

IRB Survival Guide! Getting Approved

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Credentialing

Required for all non-UH personnel accessing UH Protected Health Information (PHI) for clinical research. Must be done BEFORE you start working on a protocol.

This credentialing process allows for:

- Access to PHI for IRB-approved clinical research projects;
- A UH-based title (Research Faculty for Ph.D. researchers at Case Western Reserve University or Research Associate for all others);
- A UH log-in and email account
- Free access to UH-sponsored research training programs
- For detailed information about how to submit your Research Credentialing application please read the [Research Credentialing Standard Operating Procedure](#) (SOP). This SOP is a step by step guide explaining the process.

Credentialing, continued

If you have questions please first refer to the [Frequently Asked Questions](#) page.

If additional help is needed, contact:

- Tracey Tytko, Institutional Review Board Coordinator at **216-844-1374** or Tracey.Tytko@uhhospitals.org
- David Ehlert, Director of Research Operations at **216-844-5527** or David.Ehlert@UHhospitals.org.

Belmont Report

Complete CITI training (for certification in human subject protections), read [The Belmont Report](#)

- It outlines the 3 basic ethical principles of conducting research with people:
 - **Respect for Persons** - acknowledge autonomy and protect those with diminished capacity
 - **Beneficence** – do no harm *and* protect
 - **Justice** - Fairness in distribution of burdens and benefits of research

Collaborative Institutional Training Initiative (CITI)

- Is a subscription service providing research ethics education to all members of the research community.
- Provides initial training in Human Subjects Protection, and then every 3 years you will recertify with CREC (Continuing Research Education Credits).
 - The study PI (principal investigator) must be CITI certified.
 - No one can consent subjects for research without up-to-date CITI certification.

Starting out



1. Develop a research project proposal in collaboration with your mentor and your statistician.
2. **Write it down, review it with your mentor, revise it.**
3. Go to the IRB website on UHhospitals.org
 - Research → Institutional Review Board → Policies & Procedures → [IRB Policy, Protocol Submission Requirements](#)
 - Take your written product and add the needed sections
 - Review with your mentor and statistician
4. Develop your consent document or informational sheet using the [IRB templates](#). (Studies requiring informed consent should use the expertise of a study nurse or research coordinator)
5. **FINALLY you can begin to enter the info in iRIS™.**
 - iRIS™ is the IRB's electronic submission system. More information can be found [here](#).

How long does it take?

ALLOW 2-4 months for IRB approval

- After you have completed your thinking and writing and have entered everything into iRIS:
 - Plan for 2 weeks for departmental review (you need departmental approval prior to submitting to UH IRB)
 - You may need to revise and resubmit for departmental approval
 - Plan for 6 weeks for UH IRB review (there may be pre-review stipulations prior to being on the agenda for a meeting)
- Adequate planning and preparation will facilitate a smooth IRB submission and review process.

What is the overall process? #1

- After you have worked with your mentor and statistician, and have put your study into iRIS with all of your documents, talk with your department administrator to understand your department's process for obtaining research review and approval.
- **If you need to print your application for departmental review, DO NOT HIT SEND, hit PRINT.**
- Do not submit to the IRB and for departmental review at the same time
 - The IRB will NOT review your submission without departmental approval, and will send it back to you = delay for you.

What is the overall process? #2

- Make any revisions suggested in your departmental letter.
- **If you have departmental approval:**
 - Attach the approval letter to your application in iRIS
 - Make sure your informed consent & other docs are attached.
 - Click **SEND** (after checking in w/ your mentor...)
- **If you do not yet have approval:**
 - Revise and resubmit to departmental review before submitting to the IRB!
- Always include all of your departmental correspondence in your IRB submission.
- If you are an iRIS novice and want to ensure your application has been submitted, contact the IRB Administration Office at 216-844-1529 and inquire if your submission has been submitted.

iRIS- Tips and Tricks

- Your iRIS log on is your UH login (or Case login)
- Set up Account information with your email address or you will not receive iRIS notifications from IRB about your study!
 - On left toolbar, open My Assistant, and go to My Account
- You must fill in your iRIS application completely and sequentially or it will not let you go to the next section.
- Always click the “Attach” and “Save and Continue” buttons on the top right hand corner.
- If you are stuck or lost electronically, get help!
 - Call **216-844-1529** (IRB Administration Office, staffed during normal business hours) or
 - Stop in at the Center for Clinical Research & Technology, Lakeside 1400, during **IRB Office Hours** and ask for help (you will always be helped unless everyone is busy and then you can get an appointment).

