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| **or-logo-stacked** | **Institutional Review Board**  **Human Research Protections**  **Protocol Narrative – Expedited/Full Committee Social/Behavioral/Educational Research**  *Version June 2020* | |
| Upload this completed narrative and any supplemental documentation to the [IRB Application](https://apps.research.uci.edu/irbapp/). | | **IRB USE ONLY –**  **HS#: 2020-5968** |
| **Lead Researcher Name:** Jacob Aaron Kodner | | |
| **Study Title:** Evidentiality in Sqiliq Atayal | | |

**ABSTRACT**

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| Provide a non-technical summary of the proposed research that can be understood by IRB members with varied research backgrounds, including non-scientists and community members. The summary should include a brief statement of the **purpose of the research** and a brief description of the **procedure(s)**. |
| The purpose of this study is to examine how speakers of Sqiliq Atayal, an indigenous Taiwanese language, use grammatical marking to indicate their sources of information (i.e., their evidence) when making a statement. Participants will be given a collection of translation tasks in which they will provide voice recordings (in Sqiliq Atayal) for translations of sentences from short narratives (written in Mandarin Chinese). Results from this research could provide valuable information for the ever-growing domain of research pertaining to the linguistic phenomenon of indicating information source (known as evidentiality); in addition, this study has the potential of contributing to empirical research involving the family of Formosan (i.e., indigenous Taiwanese) languages. |

**SECTION 1: BACKGROUND AND SIGNIFICANCE OF THE RESEARCH**

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| 1. Provide the scientific or scholarly **rationale** for the research. Describe the relevant background information and the specific gaps in current knowledge that this study intends to address. |
| According to Aikehenvald (2004), there are different systems of evidentiality “scattered all over the world”, and as a result of many of these languages not having as much documentation, researching evidentiality in such languages poses, as Aikenhenvald puts it, “a particularly daunting task”. With regards to Formosan languages, Chia-Jung Pan (2018) discussed five well-documented languages that have evidentiality as grammatical categories—Sqiliq Atayal was not investigated. Therefore, in order to contribute to ongoing research in developing a comprehensive framework of evidentiality, such a study regarding Sqiliq Atayal would be beneficial, especially as the topic of evidentiality is gaining more and more prominence in the field of linguistics. |
| 1. Describe the **purpose, specific aims** or **objectives**. Specify the hypotheses or research questions to be studied. |
| In this study, the main research question I aim to address is: How does the Sqiliq Atayal language express evidentiality (i.e., information source) grammatically? As such, the purpose is to analyze the semantic parameters (i.e., meanings) of how speakers of this language express their source of information when making a statement. |
| 1. List up to **ten relevant references/articles** to support the rationale for the research. |
| Aikhenvald, Alexandra Y. (2004). *Evidentiality,* Oxford University Press. w  Egerod, Søren (1965). Verb Inflexion in Atayal, *Linguis* 15, 251-282  Egerod, Søren (1966). Word Order and Word Classes in Atayal, *Linguistic Society of America* 42(2), 346-369  Huang, Lillian M. (1994). Ergativity in Atayal, *Oceanic Linguistics* 33(1), 129-143  Pan, Chia-Jung. (2018). Evidentiality in Formosan Languages. *The Oxford Handbook of Evidentiality*.  Pan, Chia-Jung. (2015). Reported Evidentials in Saaroa, Kanakanavu, and Tsou. *New Advances in Formosan Linguistics,* 341-362  Rau, D. V. (1992). *A grammar of Atayal* (Ph.D. thesis). Cornell University |

**SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM**

|  |  |  |  |  |  |  |  |
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| 1. **List the Lead Researcher and Co-Researchers who will engage in human subject research.**   Co-Researchers are faculty, staff, students and other academic appointees who the Lead Researcher (LR) considers to be key personnel for conducting the research study.  These individuals work closely with the LR to design, conduct, and/or report on the research.   1. ***UPDATED!* List Research Personnel as required per the** [**Research Personnel Heat Map.**](https://research.uci.edu/compliance/human-research-protections/researchers/Heat-Map-04-23-20.pdf) 2. **In lieu of listing Research Personnel (as required per the** [**Research Personnel Heat Map**](https://research.uci.edu/compliance/human-research-protections/researchers/Heat-Map-04-23-20.pdf)**), the LR must maintain the** [**Study Team Tracking Log**](https://research.uci.edu/forms/docs/irb-forms/study-team-tracking-log.xlsx) **(or something similar) listing all Research Personnel who are engaged in the research.** 3. **Indicate whether the study team member will be involved in the following research activities.** 4. **If there is a Faculty Sponsor, s/he must be listed below (even if s/he is not engaged in human-subjects research\*), as s/he must be identified to provide oversight and guidance to the Lead Researcher.**   *Include additional rows for study team members as needed.*  *\*Personnel who are not interacting with participants for research purposes and/or who do not have access to identifiable private information or identifiable biospecimens (e.g., statisticians) are not engaged in human-subjects research and therefore should* ***not*** *be listed below.* | | | | | | | |
| Role | Name, Title & Degrees | Department & UCI Affiliation - Faculty, Staff, Graduate or Undergraduate Student | Recruit | Informed Consent Process | Interact with Participant | Access  Participant Identifiable Information / Biospecimen | Analyze Participant Identifiable Information / Biospecimen |
| LR | Jacob Kodner | Undergraduate Student (LSCI) | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No |
| FS | Gregory Scontras, Associate Professor, Ph.D. | Faculty (LSCI) | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No | **N/A**  Yes  No |

