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Quality Improvement vs. Research

When is IRB Review Required?

Clinical Research Regulatory Affairs

Human Subjects Protection Program

V5.24.23

Let’s first make sure we are speaking the same language

- iSTAR –
- IRB Approval -
- HSPP/IRB Administrators –
- Designated Reviewer –
- The IRB –
- Waiver of consent/HIPAA (or partial waiver) –
- A formal determination from the CHLA IRB -

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Takeaway from today's presentation;

- WHEN IN DOUBT:
  - Investigators planning quality improvement activities should submit an iStar application to the IRB. Under the category "Type of Study Review" the PI should indicate that the study falls under the category "Expedited Review". If the HSPP office concurs, a determination letter will be issued confirming that the activity is quality improvement and not research.

- CHLA IRB review and approval, certification of exemption, and/or

"not human subject research" determinations must be obtained

PRIOR to any contact with human subjects or any use of specimens, records or data.

The CHLA IRB does not grant retroactive approvals, exemptions or determinations for activities that have already been performed

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Quality Assurance (QA) and Quality Improvement (QI) Activities

- Clinical QI/QA: Systematic, data-guided activities designed to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting. Intent is limited to improving care, operations, etc.
- Non-clinical QI/QA: Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Examples include teaching evaluations or customer service surveys. Intent is limited to evaluating services or programs.

Regulatory Definitions According to 45 CFR 46.102:

- ***Human subject*** *means a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*
- ***Research*** *means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*
- ***Intervention*** *includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.*
- ***Interaction*** *includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).*
    - *Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."*

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Quality Improvement vs. Research

- Determining if an activity is **Research** or **Quality Improvement** can be challenging.
  - Federal regulations require human subject research to be reviewed and approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval.
- A QI activity may be a systematic investigation that is planned in advance and may use data collection and analysis to answer a question.
  - Although research must include systematic investigation, many non-research activities also include systematic investigation. Systematic investigation does not, in and of itself, define research.

Start at the end - INTENT

One of the keys to putting together a good QI project is to look at your end goal. Imagine getting results that point to "success," and think carefully about what you need to put in place before you even begin. Consider the primary intent ***and*** design of the project.

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The Intent to Publish

- The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.
- Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research;
  - People seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities.
  - Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

Research vs. Quality Improvement Comparison

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Examples of QI activities that are likely *NOT research* include:

- Implementing a practice to improve the quality of patient care
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
- Measuring and reporting provider performance data for clinical, practical, or administrative uses

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Non-Research Examples

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.

- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

These processes are already or are going to be routine

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Research = **Intent** to contribute to generalizable knowledge

- The activity is *NOT intended for generalizable knowledge*;
  - If the primary intent of the project is not generalizability (e.g., it is program evaluation/practice improvement related to a specific initiative) OR the project is not designed in a way that the findings would be generalizable (i.e., limitations to project design)
  - If the intended outcome is simply to report on what happened at the institution/program, this does not indicate research design or intent as it may or may not be generalizable outside of the institution.

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Examples of activities that are likely QI and research

- A project involves introducing an *untested clinical intervention* for purposes which include not only improving the quality of care but also collecting information about *patient outcomes* for the purpose of establishing scientific evidence to determine *how well the intervention achieves* its intended results.

- Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions).
  - A department decides an app will improve care, and implement the app. They collect data *as the app is implemented*, and in addition, *analyze this data for generalizable knowledge*.

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IRB review may be required when;

- In general, any research that involves either the participation of human subjects or the use of human biological specimens, medical charts, or databases **with identifying information** about humans is considered to be human research and requires IRB review.
- The funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results (Industry)
- The activity requires rigid and strict adherence to a process or protocol, indicative of a “systematic investigation” which would mean that the activity may be research
- The methodology employs a standard research design, such as randomization
- Multiple sites are involved, and all are implementing standardized procedures, indicating that the results may be generalizable, and the outcomes are likely not being used only for QI or program evaluation at the local institution

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IRB review may be required when;

- The project involves testing an experimental drug, device (including medical software or assays), or biologic; activity will try to test or prove something that is untested or unproved in other settings
- The project seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge
- The risks to the participants from the intervention are greater than minimal
- One intends to further study a completed QI project (use of secondary data) and make it generalizable (research)

iSTAR submission of your project is not the same as "needing IRB review and oversight though the life of your project" – You may get a NHSR or Exempt determination!

Journals and/or national organizations may require a formal determination from the IRB in order to submit a manuscript or abstract (you'll need IRB approval prior to the research)

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Examples of secondary data for research

- A QI project is implemented, and upon completion, the investigator realizes they want to do research about the project, and interview clinicians. The data they will collect from the interviews will be used for research, therefore, they would submit to the IRB before beginning interviews.

- A team uses biologic samples to compare two different types of tests to determine which one is better and therefore which one should be used (intent to improve care at Institution). After they complete the comparison, they realize they want to share the success of these tests because they believe it will help other institutions (intent to contribute to generalizable knowledge). They then submit to IRB and request to use the data collected for the QI project as secondary data for research before they complete further analysis.

- A surgeon believes that a certain technique will improve their own practice, so they implement it and record results as part of clinical practice. They then decide that this practice would help others, *so they go back to their data to systematically analyze and generalize outcomes and results.* They would need to submit to the IRB prior to the review of gathered data.

