Advisor Review Form unique to each student's study. Students must upload this document with their Initial Application study materials in eRA.

☑ Do you have access to eRA? If not, you may need a POI number.

All IRB-related documents are submitted through the Electronic Research Administration Portal (eRA). If you do not have a current employment relationship with CU Boulder, you will need a POI in order to access eRA. If you have a POI and still cannot access eRA, contact for help.

Research Administration

Contracts & Grants

Compliance

Animal Care & Use Program

Office of Export Controls

Human Research & IRB

General Information

Preparing Protocol Submissions

The Life of a Protocol

New to Human Subjects Research? Start Here!

Roles & Responsibilities

Initial Application

Amendment

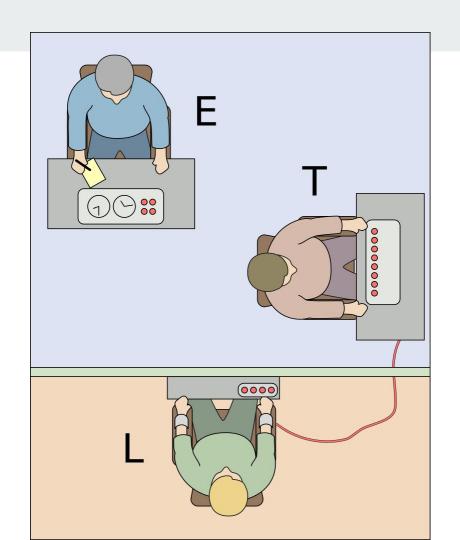


It lays out all the steps you need to take very cleanly

- 1. Get a faculty advisor (as a student)
- 2. Get a POI number if you need one (https://www.colorado.edu/researchinnovation/compliance/human-research-irb/general-information/student-pois) (undergrads??)
- 3. Complete DEPA (very short, <5m)
- 4. Complete CITI training: for us linguists, it's the Social Behavioral Research Investigators and Key Personnel module. (Not that long but it took me a while: 1-3h).
- 5. Read the investigator manual (I skimmed it and then referenced it while creating the IRB documents).
- 6. Create your 'study materials' (more on this later) (most time consuming part of the process!)
- 7. Not mentioned: get a 'local review letter' for international studies
- 8. Get IRB response (I haven't got this yet)
- 9. Get approved documents, and then start your study!

Why IRBs?

- Need to protect participants' right
- Unique challenges with a language documentation project - not the typical 'physical' or even 'affective' harm
- Need to think carefully about things like compensation and informed consent



What is NOT mentioned in that process (on the website)

- Getting a 'foreign local review letter' basically someone who is familiar with the local context who can review your study and make sure it is ethical
- There may be a different process for working with Native American/Alaskan/First Nations tribes: I'm not sure what it is! All I know is that the eRA website mentions things (maybe Andy would be a good resource?). They give this link: http://www.hhs.gov/ohrp/international/index.html

The main 'materials' you'll need

- A 'protocol' (this describes your study in depth, the largest document you'll work on by far)
- A consent document, describing the measures you've taken to ensure the consent is fair, informed and adequate (not under coercion or exploitation)
- Your recruitment materials: a flyer, script, etc.
- Your study materials, like an elicitation script
- Your project may need to submit more materials, i'm not sure

The protocol

- By far the largest part of the IRB application process!
- Extremely detailed: I'll show you mine (switch tab)
- Talk to your adviser about this, they may have a template/one they've used which you can modify!
- Some things to think quite in depth about:
 - The data management process
 - The ability of your participants to consent and the mitigating factors
- Rather than giving specific advice here I'll just show you mine and ask me questions about this

Risk and Benefits

Overall, the IRB is really about *Risks vs. Benefits*. They want to see that you're minimizing risks for participants, while ensuring that the benefits of the study are (somewhat) equitable.

Vulnerable Populations

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What vulnerable populations will be considered for this study?	
	Cognitively impaired/educationally disadvantaged individuals
	Subjects who report to or are students of the investigator
	Non-English speaking individuals
	Children under 18
	Prisoners
	Placental/Fetal tissue
	Pregnant Women (Do not select if subject's pregnancy will not be affected by the research)

Last piece of advice

When we're thinking about the specifics of our study, we often get caught up in the scientific/academic merits of it - that is *not* what the IRB cares about.

Trim down, remember you're talking to a general audience and be very frank about what the actual benefits and risks of the study are, and what's your plan to ensure it'll go as you want to go, and your

Extra Resources

- Bowern (2015) Chapter 11
- Meakins et. al Chapter 2.5 (Formal ethics applications and procedures)
- Crowley (2007) Chapter 2: for a blast to the past! Still probably applicable, but don't expect it to be an overview