1. **Training of Personnel**

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| 1. Describe the training plan that will be provided to your study team members. Who will provide the training, what will be included in the training, how will their level of knowledge be assessed to ensure they are ready to perform their assigned duties, and who will provide ongoing oversight. 2. Please identify who will interact with non-English speaking participants, if applicable. |
| The Lead Researcher has completed the CITI Training (Social/Behavioral Investigators). The Lead Researcher will be interacting with non-English speaking participants. The Faculty Mentor has completed the CITI training and has a Ph.D. in Linguistics. |

**SECTION 3: SUBJECT POPULATION(S) (INDIVIDUALS/RECORDS/BIOSPECIMENS)**

1. **Individuals To Be Enrolled on this UCI protocol (Persons/Records/Biospecimens)**

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| 1. Complete the table of participant enrollments below. *Include additional rows for subject category/group, as needed.* 2. If the study involves the use of existing records or biospecimens, specify the maximum number to be reviewed/collected, and the number needed to address the research question. | | | |
| **Category/Group**  (e.g., adults, parents, children) | **Age Range**  (e.g., 7-12, 13–17, 18 or older) | **Maximum Number to be Consented or Reviewed/Collected**  (include withdrawals and screen failures) | **Number Expected to Complete the Study *or Needed to Address the Research Question*** |
| Children | 13-17 | 20 | 5 |
| Adults | 18 or older | 20 | 5 |
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|  | | **Total: 40** |  |

1. **Eligibility Criteria**

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| 1. Identify the criteria for inclusion and exclusion. |
| To participate in the study, subjects are required to be 13 or older and bilingual in Sqiliq Atayal and Mandarin. Speaking proficiency is required for both languages. Having an account for the messaging application LINE is additionally required. |
| 1. If eligibility is based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only), provide a **scientific rationale**. |
| **[ ] Not applicable**: Subject eligibility is not based on these factors.  Eligibility is based on languages spoken, as the objective of the study is to analyze particular linguistic features within Sqiliq Atayal. Mandarin is also required, as it will serve as the language of communication between the Lead Researcher and participants. We are targeting speakers at or above the age of 13 as a way of assessing mature language competence. |
| 1. If American Indian or Alaska Native Tribes will be included in the research:    1. Specify the name of the Tribe and    2. Specify whether there is Tribal Law that may be applicable to this research and that provides additional protections for subjects (i.e., additional information to be disclosed in the consent process). |
| **[ X ]** **Not applicable**: American Indian or Alaska Native Tribes are not included in the research. |

1. **PRE-SCREENING AND DETERMINING ELIGIBILITY WITHOUT INFORMED CONSENT**

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| 1. **IMPORTANT NOTES:** 2. This section is **Not applicable** to research that is funded/supported by the Department of Justice (**DOJ**) 3. This section addresses pre-screening activities that are performed **without the written informed consent of the prospective subject or legally authorized representative (LAR).** This may be allowed without requesting a waiver of informed consent **IF the following** **guidelines are utilized**: |
| **[ X ] Not applicable**: Information and/or biospecimens will not be obtained for the purpose of screening,  recruiting, or determining eligibility of prospective subjects. *Skip to Section 4.*  MCj04347200000[1]  **[ ]** Study team will obtain information through **oral or written communication** with the prospective  subject or LAR (i.e. self-report of medical information; medical records will not be screened).    *Submit* [*recruitment script/s*](https://research.uci.edu/forms/index.html) *for IRB approval. Be sure to address minimum*  [*recruitment requirements*](https://research.uci.edu/compliance/human-research-protections/researchers/subject-selection-recruitment-and-compensation.html#Advertisements) *and address* ***the following guidelines****:*   1. *Privacy: The script must address the case where someone other than the potential subject receives the communication. Please be mindful of privacy considerations (i.e., do not disclose any private information – such as a patient diagnosis). Limit phone contact / messages to no more than 5 attempts.* 2. *Expertise: Study team member/s contacting potential subject must be knowledgeable and able to answer questions related to the screening and the main study.* 3. *Specific Information: Include a description of the information and/or biospecimens that will be obtained for the purpose of screening, recruiting, or determining eligibility and the reasons for performing the screening tests.* 4. *Confidentiality: Include a statement that informs the potential subject that if they are not eligible to participate in the study that the identifiable information and / or biospecimens will not be used for research purposes and will be destroyed at the earliest opportunity consistent with conduct of the research.*   **[ ]** Study team will **screen medical records** to determine subject eligibility.  MCj04347200000[1]  *Complete Appendix T to request a partial waiver of HIPAA Authorization.*  **[ ]** Study team will **screen medical records** to determine subject eligibility **under IRB approved**  **screening protocol.** Specify HS#:<Type here>  **[ ]** Study team will **screen non-medical records** (i.e., student records) to which they have access to  determine subject eligibility. Specify: <Type here>  **[ ]** For research accessing student records, check here to confirm that evidence of FERPA[[1]](#footnote-1) compliance has been / will be obtained (and on file) from the local school/district site prior to the initiation of research.  **[ ]** Study team will **access stored identifiable biospecimens**. |
| 1. For studies that will **screen medical records**, explain how the study team will access the clinical data. *Access to UCI Medical Center medical records for research purposes outside the capacity of the Honest Broker Services, such as access to physician notes, must be obtained from the Health Information Management Services*. |
| **[ ] Not applicable**: This study does not involve the screening of medical records.  **How Obtained: Indicate all that apply:**  **[ ]** The study team will request specific patient information/data from UCIMC Health Information Management Services.  **[ ]** The study team will review their UCI patients’ records and abstract data directly from those records.  **[ ]** The study team will request specific patient information/data from UCI Health Honest Broker Services. Describe the following:  Cohort selection criteria (e.g., use the available Clinical Terms from the Cohort Discovery Tool such as Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system): <Type here>  Expected cohort size/patient count: <Type here>  Cohort attributes or data elements (e.g., lab test values, medication, etc.): <Type here>  **[ ]** The study team will review non-UCI Health records and abstract data directly from those records. Describe the following:  Specify the non-UCI Health records that will be screened: <Type here>  Explain how the study team has access to this clinical data: <Type here>  **[ ]** Other; explain: <Type here> |
| 1. For studies that will **screen existing biospecimens**:    1. Indicate the source of the biospecimens and explain how the existing biospecimens will be obtained.    2. Indicate whether the biospecimens were originally collected for research purposes. |
| **[ ] Not applicable**: This study does not screen existing biospecimens.  **How Obtained: Indicate all that apply:**  **[ ]** UCI Health Pathology Biorepository  **[ ]** Other UCI-Health Entity; specify: <Type here>  **[ ]** Non-UCI Entity; specify: <Type here>  **[ ]** Other; explain: <Type here>  **Originally collected for research purposes:**  **[ ]** NO – Please explain: <Type here>  **[ ]** YES – UCI IRB approval granted under IRB protocol number (i.e. HS#): <Type here>  **[ ]** YES – Non-UCI IRB approval granted. Confirm **one** of the following:    **[ ]** A copy of the IRB Approval Notice and Consent Form for the original research collection will be submitted with the IRB application (APP). The IRB Approved Consent Form does not preclude the proposed activity.  **[ ]** A copy of the commercial Vendor Policy or a Letter from the Vendor attesting that the information was collected and will be shared in an appropriate and ethical manner will be submitted with the APP. The vendor’s policy does not preclude the proposed activity. |