Types of Studies



- Clinical Trial
 - Requires Full IRB review and consent and assent documents
- Expedited Review
 - This is a category of review, NOT A SPEED OF REVIEW!
 - Includes chart reviews, case series (> 3 cases), questionnaire and interview studies (in person or email) that include PHI
- Exempt
 - For questionnaires not including identifying information, and for data collected without any link to subject identity
- Not Human Subjects Research
 - Submit case reports as non human subject research under this heading, otherwise less likely you will use since it applies when receiving coded/anonymous/de-identified data/samples from a repository or data base

http://free-extras.com/images/looney_tunes_road_runner-5218.htm

Other Submission types -2

Continuing Reviews (CR)

- Submit 2 months before study expiration; **you cannot conduct research if the study is expired.**
- CR is needed even if the study is closed to enrollment- it is needed for writing and data analysis.
- If you leave the institution (e.g. graduate and leave), you must identify someone who is still here as the new PI/study contact and include this info in your CR.
- **A letter of departmental approval is required before submitting to the IRB.**

Other Submission types -3

Addenda

- If you add study personnel or change your protocol or your data gathering instruments
- If the addendum DOES NOT INCREASE SUBJECT RISK, no need for departmental approval and OK to click SUMBIT
- Allow at least 2 weeks for an addendum without risk to participants changes

Completed studies

- If you have completed your study, please close it with the IRB.

iRIS™

(Electronic IRB Submission System)

Reviewing trouble spots along the way



<http://aggie-horticulture.tamu.edu>

Key Study Personnel

- **You must list everyone who will be working on the study**
 - This includes all the residents, your mentor, any other attendings, your statistician, and any ancillary persons (students for example).
- Include the human subjects protection certification (CITI) expiration date for everyone
- Note that whomever you list in section 3.0, Key Project Personnel, will have full access to the electronic study application.

How many subjects?

- Under the “**UH IRB Study Information and Personnel**” section
- The question section is called “*Study Performance Sites and Personnel*”
 - Put as many subjects/charts as you could possibly imagine in the best of worlds you would include **BECAUSE**
 - Going over your projected number is a protocol deviation that has to be reported to IRB
 - Complete the Personnel Table to list every person who is working on the study

Risks and Registering

- Under the “**UH IRB Study Information and Personnel**” section
 - The section is called “*Are subjects at more than minimal risk?*”
 - Risk that exceeds what one is exposed to in daily life
 - Chart reviews, interviews, small volume blood draws- probably not
 - Exercise programs or other interventions – probably yes
 - Drug trials – definitely!
 - This is the Clinical trials section
 - Registering on Clinicaltrials.gov
 - Any trial with intervention arms (behavior or drug or device)
 - EFFECTIVE January 1, 2015- any study with procedures being billed to medicare must have an NCT# to be reimbursed. NCT# is issued by registering on clinicaltrials.gov

Study Populations

You are “enrolling” subjects even if a chart review.

What is an adult? A person 18 years or older.

What is a minor? A person 17 years or younger.

Who is a Vulnerable population?

- Minors are a vulnerable population
- Residents/trainees/house staff/employees
 - This means your colleagues are a vulnerable population!
- Illiterate persons
- Non-English speaking persons
- Children in foster care
- Pregnant women
- Incarcerated persons



<http://www.cartoonstock.com>

Vulnerable populations- including minors

- How do I include minors in my study?
 - ***Minors cannot be approached without first obtaining their parent/guardian's permission***
 - One parent signature ok w/ minimal risk studies
 - Teens are minors!
 - Assent is needed from the minor
 - if <7 years old no written document
 - 7-13 years an assent document
 - 14-17 years often sign the adult consent document



<http://www.sfgate.com/bayarea/cityexposed/article/Medical-clowns-deliver-healthy-dose-of-laughter-2518704.php>

Vulnerable Populations: Inclusion Justification

“Discuss the special provisions...made to include...or justify exclusion...”

Including minors: (example) “Minors are included in this protocol because they are the population of interest for the research question, and the question cannot be adequately answered without relevant data from minors. The rights and welfare of these minors will be fully protected.”

