IRB Submissions 101

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UC Irvine Urology

Steps for planning a study

1. Determine whether IRB review is required
2. Complete CITI Tutorials
3. Determine study risk level and level of IRB review
4. Timelines
5. Ancillary committees
6. IRB Application package
7. IRB Application submission tips – common errors
8. IRB review process (FC & Expedited - charts)
9. After IRB Approval - Researcher responsibilities
10. Research Roadmap
11. New Submitter's training video
12. Helpful Tips/Guidance

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Determine Whether IRB Review is Required

RESEARCH

Systematic investigation and designed to develop or **contribute to generalizable knowledge**

+

HUMAN SUBJECT

Research **about a living individual** either through **intervention/interaction** or **identifiable private information**

IRB REVIEW IS REQUIRED

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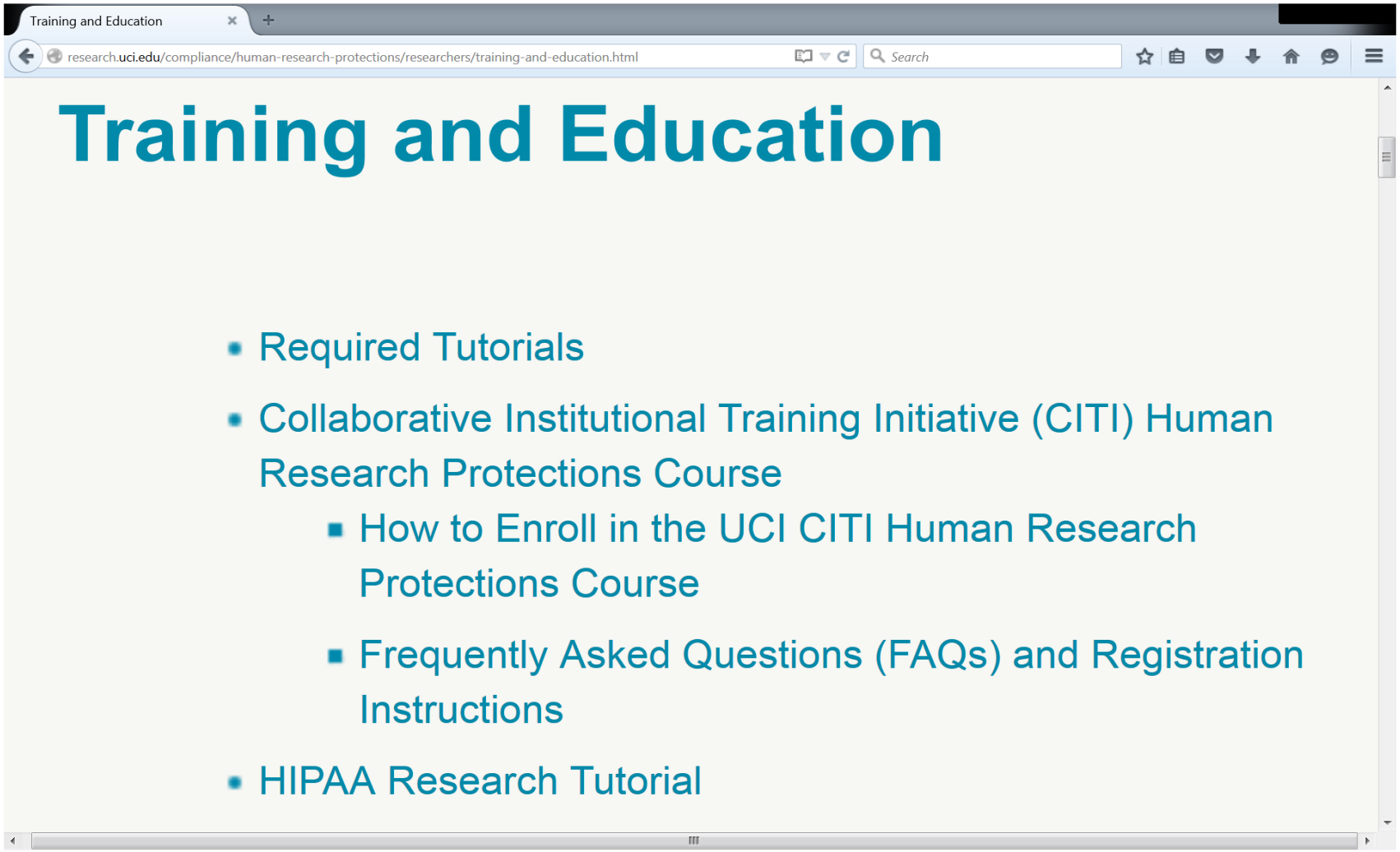
http://www.research.uci.edu/compliance/human-research-protections/researchers/activities-irb-review.html