**SECTION 4: RECRUITMENT METHODS**

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| 1. Indicate which recruitment methods will be utilized. Check all that apply: 2. Submit the required supplemental materials.   *Advertisements must adhere to UCI* [*Recruitment Guidelines*](http://www.research.uci.edu/compliance/human-research-protections/researchers/subject-selection-recruitment-and-compensation.html)*. Various templates are available on the HRP webpage* [*Application and Forms*](http://www.research.uci.edu/forms/index.html) *(see sub-section HRP and then Recruitment Templates).* | |
| **[ ]** This study involves no direct contact with participants (i.e., passive observation of public behavior or secondary use of information/biospecimens).***Skip to SECTION 5.*** | |
| **Method** | **Required Supplemental Materials** |
| **[ ]**  Flyers | Submit flyer(s) |
| **[ ]**  Newspaper Advertisement | Submit ad(s) |
| **[ ]**  Radio / Television Advertisement | Submit scripts(s) |
| **[ ]** Online Advertisements – Including Social Medial | Submit text, page mock up or description of  posting including any images. |
| **[ X ]**  Letters of Emails | Submit template letter(s) or email(s) |
| **[ ]**  Phone Call | Submit phone script |
| **[ ]**  Group or Class Presentation | Submit outline of presentation and any materials to be provided to participants |
| **[ ]** Social Sciences Human Subject Lab (SSHSL) | None |
| **[ ]** Other (specify) | Submit the recruitment materials |
| 1. Describe when, where, by whom and how potential participants will be approached. 2. If posting on your Facebook page or other social media sites, please explain. 3. If you will recruit by e-mail, phone, etc., explain how the researcher will obtain the participants’ contact information. | |
| Two contacts in Taiwan who know the Lead Researcher will be sending out recruitment materials via email to alert participants of the opportunity to participate in the study. More specifically, one contact is a graduate student of National Tsinghua University, while the other is an administrative assistant of the National Tsinghua University Indigenous Students Resource Center. Both contacts are in touch with secondary school students of the Atayal indigenous group. The correspondents are not part of the research team, and they will be only sending out recruitment materials to a group of individuals via email. The contacts will not be interacting with potential participants to determine eligibility, answering research questions, consenting participants, or administering procedures. The following language will be used by the correspondents for recruitment.  :  Subject: Opportunity to participate in research study about the Sqiliq Atayal language  Lead Researcher Jacob Kodner and Associate Professor Gregory Scontras, PhD. from the Language Science Department at the University of California, Irvine are recruiting participants for a research study about the grammar of Sqiliq Atayal. This study may help us to better understand how the language expresses various aspects of meaning.  You are eligible to participate in this study if you are 13 years of age or older, able to fluently speak Sqiliq Atayal and Mandarin, and have an account on the mobile messaging application LINE.  The entire study will take place on LINE. To download LINE, you can visit the mobile Apple Store (for iOS) or Google Play Store (for Android), install this application on your phone, and follow the directions to set up your own account.  As part of participating, you will be asked to add the Lead Researcher on LINE, who will be sending a collection of narrative translation tasks. You will be expected to send voice recorded messages to the Lead Researcher at the completion of each of the translation tasks. Your participation will last up to 30 minutes in one session, over the course of one day.  You will receive an electronic gift card valued at the equivalent of $15 USD for your participation in this study upon completion of all the translation tasks  If you participate, there is no anticipated direct benefit. The study will contribute to studies involving the grammar of the Atayal language and provide linguists with a greater understanding of how the language expresses various aspects of meaning.  If you are interested in participating in this study and/or have any questions, please contact Jacob Kodner on LINE (ID: jkodner).  Thank you very much for your time. | |