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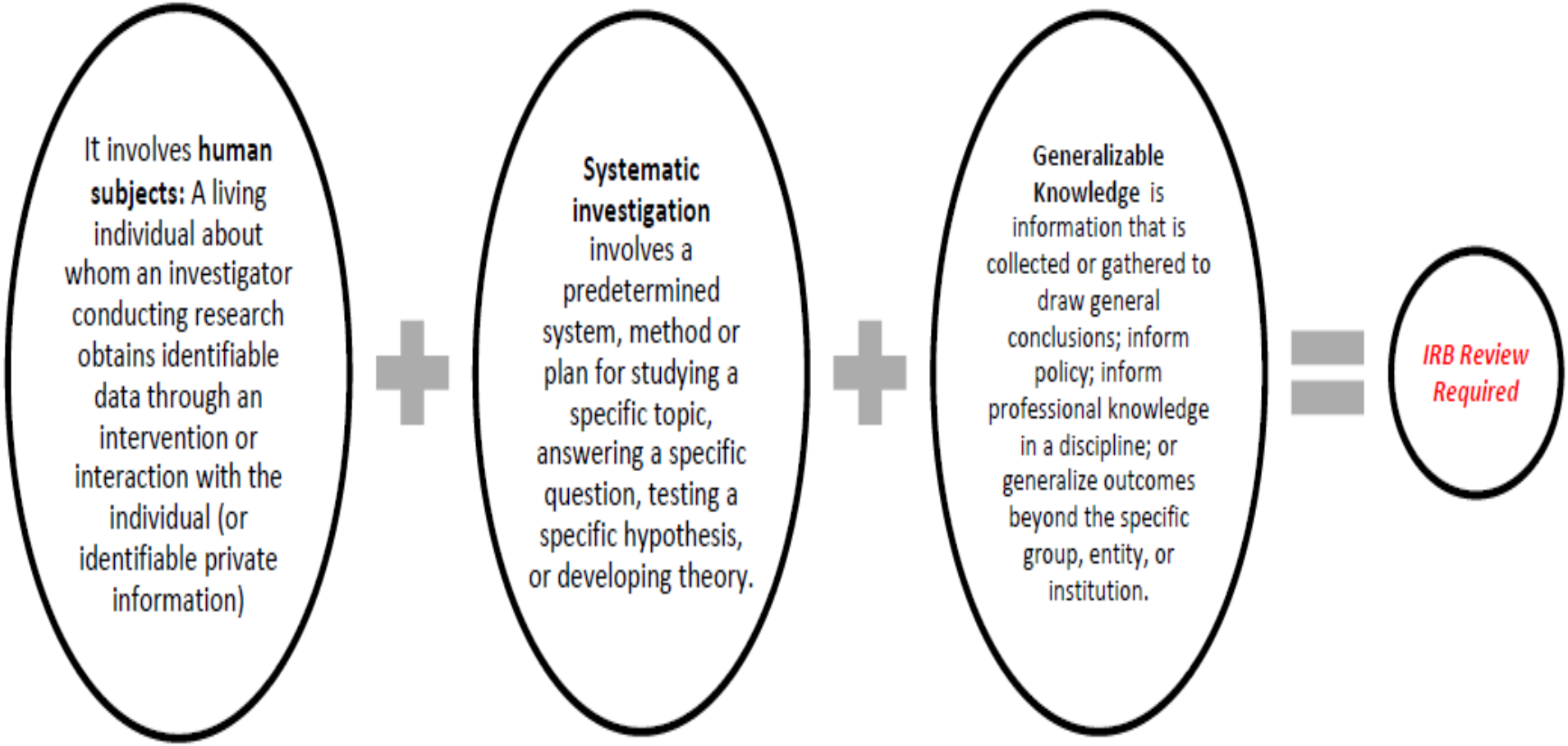
Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).



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Not Human Subjects Research (NHSR)

- The IRB's role is to oversee human subject research. Therefore, studies that do not involve human subjects or do not meet definition of research *under 45 CFR 46.102(d),* are considered Not Human Subjects Research (NHSR).

- The CHLA IRB permits investigators to apply the definitions of "research" and "human subject" in order to determine whether their proposed activities meet the definition of human research. See HRP-001 SOP: Definitions for details.

- However, investigators frequently are unsure whether their proposed activities meet the definition of "research" or "human subject." It is strongly recommended that investigators request a formal determination about whether an activity is human research.

Some funding agencies, sponsors, meetings, conferences and journals may require a formal determination from the CHLA IRB.

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IRB review is not likely required;

- If the project is intended to directly affect institutional or programmatic practice, improve a process or delivery of care within a specific health care setting

- If the intention upon designing and conducting the project is to improve or evaluate a specific practice/program locally

- If the practice being implemented/mandated is based on sufficient existing evidence that indicates the practice should be effective when implemented locally

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If submitted into iSTAR you'd receive a memo that verifies your project as "Activities not requiring IRB review"

When submitting to the IRB you may ask for a waiver of consent

- For QI projects; ***This activity could be considered part of usual care. Consent beyond what is already obtained in clinical practice is generally not necessary.***
- For HS Research; The HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when
  - the risk to the subjects is minimal,
  - subjects' rights and welfare will not be adversely affected by the waiver,
  - conducting the research without the waiver is not practicable, and
  - if appropriate, subjects are provided with additional pertinent information after their participation (45 CFR 46.116(d)).

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IMPORTANT NOTE:

- *When in doubt:* Investigators planning quality improvement activities should submit an iStar application to the IRB. Under the category "Type of Study Review" the PI should indicate that the study falls under the category "Expedited Review". If the HSPP office concurs, a determination letter will be issued confirming that the activity is quality improvement and not research.

- CHLA IRB review and approval, certification of exemption, and/or not human subject research determinations must be obtained ***prior to any contact with human subjects or any use of specimens, records or data.***

The CHLA IRB does not grant retroactive approvals, exemptions or determinations for activities that have already been performed

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How do you get an iSTAR account?

- Take an HS Research CITI training; please make sure you are registered with a free CITI account that is affiliated with CHLA using your CHLA email address. In order to avoid the paywall, go to www.citiprogram.org and click 'Register' in the far right-hand side.
- Beneath that, type "Children's Hospital Los Angeles" into the "Select Your Organization Affiliation" section. Do not select the option that includes (SSO) at the end.
- Check the boxes as they appear and then click the "Create Account" button on the left hand side. Again, avoid the SSO-specified option.
- This should set you up with a free CHLA-affiliated account. The option should be accessible from there.
- If you need to add a course to your account, from your main log-in page, scroll down to your affiliations. Next to CHLA, click the 'View Courses' button.
- On the new page, scroll down to the bottom of the page. In the grey box at the bottom, click the 'Add Courses' option.
- Select which trainings are appropriate. The most commonly selected are Human Subjects Research (choose Biomedical or Social/Behavioral, depending on the type f research you are doing)
- Once complete, an iSTAR account should be generated for you if it does not already exist. If you find you do have an iSTAR account but it will not let you submit an application, please email your HS CITI Certificate to istar@usc.edu so they can update your account.