Complete CITI and HIPAA Training



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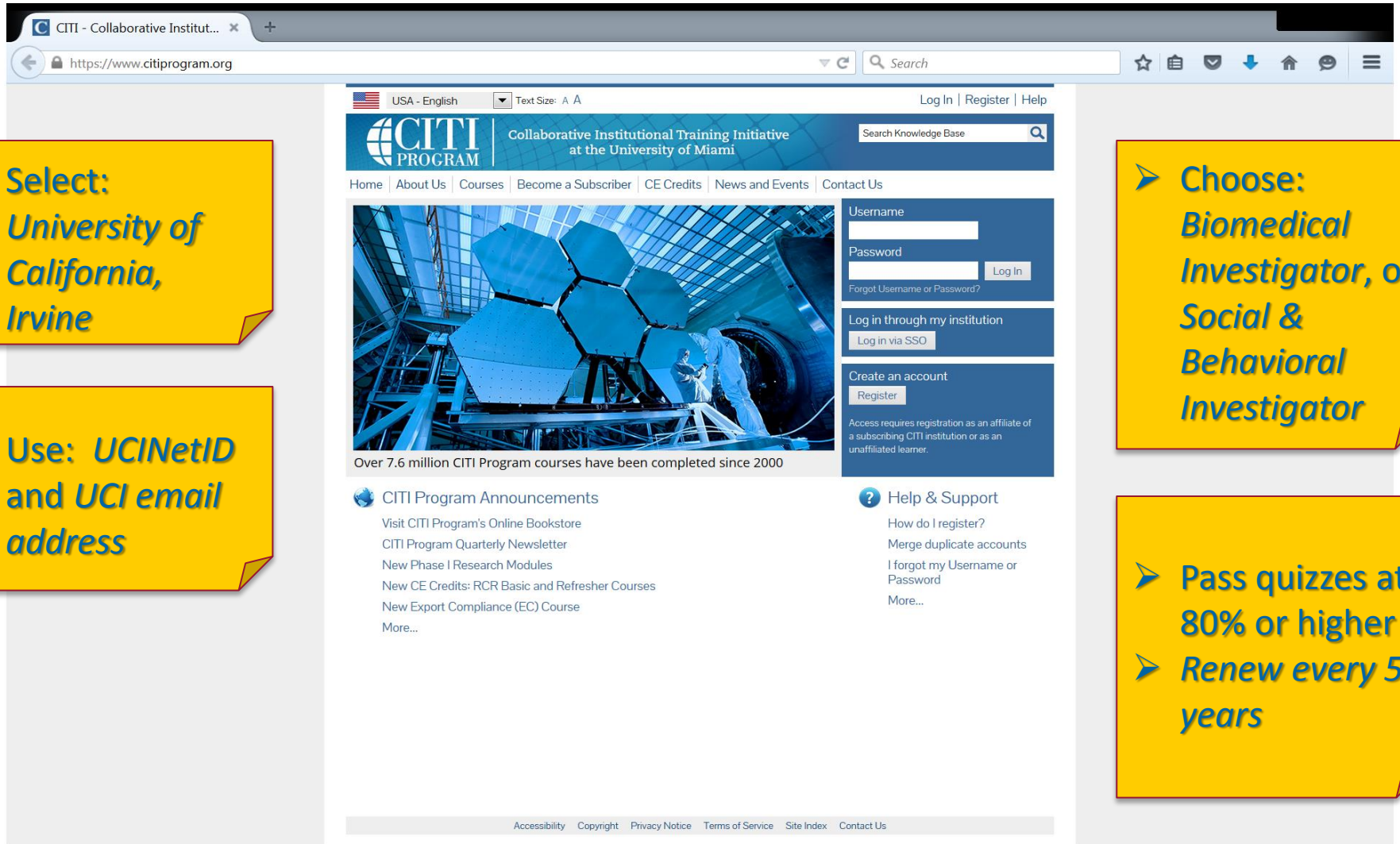
http://research.uci.edu/compliance/human-research-protections/researchers/training-and-education.html

CITI Training

- Select: *University of California, Irvine*
- Use: *UCINetID* and *UCI email address*



- Choose: *Biomedical Investigator*, or *Social & Behavioral Investigator*
- Pass quizzes at 80% or higher
- *Renew every 5 years*

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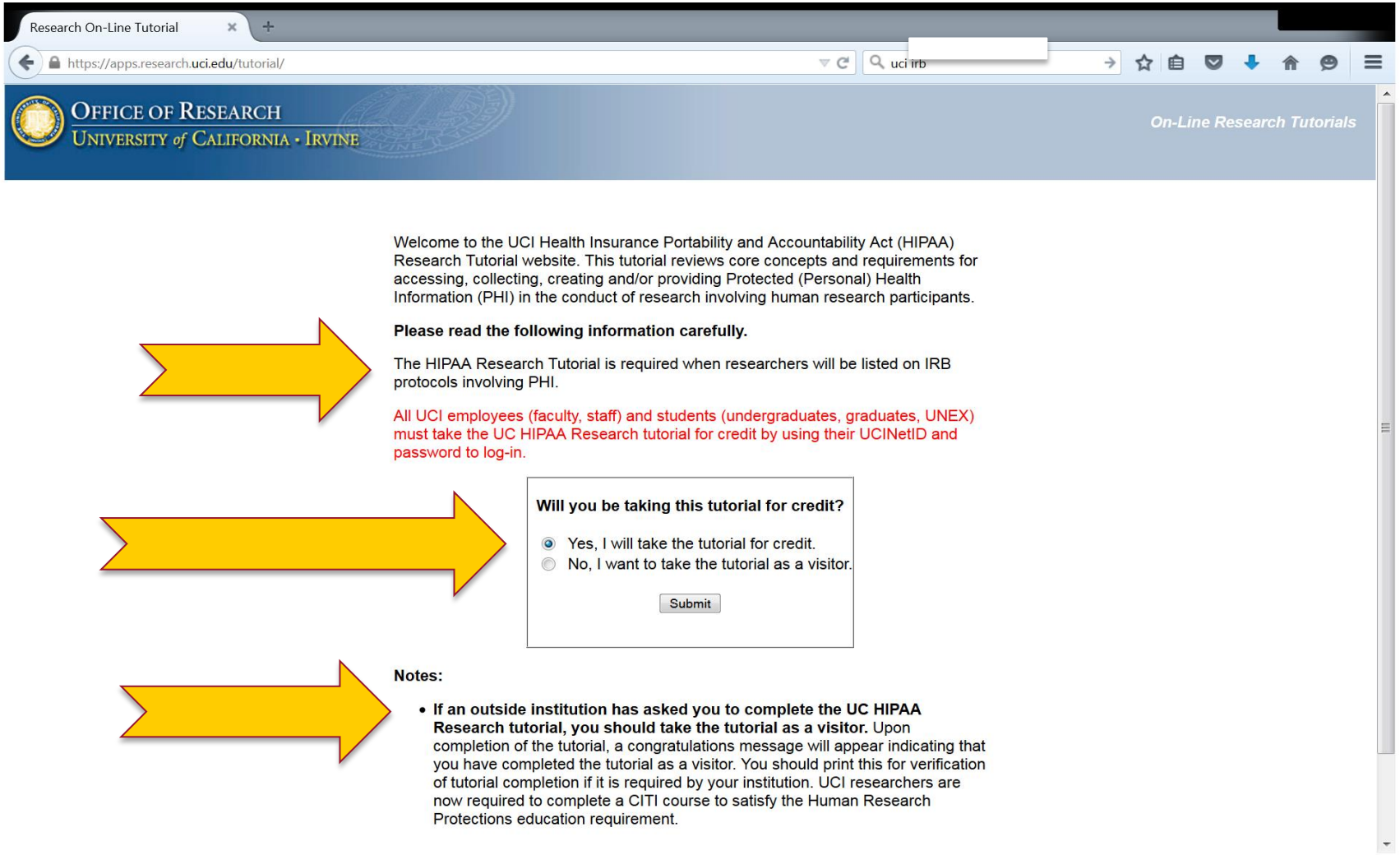
https://www.citiprogram.org

HIPAA Training



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https://apps.research.uci.edu/tutorial/