**SECTION 5: INFORMED CONSENT PROCESS**

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| 1. **Submit the Consent, Study Info Sheet, Courtesy Letter, Assent document(s). *Note:*** *After IRB Approval, distribute to participants the version of the document with the IRB-approval information in the footer.* 2. Identify the specific **steps for obtaining consent**. See [**Guidance for Consenting Process**](http://www.research.uci.edu/compliance/human-research-protections/researchers/how-to-consent.html). |
| **Check all that apply:**  **[ ] Signed informed consent will be obtained.** *Customize the Consent for SBE Research.*  **[ X ] Oral / Implied informed consent will be obtained (i.e., requesting a waiver from obtaining signed informed consent**)**.** *Customize the*[***Study Information Sheet***](http://www.research.uci.edu/forms/docs/irb-consent-forms/4_StudyInformationSheet.doc)*and Complete Appendix P.*  ***Note****: If obtaining consent online (e.g., research involves completing a survey electronically administered via AMT, EEE, etc.), participants should:*   * *View the Consent/Study Info Sheet prior to participation* * *Be prompted to verify they meet the eligibility criteria, and* * *Indicate their willingness to participate in the research (e.g., click “Yes”).*   **[ ] Requesting to seek surrogate consent from the subjects’ LAR.** Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity or serious or life-threatening disease and conditions of the research subjects. *Complete Appendix E.*  **[ ] Informed consent will NOT be obtained (i.e., requesting a *complete* waiver of informed consent). No contact with participants; using existing data, records, charts, biospecimens, etc.** *Complete Appendix O. Skip to Section 6.* |
| 1. If medical records will accessed for research purposes, identify the specific steps for obtaining HIPAA authorization.   *For additional information, see* [*Protected Health Information (HIPAA)*](https://research.uci.edu/compliance/human-research-protections/researchers/protected-health-information-hipaa.html)*. Templates are available on the*  *HRP webpage* [*Application and Forms*](http://www.research.uci.edu/forms/index.html) *(see sub-section HRP, HIPAA Documents).* |
| **[ X ] Not applicable**:Medical records will not be accessed for research purposes.  **[ ] Total waiver of HIPAA Authorization – No HIPAA authorization will be obtained (i.e., no direct**  **contact with participants).** ***Submit Appendix T.***  **[ ]**  **Written (signed) HIPAA Authorization will be obtained – A signature is required.**  ***Customize the HIPAA Research Authorization Form template.*** |
| 1. Indicate where the consent process will take place. |
| **[ ]** In a private room  **[ ]** In a waiting room  **[ ]** In an open unit  **[ ]** In a group setting  **[ X ]** Theinternet  **[ ]** In public setting  **[ ]** Over the phone  **[ ]** Other (specify): <Type here> |
| 1. Specify how the research team will assure that subjects or their LAR have sufficient time to consider whether to participate in the research. |
| **[ ]** Subjects or their LAR will be allowed to take home the unsigned consent form for review prior to  signing it.  **[ ]** Subjects or their LAR will be allowed <Type here> hours to consider whether to consent.  **[ X ]** Other (specify): Participants will be allowed to view the consent documents for review prior to providing oral consent |
| 1. If children (anyone less than 18 years old) are participants, please describe the parent/legal guardian permission process and the child assent process. |
| **[ ] Not applicable**:Children are not included in the research.  **[ ]** No parental permission or child assent will take place.  Owing to the time difference between the U.S. (the location of the research team) and Taiwan (the location of the participants), the study will take place asynchronously via the messaging application LINE. LINE was selected because it is commonly used in Taiwan, secure, and has built-in functionality for sending voice recordings (necessary for the translation task). The speed at which the researchers will respond to inquiries made via LINE will be at least as high as that of email communication, if not higher.  When a participant contacts the Lead Researcher via LINE in response to the recruitment email, LINE will create a chat room for communication with that participant. The Lead Researcher will ask the age of the participant. If the participant is younger than 18, the Lead Researcher will first send the parental permission Study Information Sheet via the LINE chat room. After consulting the Study Information Sheet and asking any questions of the researcher, the parent will indicate their consent by sending an audio recording via the LINE chat room in which they provide that consent. Having obtained parental consent, the researcher will next send the child Assent Form via the LINE chat room. The child participant will then indicate their consent via sending an audio recording via the LINE chat room.  If the participant is older than 18, the Lead Researcher will send an adult participant Study Information Sheet (different from the Study Information Sheet for parental permission). After consulting the Study Information Sheet, the adult participant will indicate their consent by sending an audio recording via the LINE chat room.  During the consent process, consent documents will be sent as a PDF file in the LINE chat room. Participants will indicate consent through sending an audio recording. If the participants have any questions while reading over the consent documents, they will be directed to utilize the chat function to send their questions via text to the Lead Researcher, who will use the chat function to answer any questions, all via LINE. |
| 1. If study team members will approach their own students or employees:    1. Explain what precautions will be taken to minimize potential undue influence or coercion.    2. Explain how compromised objectivity will be avoided.   [*See HRPP Policy*](http://www.research.uci.edu/compliance/human-research-protections/policies/40%20UCI%20Students%20and%20Employees.pdf) *for more information on this topic.* |
| **[ X ] Not applicable**: Study team will not approach their own students or employees.  Specify how undue influence or coercion will be minimized: <Type here>  Specify how compromised objectivity will be avoided: <Type here> |
| 1. Will this study include Non-English Speaking Participants? 2. Specify in ‘Section 2: Study Team’ who will be responsible for interacting with non-English speaking participants. |
| **[ ] Not applicable**: No consent process will take place.    **[ ]** Only individuals who can read and speak English are eligible for this study.  **[ X ]** The English version of the consent materials will be translated for non-English speaking participants once IRB approval is granted.An interpreter will be involved in the consenting process.***Note:*** *After IRB Approval, distribute to participants the version of the document with the IRB-approval information in the footer.* |
| 1. If [deception or incomplete disclosure](http://www.research.uci.edu/compliance/human-research-protections/docs/glossary-of-terms.html#D) is involved: |
| **[ X ] Not applicable**:No deception or incomplete disclosure is involved.  Confirm that the following documents will be submitted with the APP:  **[ ]** Debriefing Script  **[ ]** Appendices O (Alteration of Consent) and G (Deception) |
| 1. Release Form: If publications and/or presentations will include **identifiable information**, specify how the study team will obtain permission from participants. Please submit a ‘[Release Form](http://www.research.uci.edu/forms/docs/irb-forms/release-form-template.doc)’ |
| N/A |