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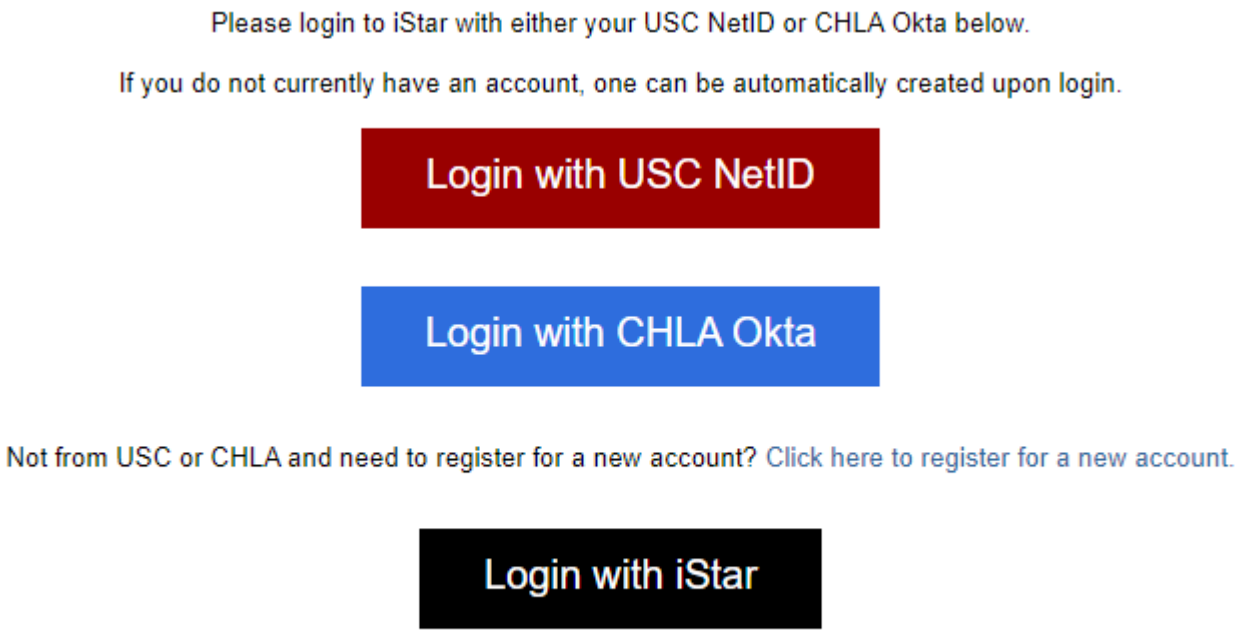
iSTAR

- https://istar.usc.edu/
- Log in with your CHLA OKTA login



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Don’t forget to fill out yearly *disclosures* or you will not be able to submit your iSTAR application!

- Please make sure to sign in with CHLA OKTA https://disclose.usc.edu/diSClose/sd/PublicCustomLayouts/SSO/Selection

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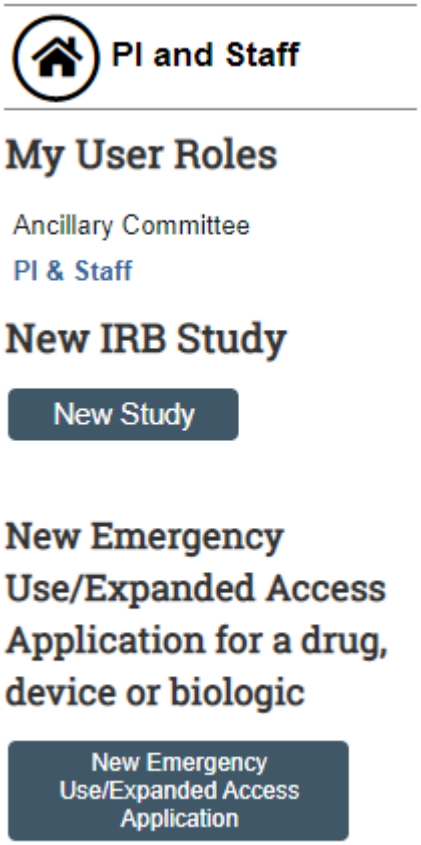
How to create your QI application;

- Click on NEW IRB Study on the left of the screen after you are logged in



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This is 1 example of a possible QI project iSTAR entry

- Screenshots may not be representative of how YOUR project should be entered
- Remember iSTAR is a USC-CHLA shared platform that has its flaws and was created for the purpose of submitting Human Subjects Research
- Once submitted your project still needs to be reviewed by dept/division heads within iSTAR as well as ancillary reviews such as IS/IT for data/PHI uses (could take over a week)
- Once it reaches an IRB Administrator in the HSPP office the length of time before you have a memo stating the determination approval depends on which type; NHSR<Exempt<Expedited<Full-committee review

Be Specific with your INTENT

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Validate | Compare

- **01. Project Identification and Abstract**
- 02. Study Personnel
- 04. Funding Information
- 05. Type of Study Review
- 05c. Type of Study Review - Coded Specimens and Data
- 11. Study Data
- 39. Conflict of Interest Information
- 40. Additional Supporting Documents
- 50. Required Approvals
- 99. Instructions for Submission

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1. Project Identification and Abstract

1.1. * **Type of Submission:**

- (●) Research Protocol or Study on Human Subjects
- ( ) Use of Humanitarian Use Device (Not Research)
- ( ) Rely on another IRB (Ceded)
- ( ) Right To Try

Clear

1.2 * **Full Title of Research Protocol**

QI example for .....