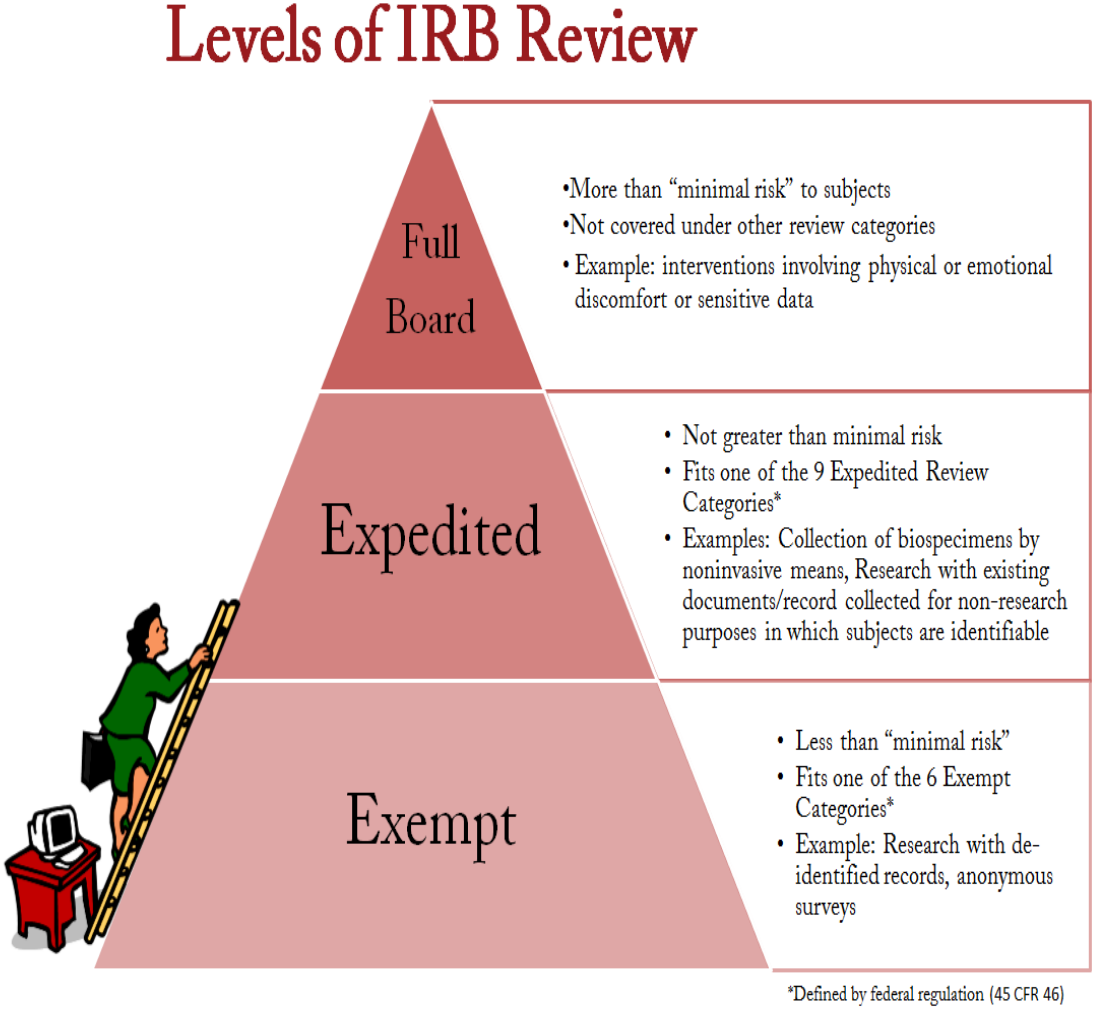
Determine Study Risk Level and Level of IRB Review

DEFINITION OF MINIMAL RISK

…the probability and magnitude of harm or discomfort…are not greater…than those ordinarily encountered in daily life* or during the performance of routine physical or psychological examinations or tests

** in the general population*

45 CFR 46.102(i)



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http://www.research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html

Timelines

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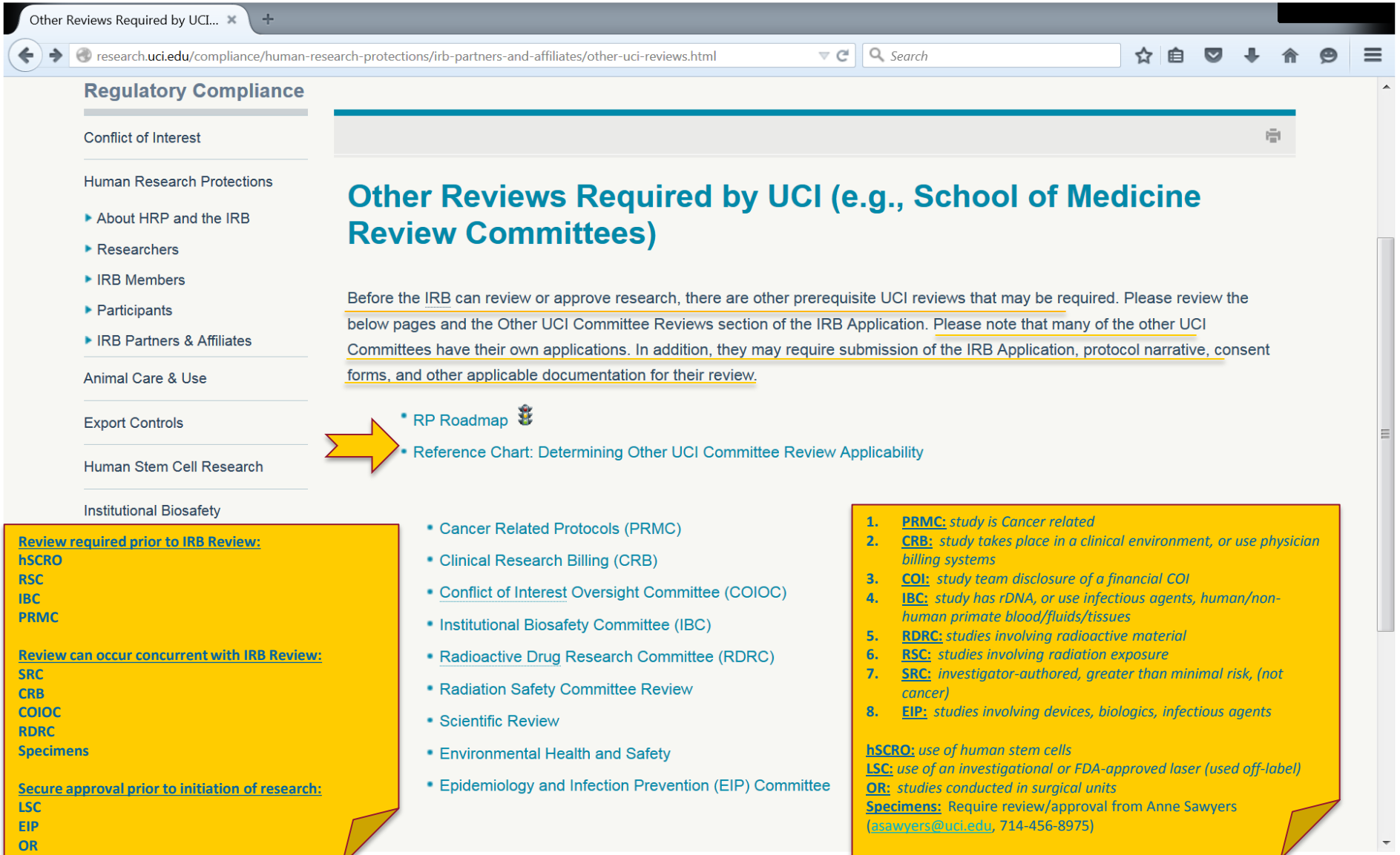
http://www.research.uci.edu/compliance/human-research-protections/docs/2014-irb-meetings-and-deadlines.pdf