**SECTION 6: RESEARCH METHODOLOGY/STUDY PROCEDURES**

1. **Study Design and Procedures**

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| 1. Provide a **description of the proposed research** (e.g., pilot testing, intervention/interaction/data collection, and follow-up) and **procedures** (e.g., surveys, interview, focus group, and observation). See [**Guidance for Online Research**](http://www.research.uci.edu/compliance/human-research-protections/irb-members/reviewing-protocols-online-mobile.html)**.**    1. Specify **where** the research will take please (e.g., UCI, local public schools, international site, private business, etc.).    2. Include an explanation of the study design (e.g., randomization, cross-sectional, longitudinal, etc.).    3. Indicate how much **time will be required of the participant**, per visit and in total for the study.    4. If a procedure will be completed more than once (e.g., multiple visits, pre and post survey), indicate **how many times** and the **time span** between administrations.    5. If a procedure will occur via a crowdsourcing Internet marketplace (e.g., AMT) or in the cloud (e.g., Google Docs), please describe. |
| The messenger application LINE will be utilized in this study. The application is a secure messaging service commonly used in Taiwan. It was selected for its ability to transmit the voice recording necessary for the study. The application incorporates a seamless voice recording software by which participants can send a voice recording at the press of a button. Due to the time difference present between the U.S. and Taiwan, as well as government restrictions on video conferencing software, LINE was chosen as the medium of communication to allow for asynchronous sending of participant questions and responses, the study materials, and the audio recordings of participant responses.        NOTE: Participation will last up to 30 minutes in one session, over the course of one day. |
| 1. **Off-Site Research –**     1. See[**Guidance for Letter(s) of Permission**](http://research.uci.edu/forms/docs/irb-forms/guidance-on-letter-of-permission.doc)    2. See [**Template Letter of Permission**](http://research.uci.edu/forms/docs/irb-appendices/letter-of-permission-template.docx) |
| **[ ]** Check here to confirm [Letter(s) of Permission](http://research.uci.edu/forms/docs/irb-appendices/letter-of-permission-template.docx) has been / will be obtained and kept on file. |

1. **Measures / Data Sources**

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| 1. List the measures that will be administered or data sources that will be accessed. 2. Submit **data collection instruments** (e.g., data abstraction sheet listing the variables that will be collected/analyzed for records reviews, measures, questionnaires, list of interview or focus group questions, observational tool, etc.). |
| There is only one research instrument that will be used, which is a collection of narrative translation tasks (see attached); these translation tasks are meant to elicit responses that test for the presence of the linguistic phenomenon under investigation. |

** IMPORTANT TIME SAVER: PLEASE ATTACH *ALL* MEASURES FOR REVIEW. APPLICATIONS ARE INCOMPLETE AND WILL NOT BE REVIEWED UNLESS MEASURES ARE PROVIDED.**

1. **Use of Identifiable Private Information and/or Identifiable Biospecimens as Part of the Main Study**