Including trainees/employees: similar approach. Must state that potential subjects will be aware that “the decision to participate or not participate in this research will not impact grades, evaluations or job advancement, and that any individual results will not be viewed by supervisors.”

Vulnerable Populations: Exclusion Justification

- You cannot tell IRB it is inconvenient for you to include non-English speaking or illiterate individuals, or that you do not have time/money to call a translator.
- If you are using a questionnaire or an interview or an assessment tool that is not available in translation or is not validated in translation, this is a potential reason to exclude these populations, but you must explain.



<http://www.pietragallo.com>

Study Population

- Section – Subject Population
- Please provide bulleted inclusion/exclusion criteria:
 - Inclusion: “Minors ages 2-10 years who underwent PE tube placement at RBC between Jan 2000 and Dec 2009.”
 - Exclusion: “Surgical procedure included an adenoidectomy; subject has severe obesity as defined by BMI>95%.”
- Recruitment- you must include obtaining permission of the potential subject’s attending physician prior to approaching the subject. How will you do this?

Informed Consent

Options:

- Written informed consent- for clinical trials or interview/intervention studies
 - Waiver of written informed consent – for many questionnaire or email studies
 - Waiver of consent – for chart reviews
-
- Must use the templates- find on [IRB website](#)
 - Assent – age related requirements
 - You must write your document in 6th grade reading level.
 - Use an on line “readability grader” such as <http://www.readabilityformulas.com/free-readability-formula-tests.php>

Types of Consent Documents

	Written Informed Consent	Waiver of signed informed consent	Waiver of consent
Type of Study	Clinical trial, intervention study, interview	Questionnaire study (in person or email)	Chart review, case series
Form used	IRB template for consent documents*	Same but change research header to "Information sheet"	No document
Language level	4-6 th grade reading	4-6 th grade reading	NA
Request for consent waiver?	No	Yes	Yes
Details	Keep it short as best you can	Info sheet contains 8 elements of informed consent	Must justify all waivers

What are the 8 basic elements of informed consent?

1. Statement of research:
 - THIS IS RESEARCH, expected duration of participation/ purpose/ procedures/ what part is experimental
2. Risks
3. Benefits
4. Alternatives
5. Confidentiality
6. Compensation
7. Contact person
8. Right to withdraw / voluntary

Plan for Informed Consent

Section - Your plan for informed consent

- Please include, referring to “potential subjects”:
- Have obtained permission to approach
- Approach parent/guardian for permission prior to minor
- Will be approached in a private area
- Will receive a copy of the signed consent/info sheet
- Will have time to read/consider/involve family /ask questions
- Study team will explain study in detail
- Subjects’ wishes and time will be respected
- If decide to enroll, will receive a copy of the document

Informed Consent – Trouble Shooting



Common omissions:

- This is a research study.
- A total of 40 people are expected to be in the study.
- If you join this study you will fill out one questionnaire.
- Being in this study will take 60 minutes of your time.
- There is no direct benefit to you of being in this study.
- The alternative to being in this study is not joining it.
- There is no physical risk to joining this study. There is a small risk of loss of confidentiality of your information.

Common errors:

- Putting gift card info into benefits- goes into compensation section.
- Not including your name with direct phone contact.

http://www.housemdquotes.com/303_informed_consent.html

Vulnerable Populations: Consent Process for illiterate subjects

“We will include illiterate/seeing impaired parent(s) in the consent process for their child. In this situation, the consent form in its entirety, will be read to the parent(s). There will be time allowed for discussion and questions. The research staff will assess the understanding of the parent(s) and if adequate, and the parent(s) agree for their child to participate, the parent(s) will be asked to make their mark on the signature section of the consent document. A witness who is not a family member, a friend or a study team member will be present for this entire process.”

Vulnerable Populations: Consent Process for non-English speakers

“We will include non-English speaking parent(s) in the consent process for their child. Non-English parent(s) will be approached using a translator or member of the medical team who speaks their language and the use of translation services will be documented in the research record. Through discussion, the investigators will document the parent(s) understanding of the risks and benefits involved with participation in this research study. We will confirm the non-English speaking parent(s)’ understanding through discussion with the translator who assisted with the consent process. If any non-English speaking subject uses a short form consent document, the approved consent will then be translated in the event that another non-English speaking family may be approached for study participation. A witness who is not a family member, a friend or a study team member will be present for this entire process.”