1.3 * **Short Title**

QI example

1.4 * **Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sente endpoints or outcomes; follow-up; statistics and plans for analysis.**

explain it is QI
explain that it is not research per x.y.z. or not human subjects research per a.b.c. etc.

1.5. * **Select which IRB you are requesting review from:**

- ( ) USC - Biomedical IRB
- ( ) USC - Social Behavioral IRB
- (●) CHLA - Institutional Review Board (CHLA)

Clear

Visit https://www.chla.org/research/hspp for information about the CHLA HSPP and IRB

1.6 * **To the investigator's knowledge, does the Institution have financial and/or intellectual** *conducted by its employees or students or to create an unacceptable risk to human subjects.*

( ) Yes (●) No Clear

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2. Study Personnel

2.1. Study Personnel and their roles:

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data	Manage Audit Access to PHI/ePHI (CHLA Only)
Update	Mulder	Candice	CHLA-CLINICAL INVESTIGATION CENTER	Principal Investigator	HS, GCP, HIPAA	no	no	yes	yes

+ Add

Who may be included as "key personnel" on an IRB submission?

Key Personnel are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. Individuals who should be named on an IRB application are those who in the following:

a. conducting research through an interaction or intervention with human subjects for research purposes
b. participating in the consent process by leading it or contributing to it
c. directly recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study

Who should NOT be listed as key personnel on an IRB submission:

Individuals paid by the institution to perform a service not part of or paid by the research project performing services that are typically performed for non-research purposes or fee for service:

- honest broker
- pharmacy employees dispensing investigations drugs
- hospital employees obtaining blood through a blood draw or collect urine and provide such specimens to investigators as a service
- radiology clinic employees performing chest x-rays and sending results to investigators as a service
- routine laboratory analyses of blood samples for investigators as a commercial service
- transcription of research study interviews as a commercial service
- not administering any study intervention being tested or evaluated under the protocol

2.2. Is the Principal Investigator a staff member, student, resident, fellow, postdoctoral scholar, other trainee, visiting scholar, or visiting faculty member at USC/CHLA?

○ Yes ● No Clear

2.3. Are there any individual collaborators from other institutions?

○ Yes ● No Clear

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4. Funding Information

4.1. * **What existing or pending support will be used for this study?** (check all that apply)

- [ ] Cooperative Group (SWOG, COG, RTOG, etc.)
- [ ] CTSI
- [ ] Department of Defense (DOD) Funds
- [ ] Departmental/Institutional Funds
- [ ] Federal Grant/Contract
- [ ] Foundation Grant/Contract
- [ ] Industry
- [ ] Intramural/Internal Grant
- [ ] Residual Funds
- [ ] State or Local Grant/Contract
- [ ] Subcontract from another institution
- [x] No Funding
- [ ] Other

Change of existing/addition of new funding sources and agencies will require an amendment.

4.4. **Add the details of each source of funding for this study.**

Sponsor	Principal Investigator
There are no items to display	

+ Add

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5. Type of Study Review

5.1. Select the type of review that you are requesting for this study:

- ○ Full Committee Review
- ● Expedited Review
- ○ Exempt Review
- ○ Coded Specimens/Data

Clear

A study may

*Minimal risk

If you are unsu

5.2. Attach the protocol here. All studies require a fully developed protocol. If you have questions contact the IRB office to discuss.

+ Add

Name	Version	Modified

There are no items to display

Template protocols are available on the CHLA HSPP website: https://www.chla.org/research/hspp.

5.3. Attach the sponsor's template informed consent here.

+ Add

Name	Version	Modified

There are no items to display

5.4. If any study documents are password protected, enter the passwords here.

5.5. If there is a sponsor protocol number associated with this file, specify it here:

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6. Study Locations

6.1. Identify the locations where the research activities described in this application will be performed (check all that apply):

- [ ] USC HSC - Health Sciences Associated Locations
- [ ] USC UPC - University Park Associated Locations
- [x] CHLA
- [ ] Other

6c. CHLA Locations

This screen is required if your study is being conducted at CHLA

6c.1. CHLA Locations:

- [x] CHLA facilities
- [ ] Arcadia
- [ ] Encino
- [ ] Santa Monica
- [ ] South Bay
- [ ] Valencia
- [ ] Other

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Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. NOTE: Review the information under the blue question mark before answering this question.

- [x] The study procedures involve interactions or interventions with participants (e.g., medical procedures, online surveys, in person interviews).
- [x] Secondary Analysis: This study involves use of data/specimens **that have been or will be collected/generated for non-research purposes** (e.g., medical records, student records).
- [x] Secondary Analysis: This study involves use of data/specimens **that have already been collected/generated for another research purpose** (e.g., existing research datasets, existing specimens collected for research).

9.2. **Study Procedures:** (check all that apply)

- [ ] Audio/Video Recordings or Photographs
- [ ] Behavioral Observations and/or Behavioral Experimentation
- [x] Behavioral Interventions
- [ ] Deception
- [x] Interview/Focus Groups
- [ ] Population-based Field Study
- [ ] Psychophysiological Testing
- [x] Surveys/Questionnaires/Psychometric Testing
- [ ] Anatomic Pathology Specimens
- [ ] Approved/Investigational Devices
- [ ] Approved/Investigational Drugs and Biologics
- [ ] Biohazardous Substances (e.g. fresh tissue or tissue fluids, infectious agents, microorganisms, recombinant DNA

9.3. Is this a clinical trial? [The NIH defines a clinical trial as a prospective research study to evaluate the effects of one or more interventions on health-related biomedical or behavioral outcomes.]

○ Yes ● No Clear

9.5. Will data from this study be subject to the NIH Genomic Data Sharing (GDS) policy?

○ Yes ● No Clear

9.6. Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?