Reviews from Ancillary Committees



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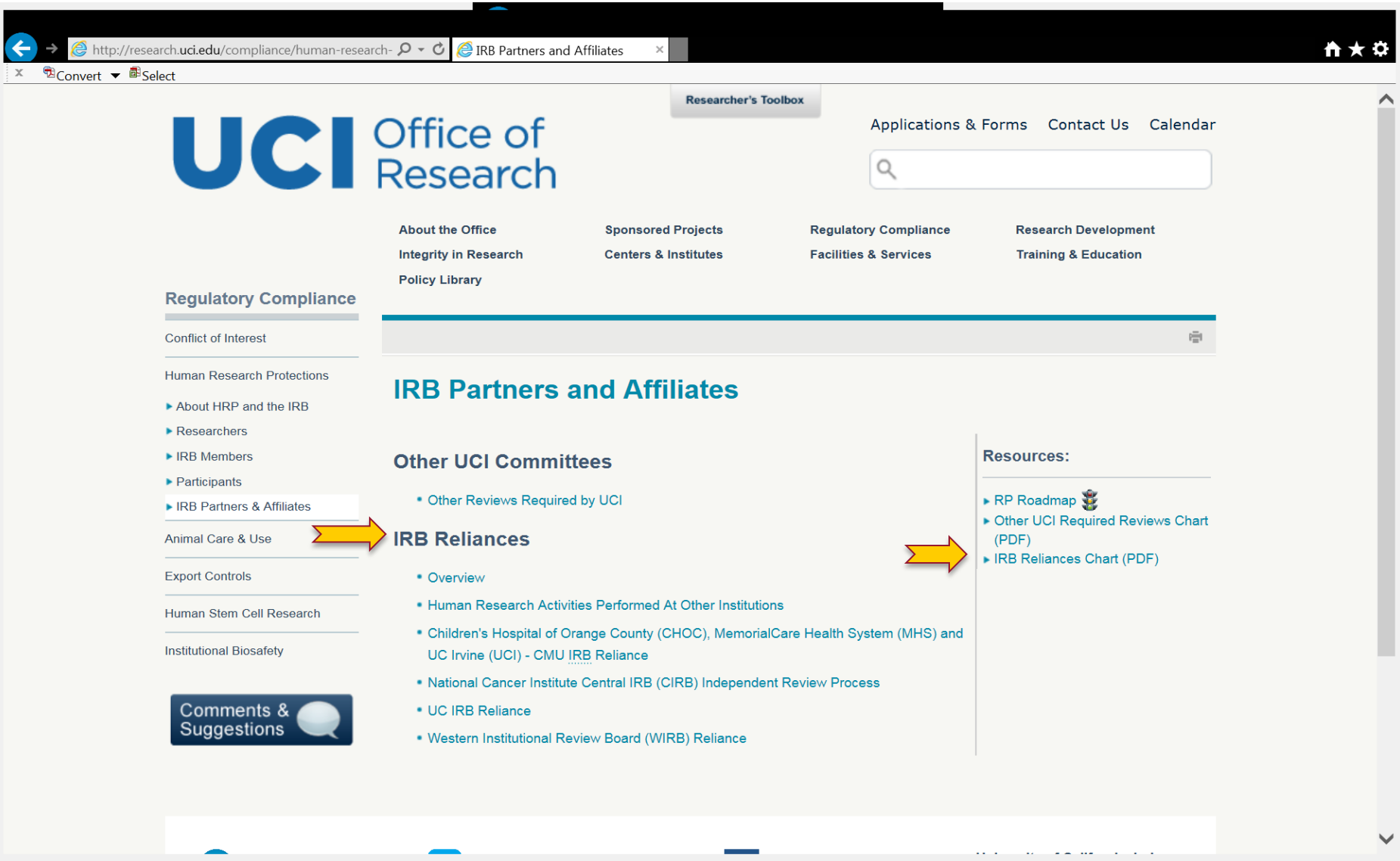
http://research.uci.edu/compliance/human-research-protections/irb-partners-and-affiliates/other-uci-reviews.html

IRB Reliances



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http://research.uci.edu/compliance/human-research-protections/irb-partners-and-affiliates/index.html

IRB Application Package

- ✓ *CITI TRAINING (staff engaged in research)**
- ✓ *IRB APPLICATION (signed)***
- ✓ *PROTOCOL NARRATIVE*
  - ❑ *Choose: Biomed, or SBE, or Exempt*

When applicable:

- ❑ *Consent Forms: Assent, Minors, Verbal, Debriefing, HUD, Biomed, SBE, Human Stem Cell, Translated, Surrogate, Informant, Pregnant Partner*
- ❑ *HIPAA Authorization*
- ❑ *Recruitment Material*
- ❑ *Etc.*