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| --- |
| 1. For studies that will use **existing identifiable biospecimens** as part of the **main study** (not for determining eligibility):    1. Indicate the source of the biospecimens and explain how the existing biospecimens will be obtained.    2. Indicate whether the biospecimens were originally collected for research purposes. |
| **[ X ] Not applicable**: This study does not use existing biological specimens as part of the main study.  **How Obtained: Indicate all that apply:**  **[ ]** UCI Health Pathology Biorepository  **[ ]** Other UCI-Health Entity; specify: <Type here>  **[ ]** Non-UCI Entity; specify: <Type here>  **[ ]** Other; explain: <Type here>  **Originally collected for research purposes:**  **[ ]** NO – Please explain: <Type here>  **[ ]** YES – UCI IRB approval granted under IRB protocol number (i.e. HS#): <Type here>  **[ ]** YES – Non-UCI IRB approval granted. Confirm **one** of the following:    **[ ]** A copy of the IRB Approval Notice and Consent Form for the original research collection will be submitted with the IRB application (APP). The IRB Approved Consent Form does not preclude the proposed activity.  **[ ]** A copy of the commercial Vendor Policy or a Letter from the Vendor attesting that the information was collected and will be shared in an appropriate and ethical manner will be submitted with the APP. The vendor’s policy does not preclude the proposed activity. |
| 1. For studies that will **use identifiable clinical data** as part of the **main study** (not for determining eligibility),indicate the source and how the study team will access the medical records. *Access to UCI Medical Center medical records for research purposes outside the capacity of the Honest Broker Services, such as access to physician notes, must be obtained from the Health Information Management Services*.   MCj04347200000[1] *For investigator initiated/authored studies only, submit a data abstraction sheet that includes a*  *complete list of data elements/information that will be collected from (existing) records or submit*  *the case report form (CRF; eCRF).* |
| **[ X ] Not applicable**: This study does not involve the use of identifiable clinical data as part of the main study. *Skip to Section 6.D.*  **How Obtained: Indicate all that apply:**  **[ ]** The study team will request specific patient information/data from UCIMC Health Information Management Services.  **[ ]** The study team will access their UCI patients’ records and abstract data directly from those records.  **[ ]** The study team will request specific patient information/data from UCI Health Honest Broker Services. Describe the following:  Cohort selection criteria (e.g., use the available Clinical Terms from the Cohort Discovery Tool such as Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system): <Type here>  Expected cohort size/patient count: <Type here>  Cohort attributes or data elements (e.g., lab test values, medication, etc.): <Type here>  **[ ]** The study team will request non-UCI Health records and abstract data directly from those records. Describe the following:  Specify the non-UCI Health records that will be screened: <Type here>  Explain how the study team has access to this clinical data: <Type here>  **[ ]** Other; explain: <Type here> |
| 1. For studies that involve use of existing (i.e. on the shelf; currently available) clinical data, specify the time frame of the clinical data to be accessed (e.g. records from January 2002 to initial IRB approval). |
| <Type here> |
| 1. **For studies that involve use of student data, including UCI student data:** The Family Educational Rights and Privacy Act (FERPA) is a Federal law that protects the privacy of student educational records. |
| UCI student records: Provide evidence of FERPA[[2]](#footnote-2) clearance from the UCI Registrar. For more information about FERPA *as it applies to UC Irvine*, please refer to the [UCI Privacy and Student Records](http://www.reg.uci.edu/privacy/) page. For questions and FERPA clearance, email the [FERPA Analyst](mailto:mark.fonseca@uci.edu).  Non-UCI student records: Provide evidence of FERPA6 clearance from the local school/district site. |

1. **Collection of Photographs, or Audio/Video Recording**

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| **Will any of the study procedures include collecting photographs, audio recordings and/or video recordings?** |
| **[ ] Not applicable**: No photos, audio or video recordings will be taken.  **[ ]** Photos, audio or video recordings will be taken. Text regarding the photos or recordings will be included in the consent document and specific permission to record identifiers will be obtained from participants.  **Check one of the following:**  **[ ]** Facial image will be in video or photo  **[ ]** Participants’ names will be collected or recorded in either video, photo or audio recording  **[ ]** Collecting photographs, as well as audio and video recordings will be optional for the participant  **[ X ]**  Other: Audio recordings will be collected and anonymized via codes corresponding to each participant. |

1. **Sharing Results with Subjects**

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| 1. Describe whether individual results (results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subject or others (e.g., the subject’s primary care physician). *Only tests ordered by a physician and conducted in a CLIA certified lab may be shared.* 2. Explain what information will be shared and how the results will be shared. |
| **[ X ] Not applicable**: Individual results will not be shared with subjects. |
| 1. Describe whether overall study results will be shared with subjects. 2. Explain how results will be shared. |
| **[ X ] Not applicable**: Final study results will not be shared with subjects.  **[ ]** The overall study results will be listed on [Clinicaltrials.gov](http://clinicaltrials.gov/ct2/help/for-researcher). *All Applicable Clinical Trials must be*  *registered.*  **[ ]** Other: |

**SECTION 7: RISK ASSESSMENT AND POSSIBLE BENEFITS**

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**A. Level of Risk**

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| 1. Indicate the level of review, based upon the investigator’s risk assessment. |
| **[ ]** This study involves **greater than minimal risk** and requires **Full Committee review.**  **[ X ]** This study involves **no more than minimal risk** and qualifies as [**Expedited research**](http://www.research.uci.edu/compliance/human-research-protections/docs/categories-of-expedited-human-subjects-research.pdf). |
| 1. If this study involves no more than minimal risk, provide justification for the level of review and for all applicable Expedited Categories you have chosen. |
| This study would have qualified to be an Exempt (3.i.A) study, but as a result of including children for the completion of translation tasks (without providing identifiable information), this study falls under Expedited Review Category 6. |

**B. Risks and Discomforts**

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| 1. Describe the **risks/potential discomforts** (e.g., emotional reaction from personal or sensitive information included in surveys, interviews, focus group, etc.; embarrassment or stigma; invasion of privacy) associated with **each** intervention or research procedure. |
| Participants may experience feelings of stress and/or boredom from providing accurate translations. Moreover, there is a risk of a breach of confidentiality.  **[ X ] This study involves the collection of participant identifiable data** (even if temporary such as for recruitment or compensation purposes), and as such, a breach of confidentiality is a risk associated with the research. |
| 1. Discuss what steps have been taken and/or will be taken **minimize and prevent** any risks/potential discomforts described above. |
| To mitigate risks associated with boredom and anxiety, there will be no measures of accuracy in the study, and feedback regarding responses will not be provided  Given that LINE IDs will be collected, there is a potential risk of breach of confidentiality. The data file pertaining to each participant will have a code so as to keep anonymity, and these codes will only be available to the Lead Researcher. LINE IDs collected and used for compensation will be destroyed two weeks after the data collection process is finished. |