○ Yes ● No Clear

9.7. Will data from this research be submitted to the US Food and Drug Administration or will data be held for inspection by the FDA?

○ Yes ● No Clear

10. Characteristics of the Study Subject Population

10.1. What is the maximum number of subjects you plan to recruit for this site? (Integer values only)

120

10.1.1. If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)

10.1.2. If necessary, provide further explanation of accrual goals for all subject populations.

we will look at 100 patient records and not record identifiers (or code them)
survey 20 physicians anonymously

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13. Methods and Procedures - Collection of Data/Specimens

13.1. **Does the study involve collection of data, records or specimens from deceased individuals?**

○ Yes ● No Clear

13.2. **Attach a copy of any data collection sheets that will be used to record or collect data for this research study. If you are recording or collecting data from another source (e.g., medical record, study record) be sure to include all of the data points that will recorded for this research.**

+ Add

Name	Version	Modified

There are no items to display

13.6. **Retrospective Data Disposition:** (select if applies to this study)

☐ Submission of Data or Tissue to an Existing Repository

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19. Methods and Procedures - Interview/Focus Groups

This screen is required if you indicated the use of Interview or Focus Groups as a procedure (Question 9.2.)

19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.

+ Add

Name	Version	Modified

There are no items to display

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing (Question 9.2.)

21.2. Attach copies of all measures/instruments that will be used for this study.

+ Add

Name	Version	Modified

There are no items to display

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22. Special Subject Populations

22.1. Indicate any special subject populations you intend or expect to enroll in the research: (check all that apply)

- [ ] Healthy Volunteers
- [x] Employees or Students
- [ ] Adults not Competent to Consent (or likely to lose the capacity to consent during the study)
- [ ] Non-English Speaking Populations
- [x] Minors (subjects under 18 years of age)
- [ ] Pregnant Women / Human Fetuses
- [ ] Neonates (infants under 30 days old)
- [ ] Prisoners/Detainees
- [ ] Wards
- [ ] None of the above

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22b. Special Subject Populations - Employees/Students

This screen is required if you indicated Employees or Students as a special subject population (Question 22.1.)

22b.1. Describe how you will minimize the potential for employees and/or students to feel coerced to participate. Discuss how the potential confusion in roles will be addressed.

PI/Co-I/Faculty advisor won't approach doctors for participation, the research assistant will....
surveys are anonymous via....
email will go to all of them and we won't know who answered survey...
optional survey...
everyone will be reminded that they choose to not do it without penalty...

REMINDER: If the subject population includes anyone under the age of 18, please ensure the Minors special population is checked: (the following is what you checked in 22.1)

- [x] Employees or Students
- [x] Minors (subjects under 18 years of age)

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22e. Special Subject Populations - Minors

This screen is required if you indicated Minors (subjects under 18 years of age) as a special subject population (Question 22.1.)

22e.1. Provide a justification for involving minors in this research: (check all that apply)

- [x] The condition, situation, or issue under study affects minors.
- [ ] Adults have already been studied, but we do not yet know how minors are affected.
- [ ] The condition does not affect adults, only children.
- [ ] Other

22e.2. Choose the proposed category of permissible research with children.

Category
(●) a. 46.404 - Research not involving greater than minimal risk.
( ) b. 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
( ) c. 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
( ) d. 46.407 - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Clear

22e.3. Indicate the age ranges of the minors involved in this research: (check all that apply)

- [ ] Neonates under 30 days
- [ ] 30 days - 6 years
- [x] 7 years - 13 years
- [ ] 14 years - 17 years

23. Study Resources

23.1. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient. Please check-off the items that apply to this study.

- [x] Employed interns, residents, fellows, or postdocs with dedicated time to conduct this research.
- [x] Employed faculty and or staff with dedicated time to conduct this research.
- [x] Students with dedicated time as part of their training to conduct this research.
- [x] Volunteers
- [ ] Other

23.2. Describe the staff and justify their qualifications. Please check-off the items that apply to this study.

- [x] All biomedical investigators are privileged and credentialed to perform the study activities in the study locations.
- [x] All study staff are trained and credentialed to perform the duties assigned to them.
- [x] All study staff have fulfilled the training mandated by their respective departments or institutions.
- [ ] Other

23.3. Describe the study facilities and justify they are adequate.

dept of X has offices for private viewing of pt charts for data extraction etc..

23.4. Describe how staff and others will receive necessary information and training to assist in the conduct of this study.

monthly meetings...weekly meetings...

24. Subject Recruitment and Informed Consent

Go to forms menu | Print

24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use c distribution of the recruitment tool): (check ALL that apply)

- [ ] Brochures
- [ ] Clinical Data Warehouse
- [x] Email/Electronic Mailing Lists
- [ ] Flyers
- [ ] Letters
- [ ] Newspaper/Magazine Advertisements
- [ ] Radio/Television Announcements
- [ ] Subject or Participant Pools
- [ ] Telephone Scripts
- [ ] Verbal (Personal Solicitation)
- [ ] Websites / Social Media Outlets
- [ ] Other
- [ ] None of the above

24.1.2. Describe how you will be obtaining contact information:

emailing clinic PIs using their chla email addresses...