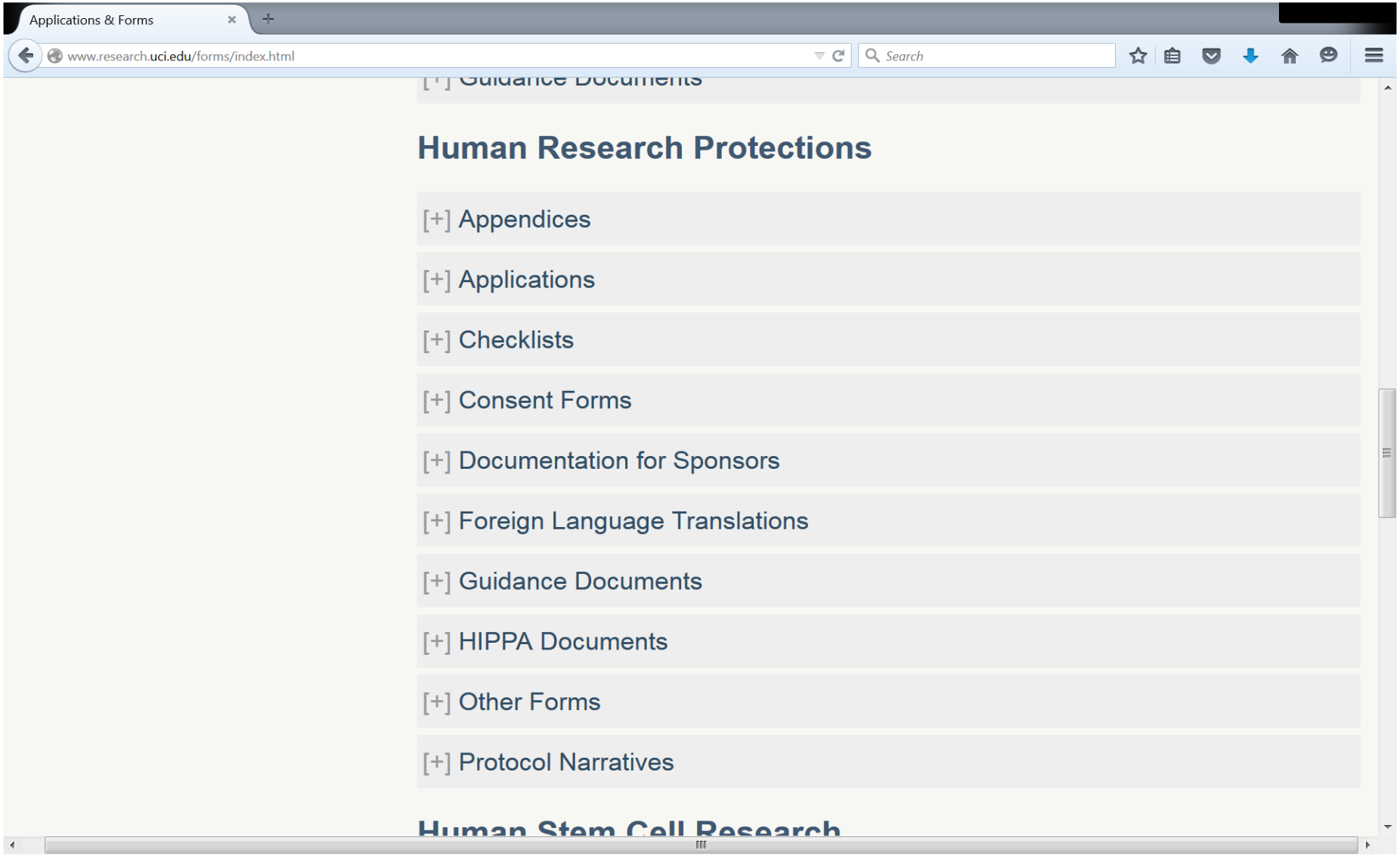
SUPPORTING DOCUMENTS

When applicable:

- ❑ *Appendices*
- ❑ *Sponsor / FDA*
- ❑ *Letter of Permission*
- ❑ *Certificate of Confidentiality*
- ❑ *Release Form*
- ❑ *DOD Supplement*
- ❑ *Decisional Capacity*
- ❑ *Etc.*

http://www.research.uci.edu/compliance/human-research-protections/researchers/protocol-preparation-checklist.html

Application & Forms



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http://www.research.uci.edu/forms/index.html

Application & Forms

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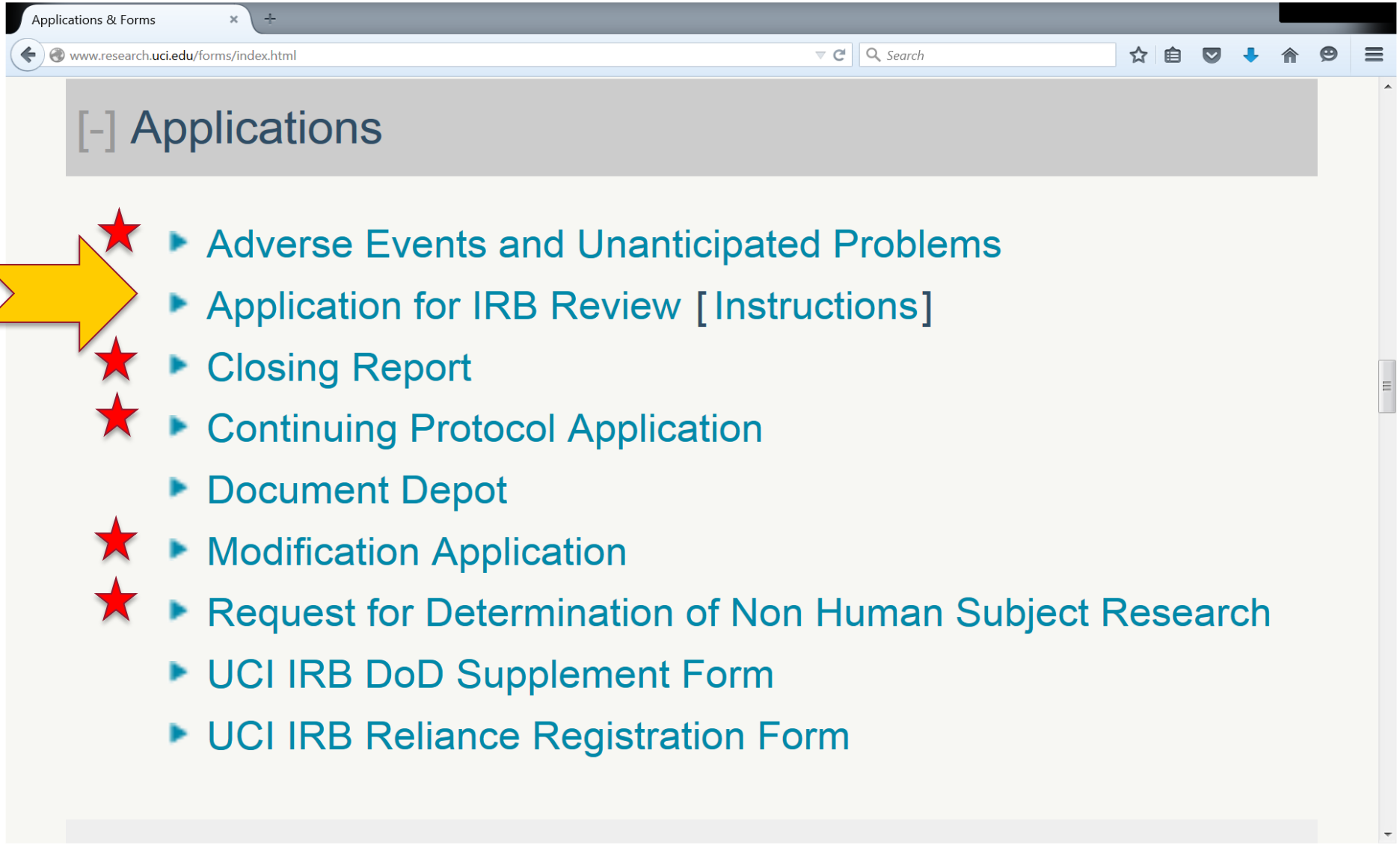
Application & Forms