**C. Potential Benefits**

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| Discuss the potential benefits directly **to the participant and to society**.  **Compensation (i.e., gift cards, cash, course credit, etc.) is *not* a benefit.** |
| **[ X ]** There is no direct benefit anticipated for the participant.  There may be indirect societal benefits as a result of this research, in the form of a better understanding of the grammar of Sqiliq Atayal for the researchers and speakers of the language. |

**SECTION 8: ALTERNATIVES TO PARTICIPATION**

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| Describe the alternatives to participation in the study availableto prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable. |
| **[ X ]** No alternatives exist. The only alternative to study participation is not to participate in the study.  **[ ]** There are routine standard of care alternatives available; specify: <Type here>  **[ ]** There are other alternatives to study participation; specify: <Type here> |

**SECTION 9: PARTICIPANT COMPENSATION AND REIMBURSEMENT**

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| 1. If subjects will be compensated for their participation, explain the method/terms of payment (e.g., money; check; extra credit; gift certificate). |
| **[ ] Not applicable**: This study involves no interaction/intervention with research subjects. *Skip to Section 10.*  **[ ]** No compensation will be provided to subjects.  **[ X ]** Compensation will be provided to subjects in the form of cash/gift certificate.  **[ ]** Compensation will be provided to subjects in the form of a check issued to the subjects through the UCI Accounting Office. The subject’s name, address, and social security number, will be released to the UCI Accounting Office for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS).  **[ ]** Other: <Type here> |
| 1. Specify the schedule and amounts of compensation (e.g., at end of study; after each session/visit) including the total amount subjects can receive for completing the study. *Compensation should be offered on a prorated**basis when the research involves multiple visits.*   *For compensation ≥ $600, subject names and social security numbers must be collected. This information must be reported to UCI Accounting for tax-reporting purposes.* |
| **[ ] Not applicable**: This study involves no compensation to subjects.  Subjects will be compensated with the following schedule and amounts: electronic gift card equivalent of $15 USD at end of providing translated responses The gift card will be transmitted via the LINE chat room. |
| 3. Specify whether subjects will be reimbursed for out-of pocket expenses. If so, describe any requirements for reimbursement (e.g., receipt). |
| **[ X ] Not applicable**: This study involves no reimbursement to subjects.  Subjects will be reimbursed; specify: <Type here> |

**SECTION 10: CONFIDENTIALITY OF RESEARCH DATA**

* + - 1. **Information and/or Biospecimens Storage**

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| 1. Indicate how information and/or biospecimens will be stored and secured. Check all that apply: |
| **[ X ]** Information will be maintained electronically. Information will be password protected and  maintained in an [encrypted](https://security.uci.edu/secure-computer/encryption.html) format. *Researchers may access UCI-contracted data sharing and*  *storage tools through* [*UCI OIT*](https://www.oit.uci.edu/)*.*  **[ ]** Information will be maintained in hard copy. Information will be stored in a locked area that is not accessible to non-study team members.  **[ ]** Biospecimens will be stored in a locked lab/refrigerator/freezer that is not accessible to non-study  team members. |
| 1. List the location(s) where the data and/or biospecimens will be stored**.** |
| Data will be stored in an encrypted form via Microsoft OneDrive on the Lead Researcher’s password-protected personal laptop. |
| 1. Indicate all subject identifiers that may be retained with the information and/or biospecimens collected for the research study. *If any study-related data will be derived from a medical record, added to a medical record, created or collected as part of health care, or used to make health care decisions the HIPAA policy applies. The subject’s HIPAA Research Authorization is required or a waiver of HIPAA Research Authorization must be requested by completing Appendix T.* |
| **[]** This study does not involve the collection of subject identifiers.  Check all the following identifiers will be used, created, collected, disclosed as part of the research:  **[ ]** Names **[ ]** Social Security Numbers **[ ]** Device identifiers/Serial numbers  **[ ]** Dates\* **[ ]** Medical record numbers **[ ]** Web URLs  **[ ]** Postal address **[ ]** Health plan numbers **[ ]** IP address numbers  **[ ]** Phone numbers **[ ]** Account numbers **[ ]** Biometric identifiers  **[ ]** Fax numbers **[ ]** License/Certificate numbers **[ ]** Facial Photos/Images  **[ ]** Email address **[ ]** Vehicle id numbers **[ ]** Any other unique identifier  **[ X ]** Other (Specify all): LINE ID  \* *birth date, treatment/hospitalization dates* |
| 1. Indicate if a code be used to link subject identifiers with the information and/or biospecimens. |
| **[ ] Not applicable:** No subject identifiers will be collected.  **[ X ]** A code will be used (i.e. information and/or biospecimens will be coded). Subject **identifiers** will be  **kept separately** from the information and/or biospecimens. The code key will be destroyed at the  earliest opportunity, consistent with the conduct of this research.  **[ ]** A code will not be used. Subject **identifiers** will be **kept directly** with the information/biospecimens. |
| 1. If **subject identifiable data** will be transported or maintained on **portable devices**, explain why it is necessary use these devices. *Only the “minimum data necessary” should be stored on portable devices* *as these devices are particularly susceptible to loss or theft. If there is a necessity to use a portable device for the initial collection of identifiable private information, the research files must be encrypted, and subject identifiers transferred to a secure system as soon as possible.* |
| **[ ] Not applicable**: Research data will not be transported or maintained on portable devices.  **[ X ]** Research data will need to be maintained on the following portable device(s) for the following reason(s): Given the restrictions on on-campus work due to the current pandemic, data will be stored in an encrypted form via Microsoft OneDrive on the Lead Researcher’s password-protected personal laptop. |