24.2. Attach copies of all recruitment tools that will be used by the local site. *(Do not attach any advertising or recruitment materials that will not be used at the local site or under control of the local site.)*

+ Add

24.3. Informed Consent and Waivers:

** Please note that child assent and parental permission will be addressed on subsequent pages. Do not complete the following consent questions if adults will not be participating in the study. **

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

- [ ] Written/signed consent (participants will sign an informed consent document)
- [ ] Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)
- [ ] Waiver of signed informed consent (informed consent document without the signature sections will be provided)
- [x] Waiver of consent (participants will not be asked to sign or be given a consent document)

24.5. You indicated you are requesting a waiver of consent or a waiver/alteration of one or more elements of informed consent. The following questions are required:

24.5.1. The research involves no more than minimal risk to subjects and the waiver/alteration will not adversely affect the rights and welfare of the subjects because: (check ALL that apply and at least one answer from A at least one answer from B)

A. The study will: (check all that apply)

- [x] Only collect retrospective data or be performing secondary data analyses on existing data
- [ ] Only collect information from observation of public behavior
- [x] Only collect information from standard of care procedures
- [x] Not contact participants
- [ ] Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment records, etc.)
- [x] The requested waiver of consent is NOT for the storage, maintenance, or secondary research use of identifiable private information or identifiable biospecimens for those who refused to provide broad consent

B. All Data/Information collected will: (check ALL that apply)

- [x] Not contain any identifiable information
- [ ] Be coded and the key codes kept separately and securely
- [ ] Be kept in a locked/password protected area accessible only to study staff
- [ ] Other

24.5.2. Explain why the research could not practicably be carried out without the waiver or alteration: (check ALL that apply)

- [x] The data being collected are from existing records. Many of the subjects are lost to follow up, no longer seen at the hospital/facility, or deceased.
- [x] Participation in this study does not involve personal contact. The participants are not available to provide informed consent.
- [ ] The study will be examining records from a large number of subjects. It is not feasible to attempt to contact all of them.
- [ ] Other

24.5.3. Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation: (check ALL that apply)

- [x] There is no foreseeable need to provide information to the subjects. If there is a need, the IRB will be contacted to discuss the specific situation.
- [x] The study is observational and any results generated from the study will not be applicable to the subjects or the care of the subjects.
- [ ] Other

24.5.4. If the research involves using identifiable private information or identifiable biospecimens, explain why the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format.

24A. Assent

24A.1. Assent and Waivers:
Check the type(s) of assent or waiver of assent planned for this study: (check ALL that apply)

- [ ] Written assent (participants will sign an assent document)
- [ ] Waiver of signed assent (assent document without the signature sections will be provided)
- [x] Participants will not be assented

24A.3. Indicate the applicable justification(s) for not obtaining assent:

- [ ] The age, maturity, or psychological state of children to be enrolled make them incapable of providing assent.
- [ ] The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or v current context of the research.
- [x] The research involves no more than minimal risk to children; the waiver would not adversely affect the rights and welfare of th out without the waiver; and, if appropriate, participants will be provided with pertinent information after participation.

In order to qualify for a waiver of assent where the research is no more than minimal risk (the third option above), the f

24A.3.1. The research involves no more than minimal risk to subjects and the waiver will not adversely affect the rights ar
apply and at least one answer from A and B)

A. The study will: (check all that apply)

- [x] Only collect retrospective data or be performing secondary data analyses on existing data
- [ ] Only collect information from observation of public behavior
- [x] Only collect information from standard of care procedures
- [x] Not contact participants
- [x] Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment
- [x] The requested waiver of consent is NOT for the storage, maintenance, or secondary research use of identifiable pri who refused to provide broad consent

24P.1. Parental Permission and Waivers:

Check the type(s) of parental permission or waiver of permission planned for this study: (check all that apply)

- [ ] Written permission (parents or legal guardians will sign a consent document)
- [ ] Alteration of the elements of permission (parents or legal guardians will sign a consent document, but one or more of the basic rec
- [ ] Waiver of signed parental permission (parental permission document without the signature sections will be provided)
- [x] Waiver of permission (parents or legal guardians will not be asked to sign a consent document or be given an information sheet)

24P.3. Parental Permission Waiver:

Check the applicable justification for a waiver of parental permission:

- [x] The research involves no more than minimal risk to children; the waiver would not adversely affect the rights and welfare of the ch out without the waiver; and, if appropriate, participants will be provided with pertinent information after participation.
- [x] Parental permission is not a reasonable requirement to protect the participants in the study (e.g., neglected, abused, or homeless minimal risk to children; the waiver would not adversely affect the rights and welfare of the children; the research could not practic appropriate, participants will be provided with pertinent information after participation.

You indicated you are requesting a waiver permission or alteration of one or more elements of parental permission. The follov

24P.3.1. The research involves no more than minimal risk to subjects and the waiver/alteration will not adversely affect the rig all that apply and at least one answer from A and B)

A. The study will: (check all that apply)

- [x] Only collect retrospective data or be performing secondary data analyses on existing data
- [ ] Only collect information from observation of public behavior
- [x] Only collect information from standard of care procedures
- [x] Not contact participants
- [x] Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment reco
- [x] The requested waiver of consent is NOT for the storage, maintenance, or secondary research use of identifiable private i who refused to provide broad consent

25. Financial Obligation and Compensation

25.1. Financial Obligation: Choose the response that best describes the cost to participants.

- ○ All costs are covered by the sponsor or funder.
- ○ Research costs are paid by the sponsor or funding agency; routine health care costs are th
- ○ All costs are the responsibility of the participants and/or their healthcare plans.
- ○ Drug trials sponsored by the National Cancer Institute or other national institutes.
- ● There are no costs related to participation.
- ○ Other

Clear

25.2. Payment for Participation: Describe how much, if any, financial or other form of compens be fulfilled to receive full or partial compensation. Describe the proposed method of timi compensation will be distributed to children.

na

25.3. Research-Related Injury and Compensation for Injury: For studies of greater than minima consequence of the research, who will provide this care? If applicable, describe who will

Medical and/or psychological care/treatment will be offered. In addition:

- ○ Costs for medical care from research-related injuries will be paid by the sponsor or funder.
- ○ Costs for medical care from research-related injuries will not be paid by the sponsor or fun
- ● Study has no sponsor or funder who accepts liability for injury.