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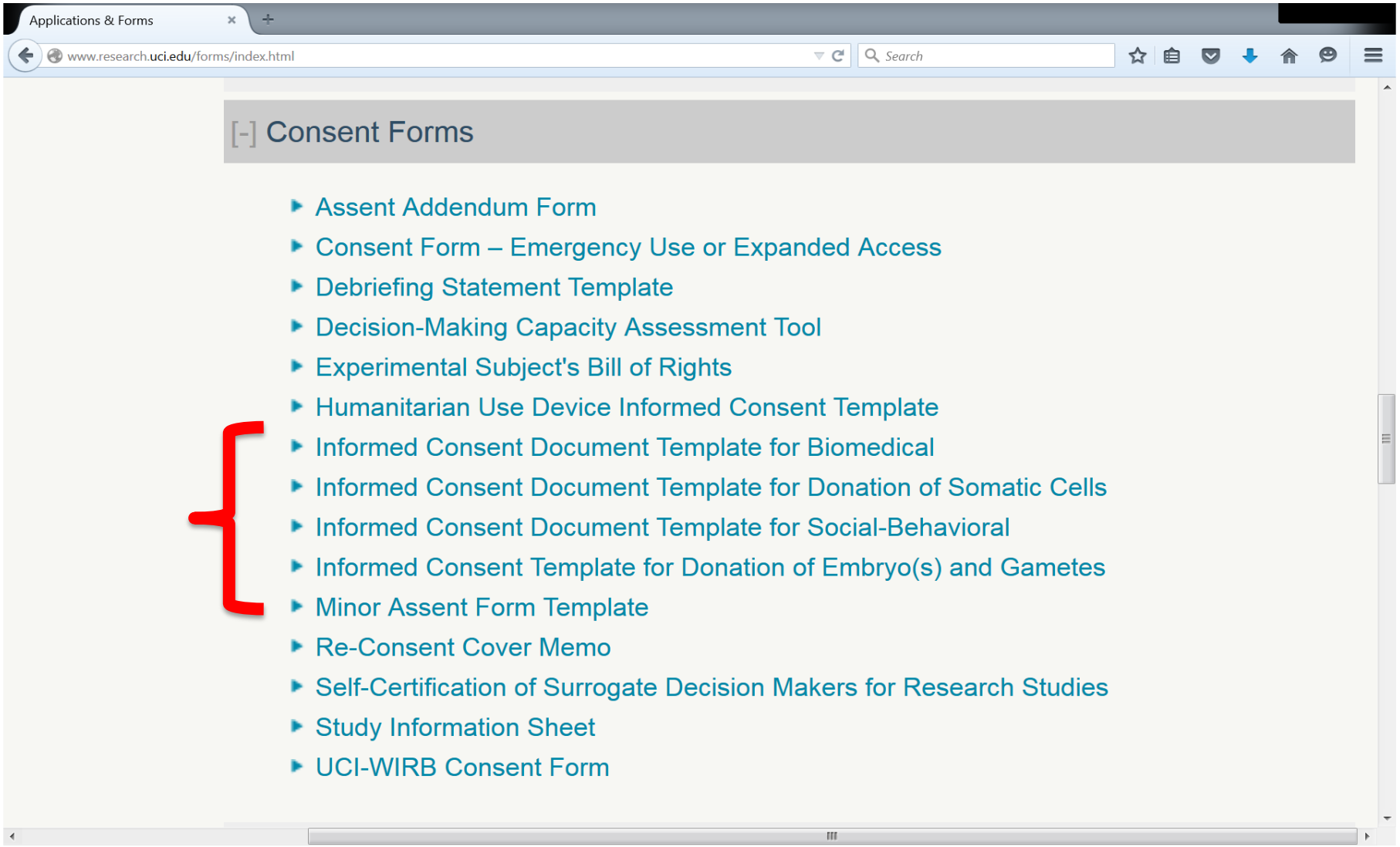
http://www.research.uci.edu/forms/index.html