* + - 1. **Information and/or Biospecimens Access**

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| 1. Specify who will have **access to subject identifiable information and/or biospecimens** as part of this study. Check all that apply. |
| **[ ] Not applicable**: No subject identifiers will be collected.  **[ ]** Authorized UCI personnel such as the research team and appropriate institutional officials, the study sponsor or the sponsor’s agents (if applicable), and regulatory entities such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), and the National Institutes of Health (NIH).  **[ X ]** Other: The Lead Researcher will have access to the participants’ LINE IDs, which are custom strings created by the user during the registration of an account. Additional information about the participants cannot be obtained on the basis of LINE IDs. |
| 1. Specify whether subject identifiers be disclosed in presentations and/or publications. |
| **[ ] Not applicable**: No subject identifiers will be collected.  **[ X ]** Subject identifiers will **not** be disclosed.  **[ ]** Subject identifiers will be disclosed. Text regarding the disclosure will be included in the consent document and specific permission to disclose will be discussed with subjects. |
| 1. Specify whether **information and/or biospecimens be shared** with other researchers **outside of the study team** (i.e., UCI / non-UCI researchers) for secondary research purposes. |
| **[ X ] Not applicable**: information and/or biospecimenswill **not be shared**  **[ ] Identifiable** information and/or identifiable biospecimens may be shared. Text regarding the information/specimens sharing will be included in the consent document and specific permission to share information will be discussed with subjects.  **Check one of the following:**  **[ ]** A biorepository will be established and manage by the UCI study team. ***Submit Appendix M.***  **[ ]** Subject identifiers will be retained in an established non-UCI biorepository (i.e. not managed by the UCI study team). The non-UCI biorepository has a current IRB approval on file. Specify the non-UCI biorepository: <Type here>  **[ ] De-identified** information and/or de-identified biospecimens may be shared (i.e. research participants cannot be identified by other researchers). Text regarding the information/biospecimens sharing will be included in the consent document, as applicable.  **Check one of the following:**  **[ ]** No subject identifiers will be retained by the study team beyond initial collection (i.e. information/biospecimens cannot be linked to an individual and a key code does not exist). Requests for de-identified information and/or de-identified biospecimens will be managed by the UCI study team.  **[ ]** Subject identifiers will be retained by the study team beyond initial collection (i.e. information/biospecimens can be linked to an individual and/or a key code exists). A biorepository will be established and managed by the UCI study team. ***Submit Appendix M.***  **[ ]** Subject identifiers will be retained by the study team beyond initial collection (i.e. information/biospecimens can be linked to an individual and/or a key code exists). De-identified information/biospecimens will be retained and managed in an established non-UCI biorepository (i.e. not managed by the UCI study team). The study team will remove any information that could potentially allow for the re-identification of participants prior to sending the information/biospecimens to the non-UCI biorepository. Specify the non-UCI biorepository: <Type here>  **[ ]** Other: <Type here> |

* + - 1. **Research Information and/or Biospecimens Retention**

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| 1. Indicate how long research information and/or biospecimens will be retained. |
| ***UPDATED!***  **[ X ]** In accordance with [UCOP policy](https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/record-retention/tables.html#irb), information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.  **[ ]** In addition, if the research involves the investigation of [FDA regulated](https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate) products, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per [FDA sponsor requirements.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4)  **[ ]** This research includes the potential for future **secondary research using information/biospecimens** which will be stored and maintained indefinitely. |

* + - 1. **Photographs, Audio/Video Recordings**

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| 1. If subject identifiable audio or video recordings will be collected, specify the timeframe for the transcription, as applicable or indicate why data will not be transcribed. |
| ***UPDATED!***  **[ ] Not applicable**: Identifiable audio/video recordings will not be collected.  **[ X ]** Audio or video recordings transcribed; specify time frame: Audio recordings will be transcribed over a period of two months. These audio files will be anonymized immediately upon collection via a code independent of the LINE ID.  **[ ]** Audio or video recordings will NOT be transcribed; specify why: <Type here> |
| 1. If subject identifiable photographs will be collected, describe de-identification of photos, as applicable or indicate why photographs will not be de-identified. |
| ***UPDATED!***  **[ X ] Not applicable**: Subject identifiable photographs will not be collected.  **[ ]** Subject identifiable photographs will be de-identified; specify time frame: <Type here>  **[ ]** Subject identifiable photographs will NOT be de-identified; specify why: <Type here> |

* + - 1. **Certificate of Confidentiality**

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| 1. Indicate whether a Certificate of Confidentiality (CoC) has been or will be requested. |
| **[ X ] Not applicable**: No CoC has been requested for this study.  **[ ] This is a non-NIH funded/supported study. Choose one of the following:**  **[ ]** A CoC will be requested for this study. *The CoC application must be submitted to the IRB staff for review after IRB approval.*  **[ ]** A CoC has been obtained for this study. *Provide a copy of the CoC Approval Letter.* The expiration date of this CoC is: <Type here>  **[ ] This is an NIH funded/supported study** anda CoC will be automatically issued for studies that  involve identifiable, private, and sensitive information. |
| 1. Explain in what situations the UCI study team will disclose identifiable private information protected by a CoC. |
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1. *34 CRF 99:* [*Family Educational Rights and Privacy Act*](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) *(FERPA) applies to this research.* [↑](#footnote-ref-1)
2. *34 CRF 99:* [*Family Educational Rights and Privacy Act*](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) *(FERPA) applies to this research.* [↑](#footnote-ref-2)