26.1. Privacy Protections: Privacy is a participant's ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

- [x] Research procedures will be conducted in person in a private setting.
- [x] Data will be captured and reviewed in a private setting.
- [x] Only authorized research study personnel will be present during research related activities.
- [x] The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- [ ] Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
- [ ] Other (specify below)

26.2. Confidentiality Precautions: Confidentiality is an extension of the concept of privacy; it refers to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be labeled? (check ALL that apply)

- [ ] Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
- [x] Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)
- [x] Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)
- [ ] Other (explain below)

26.2.2. If you are recording data in more than one way, please explain and provide justification:

26.3. Study data/specimen will be stored:

- [x] Physically
- [x] Electronically

Please confirm that, at a minimum, the following measures will be taken and enforced:

- [x] Information or specimens maintained physically will be stored with appropriate physical safeguards, such as in locked cabinets and/or in restricted areas limited to authorized study personnel
- [x] Copying and use of study related materials will be restricted

26.4. Will coded or identified data and/or specimens be sent outside the institution to a third party (such as a study sponsor, federal agency, or another institution)?

○ Yes ● No Clear

26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

- [ ] Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased)
- [x] Retained for study record keeping purposes per institutional policy
- [ ] Retained by the investigator for future research use
- [ ] Retained for future research use (submit data or tissue to an existing repository/bank)
- [ ] Restricted use data will be destroyed or returned to the source
- [x] No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator
- [ ] This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations
- [ ] The NIH requires that the records be retained for three years following the completion of the study
- [ ] Data to be provided to CHLA I.S. for secure destruction after collection
- [ ] Other (specify below)

26.5.2 Provide the FULL PATH, URL, or IP where the data will be retained (i.e. \\server\share\folder, https://redcap.med.usc.edu/, or 172.1.1.250, etc.):

26.5.3 Provide how long this data will be retained (years + months)

26.6. Do you have, or plan to apply for, a Certificate of Confidentiality for this study?

○ Yes ● No Clear

27. Risk/Benefit Assessment - Risks

27.1. Risks, Discomforts and Potential Harms: Describe the risks associated with each research intervention. Include consideration of physical, psychological, social, and other factors. (check all that apply)

- [ ] Discrimination based on genetic findings.
- [ ] Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.
- [x] Some of the questions may make the participant feel uneasy or embarrassed.
- [x] There is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.
- [ ] The participants are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, they could have problems getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, they could be charged with a crime.
- [ ] Biomedical risks, including drug, device, biologics, radiation, surgery or other research procedures (please specify).
- [ ] The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide.
- [ ] Venipuncture risks including: mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).
- [ ] Other (specify below)

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27.2. Describe the precautions that will be taken to minimize risks/harms. (check all that apply)

- [x] We will use our best efforts to keep the findings in this study as confidential as possible.
- [x] Subjects can choose to skip or stop answering any questions that make them uncomfortable.
- [ ] Data will be coded and identity stored separate from data.
- [ ] Data will be collected anonymously.
- [ ] Biomedical precautions, including precautions relating to drugs, devices, biologics, radiation, surgery or other researc
- [ ] Venipuncture by individuals certified and privileged to perform the procedure.
- [x] Other (specify below)

27.2.1. Other precautions (including biomedical precautions) that will be taken to minimize risks/harms include:

-trying to click coded and anonymous above to describe the different types but istar won't allow both to be clicked

7.3. Who will monitor the research for the safety of the participants? (check all that apply)

- [x] The USC/CHLA Principal Investigator (or designee)
- [ ] A USC/CHLA Data Safety Monitoring Committee/Board
- [ ] A Non-USC/CHLA Data Safety Monitoring Committee/Board
- [ ] The Sponsor/Funding Agency
- [ ] Other (specify below)

27.3.2. [x] **All Reportable Events or unanticipated problems will be submitted to the IRB in compliance with USC/C sponsor requirements (as applicable).**

27.3.4. Attach the CHLA Research Monitoring Plan

[None] Upload

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study: (check all that apply)

- [x] There are no direct benefits to research participants
- [ ] Improvement in some or all of participants' symptoms
- [ ] Improvement in some or all of participants' survival or longevity
- [ ] Information gained from testing or monitoring procedures
- [ ] Provision of drug or device
- [ ] Reduced side effects
- [ ] Other (explain below)

28.2. Describe potential benefits to society, if any. (check all that apply)

- [x] The advancement of knowledge
- [ ] A new treatment or therapy for the condition under study
- [ ] None
- [ ] Other (explain below)

28.3. What are the alternatives to participation? (check all that apply)

- [x] Not participating
- [ ] Continue current medical care for their condition
- [ ] Participation in other research studies

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use, or disclose Protected Health Information (PHI/ePHI) which includes either patient and/or participant data, in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)
    - Name/Initials
    - Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
    - All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
    - Elements of date, including year, for persons 90 or older
    - Telephone number
    - Fax number
    - Electronic mail address
    - Social Security Number
    - Medical record number
    - Health plan identification number
    - Account number
    - Certificate/license number
    - Vehicle identifiers and serial numbers, including license plate number
    - Device identifiers and serial number
    - Web addresses (URLs); Internet IP addresses
    - Biometric identifiers, including finger and voice print
    - Full face photographic images and any comparable images
    - Any other unique identifying number, characteristic, or code*

● Yes ○ No Clear

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed above), in your research?

● Yes ○ No Clear

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36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

- ○ Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants
- ● None of the Above

Clear

36.2. If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.

- ○ Obtaining HIPAA authorization from participant
- ● Full Waiver of HIPAA Authorization
- ○ Both

35.2 says insert a CHLA Data Use Agreement, but it is not necessary to attach anything there…

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38b. Full Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Full Waiver of HIPAA Authorization (Question 36.2.)

If you are applying for a full waiver of authorization provide justification per 45 CFR 164.

38b.1. How will you protect PHI/ePHI (Protected Health Information) from improper use and disclosure? (check all that apply)

- [x] No identifiers or links to identifiers will be recorded during the data collection process.
- [x] All source and research documents containing PHI/ePHI will be stored and maintained in a locked/password protected area accessible only to study staff.
- [ ] Study data will be coded or de-identified prior to being sent outside the study team.
- [ ] Other

38b.2. How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research? (check all that apply)

- [x] No identifiers or links to identifiers will be recorded during the data collection process.
- [x] Direct or Coded Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.
- [x] The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.
- [ ] Other

38b.3. By checking the "I Agree" box you are providing assurance that PHI/ePHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI/ePHI is permitted by the Privacy Rule.