Application & Forms



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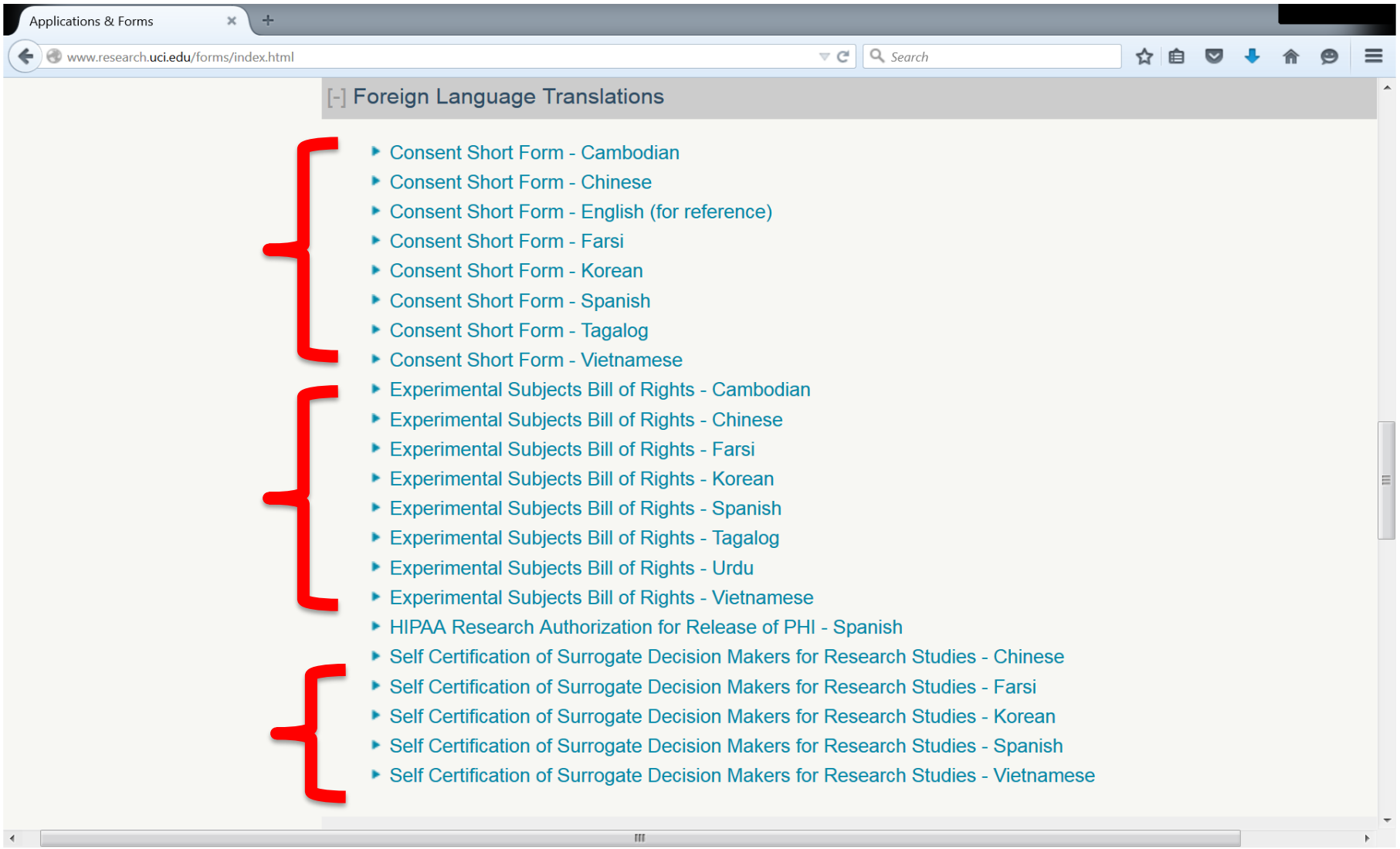
http://www.research.uci.edu/forms/index.html

Application & Forms



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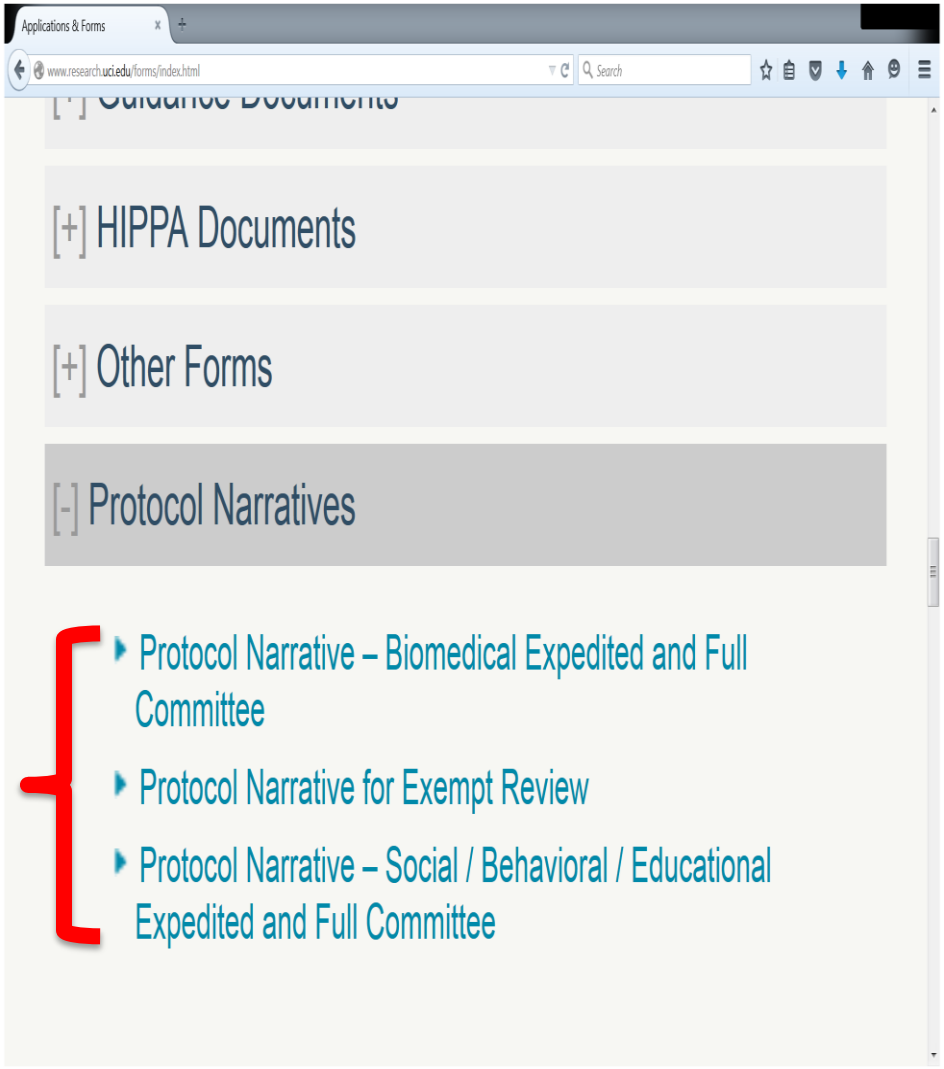
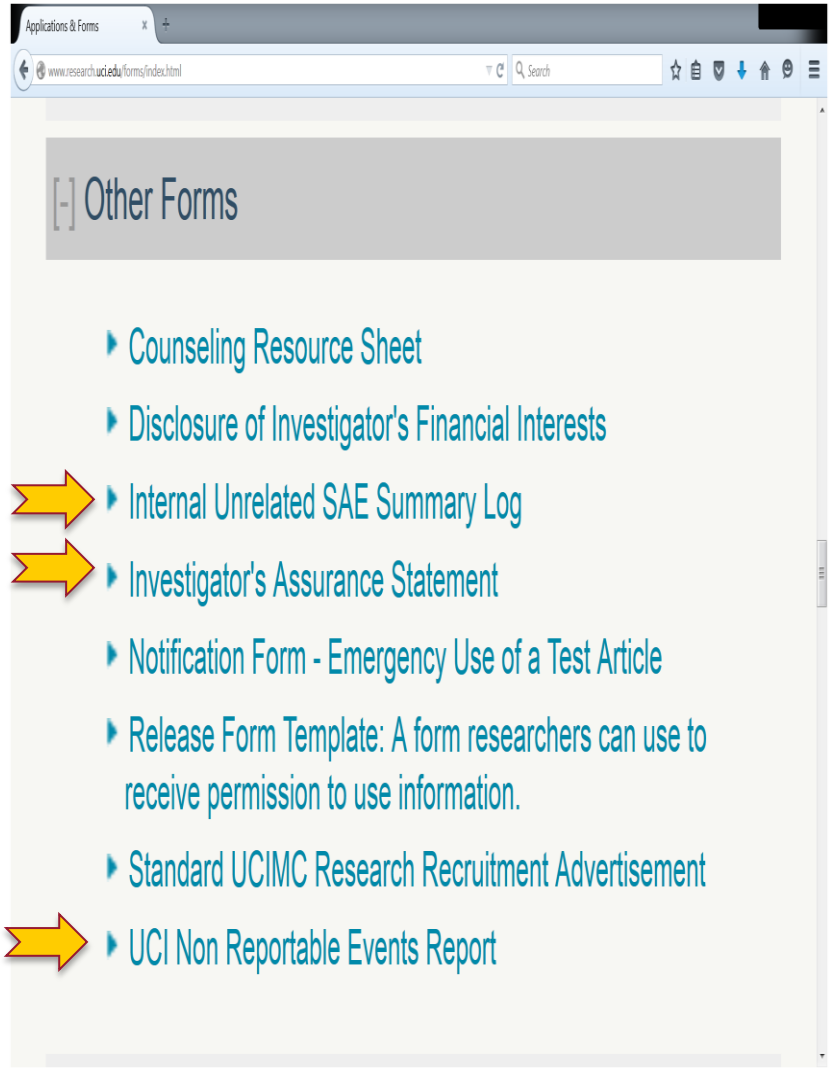
http://www.research.uci.edu/forms/index.html