Vulnerable Populations: Consent Process for Residents

“Trainees/students/employees that are members the subject pool may choose to not participate or to withdraw from this study without affecting their employment, their evaluations, or their class standing, and nor will their results or their decision to participate or not participate be shared with their supervisor. Consent for these potential subjects will be under direct supervision of the study investigator, and if he/she is a supervisor, then will be obtained by a neutral party who is CITI credentialed and authorized to obtain informed consent.”

Are Privacy and Confidentiality (and data security) different?

YES!

- **Privacy** is before you collect data
 - **Confidentiality** is after you collect the data (how it is handled and identified)
 - **Data security** relates to physical and electronic guarding of your data
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- These are not the same.
 - Please be aware of this when filling out the iRIS sections for privacy, confidentiality and data security.

Privacy

- Please include the following in the relevant iRIS section:
 - Obtain permission from potential participant's attending physician BEFORE approaching for study
 - Discuss the study with consent process in a private location such as a patient room
 - Maintain all study data in research files rather than in the clinical record
 - No discussion of study data in clinical areas

Confidentiality

- Examples of how you will describe efforts to keep the data you collect confidential
 - Protect the confidentiality of the subjects by using a linking log- so each subject has a study number
 - Where is the log kept and who has access
 - The log and the study data by study number are in separate locations
 - Collect only that PHI which is necessary for answering the research question(s)
 - Protect confidentiality by using only de-identified information

Data Security

The iRIS section needs to explain how the data is “physically” protected, with details.

- **Paper files**

- Locked file in whose office (name) in which room (room number) in which building, and only [study team] has access

- **Electronic files**

- Password protected computer belonging to [who] kept [where-
whose office, which room #, which building]
- Encrypted computer/iron key jump drive if PHI
- [REDCap](#) data system for data storage a great option
- Who has access to the electronic files



Trouble shooting

Chart reviews, waivers, and other friends



Trouble-shooting paper-jams

<http://blogs.uct.ac.za/blog/call-me-cassandra/page/5>

Chart Review

- You are “enrolling” subjects for a chart review project, the consent process will be modified.
- You must specify:
 - The dates of your review & number of charts you expect to review
 - The inclusion/exclusion criteria for your review
 - How you will identify charts /who will access charts/ who will collect the data
 - Which EMR you will use
 - Whose practice/whose charts you are reviewing
 - List of the specific data that you will need
- You will request a waiver of Consent and HIPPA
 - Justification example: Waiver does not adversely affect the rights and welfare of the subjects because the main risk of the study is the risk of loss of confidentiality and we will carefully protect the information and PHI as described below. Most subjects are not available due to no forwarding information or having moved. Subjects’ medical care is complete and no further options or interventions are offered in the research so contacting subjects provides no benefit.

Waivers

- A waiver may be granted if all of the following are met:
 - The research involves no more than minimal risk to the participants;
 - The waiver or alteration will not adversely affect the rights and welfare of the participants;
 - The research could not practicably be carried out without the waiver or alteration;
 - Whenever appropriate, the participants will be provided with additional pertinent information after participation; and
 - The research is not subject to FDA regulation.
- Waivers have to do with PARTICIPANTS not with PI convenience!

Professionalism

“A Scholar” by Rembrandt



From: <http://blog.emergingscholars.org>

Professionalism- how does this apply?

- Your mentor(s) needs to be in the loop
- **This means you will** collaborate, discuss and formally **have his or her approval:**
 - To submit your proposal for departmental approval
 - To then submit your proposal to the UH IRB
- Mentor(s) may not only WANT to be engaged, but must be engaged.
- It would be a professional lapse to have a person's name on a written document without full access and full approval.

And that's not quite all...

- Your mentor also must work with you on all “post IRB approval” aspects of your project!
- This is also a professionalism issue.
- Your mentor must:
 - Review your data and its interpretation with you
 - See and approve your abstract prior to submission
 - See and approve your powerpoint prior to submission
- Academic collaboration is wonderful and powerful- make sure you allow the TIME for your mentor to review and collaborate with you.

Help is a phone call away

- Keep circling back to your mentor
- Make use of the [IRB website](#), especially the “[Forms & Templates](#),” and “[Policies & Procedures](#)” sections.
- You can always consult the [IRB Administration Office](#) staff at (216-844-1529).
- Your project is about the process as much as the result, and working with the IRB is part of the process.

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