- [x] **I Agree**

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38b.4. The research could not practicably be conducted without the requested waiver or alteration because: (check all that apply)

- [ ] It is not feasible to individually contact the large numbers of participants.
- [ ] It is not possible to locate many of the potential participants because they have left the area or are otherwise lost to follow up.
- [x] Other

38b.4.1. Explain why the research could not practicably be conducted without the requested waiver:

subjects will not be approached...

if waiver of consent or waiver of signed consent, you can say subjects are not approached for signatures etc...

or that would be only record linking them to study

38b.5. The research could not practicably be conducted without access to and use of the PHI/ePHI because: (check all that apply)

- [x] The data required for this study is only available in the (PHI/ePHI) / medical records.
- [ ] Other

38b.6. By checking the "I Agree" box you are providing assurance that PHI/ePHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.

- [x] **I Agree**

39. Conflict of Interest Information

39.1. Instructions: Click on the name of each study team member and indicate whether they have a potential financial conflict of interest related to this study. If they have a conflict of interest, click on the conflict that has been reported in diSClose. If the conflict is not listed, ask the study team member to update their disclosure information in diSClose before completing this section.

Study Staff	Role	COI Annual Disclosure Status	Conflicts
Candice Mulder	Principal Investigator	Current: due on 7/31/2022	No conflicts identified

CHLA policy requires all study team members to have a current COI disclosure in DiSClose. If a study team member has not completed a disclosure form or the disclosure form has expired, you must submit a new disclosure in DiSClose. Hover over the annual disclosure status for more details.

Please note that first time users of diSClose will need to create a diSClose account using the "Login with CHLA Okta" option to ensure disclosure data from diSClose appears in this Section.

-Section 40 lets you attach additional info and/or describe anything additional that was not covered elsewhere.
-Section 50 you will likely say NO to every question in there as it deals with lab/radiation/path/ER/nursing/data-sharing/heartinstitute pts.

Click save & submit when ready!

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Need Help?

- Contact the iStar Technical Support Desk:
- istar@usc.edu

- Candice Mulder cmulder@chla.usc.edu
- RegulatoryAffairs@chla.usc.edu
- HSPP@chla.usc.edu

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References/Resources

- https://www.chla.org/research/hspp
- Differences Between Research and Quality Improvement Activities
- Activities that Require IRB Review
- HRP-001 SOP: Definitions
- https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4857497/
- Worksheet developed by Rachel Nosowsky, Esq. and is based on The Hastings Center Report The Ethics of Using QI Methods to Improve Health Care Quality and Safety Download the Worksheet.
- worksheet developed by the CHOP Quality Improvement Committee (QIC) Ethics Subcommittee Download the CHOP QI Screening Checklist.
- The SQUIRE Website(link is external) has numerous useful tools and guidelines for those doing Quality Improvement work.
- Publication Guidelines for Quality Improvement Studies in Health Care: The Evolution of the Squire Project *Annals of Internal Medicine, 2008*
- http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

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Additional Resources

- 45 CFR 46.102(e)(1): Federal Policy's definition of Human Subject (v 2018)
- 45 CFR 46.102(l): Federal Policy's definition of Research (v 2018)
- 45 CFR 46 (v 2018): Preamble for Quality Improvement Activities
- IRB Ethics & Human Research, Vol 39(3), May-June 2017, Pages 1-10
- Journal of Empirical Research on Human Research Ethics, 2015, Vol 10(2), Pages 209-210
- 45 CFR 164.506 (2013): Definition of Health Care Operations
- IRB Ethics & Human Research, Vol 35(5), September-October 2013, Pages 1-8
- Research Compliance Professional's Handbook, 2nd Edition, 2013, Chapter 8, Page 79
- OHRP Quality Improvement Activities FAQ (2010)
- 2005 California Senate Bill 13 (SB 13) (*when applicable)
- Example of a published *QI **Project***
- Paper on quality improvement in healthcare by Paul Batalden and Frank Davidoff
- BMJ video on quality improvement
- Exempt - https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101
- Expedited - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

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Other Helpful Links

1. The Ethics of Using Quality Improvements in Health Care contains a detailed discussion of the differences between QI and research
2. The Common Rule and Continuous Improvement in Health Care a discussion paper sponsored by the Institute of Medicine discusses the interactions and overlap between QI and research.
3. Vogelsang J. Quantitative research versus quality assurance, quality improvement, total quality management, and continuous quality improvement.(link is external)
4. Casarett et al. Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications.(link is external)
5. Finkelstein et al. Oversight on the borderline: quality improvement and pragmatic research(link is external)
6. Baily et al. Special Report: The Ethics of Using QI Methods to Improve Health Care Quality and Safety(link is external)
7. Lynn et al. The ethics of using quality improvement methods in health care.(link is external)
8. Grady C. Quality improvement and ethical oversight.(link is external)
9. Davidoff et al. Publication guidelines for improvement studies in health care: evolution of the SQUIRE Project.(link is external)
10. Baily MA. Harming through protection?(link is external)
11. Miller and Emanuel. Quality-improvement research and informed consent

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**All services available for group or one-on-one study staff training sessions*

For guidance, training & regulatory assistance on federal, state and local policies & CHLA procedures regarding research & clinical trials at CHLA Email RegulatoryAffairs@chla.usc.edu for assistance

Candice B. Mulder, MPH, CCRP, CIP | (she/her/ella)

Manager, Clinical Research Regulatory Affairs - Human Subjects Protection Program

Children's Hospital Los Angeles

Ph: 323-203-7538 cmulder@chla.usc.edu

Please visit the HSPP website https://www.chla.org/research/hspp

for guidance documents & templates.

Additional Clinical Research Tools - https://chla.sharepoint.com/sites/crso

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