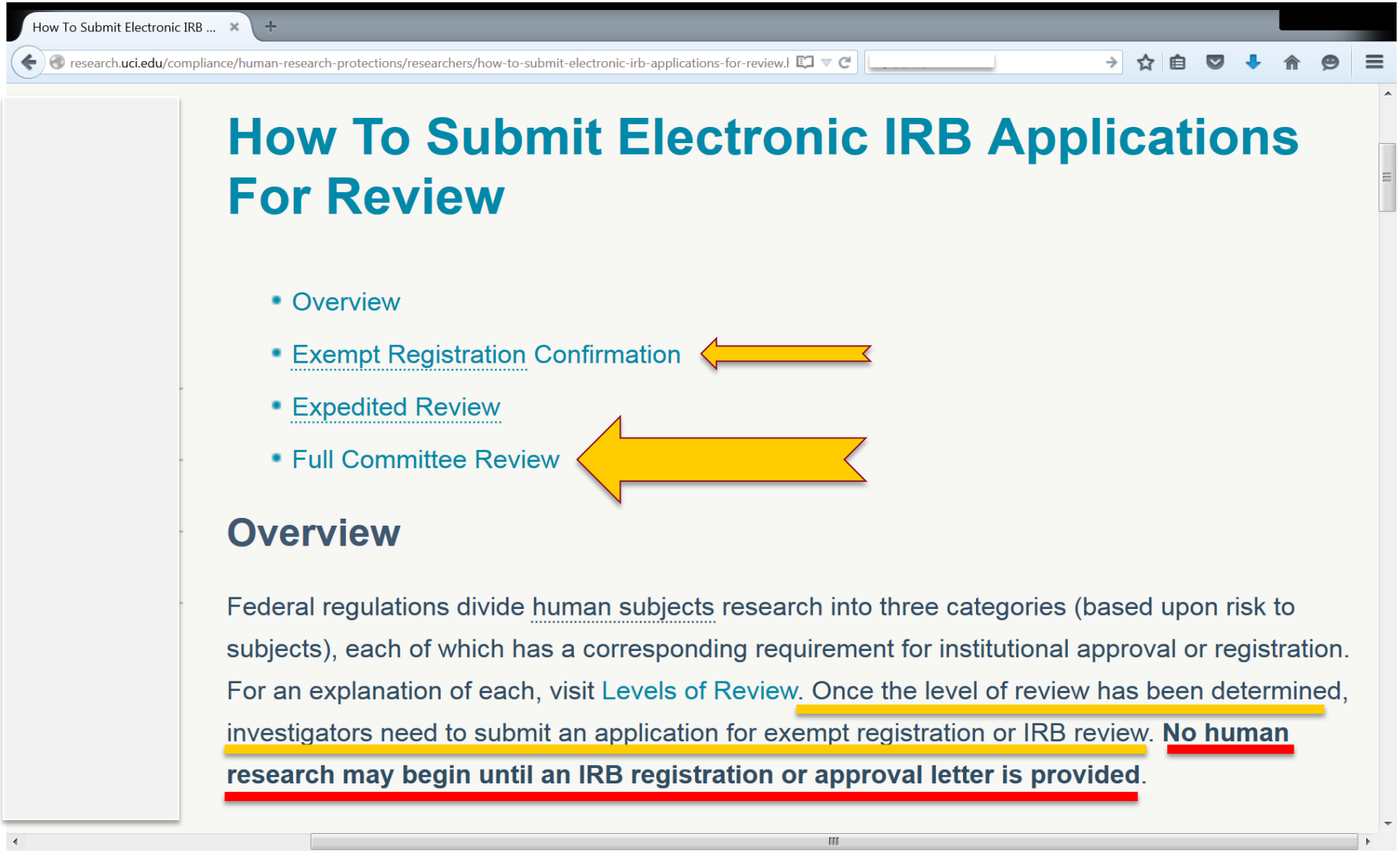
Applications & Forms





http://www.research.uci.edu/forms/index.html

Electronic IRB Application



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http://research.uci.edu/compliance/human-research-protections/researchers/how-to-submit-electronic-irb-applications-for-review.html

IRB Application Submission Tips

COMMON ERRORS:

- ***There is inconsistency between study documents***
- ***Ancillary Committee requirements are not addressed***
- ***Research staff have not completed the CITI training***
- ***Off-site IRB approval are not provided (where applicable)***
- ***Applicable appendices are not provided***
- ***Protocol Narrative: instructions located in grey box are not addressed***
- ***Consent Form: (applicable) instructions in red text are not addressed***
- ***Recruitment materials: materials are not submitted***

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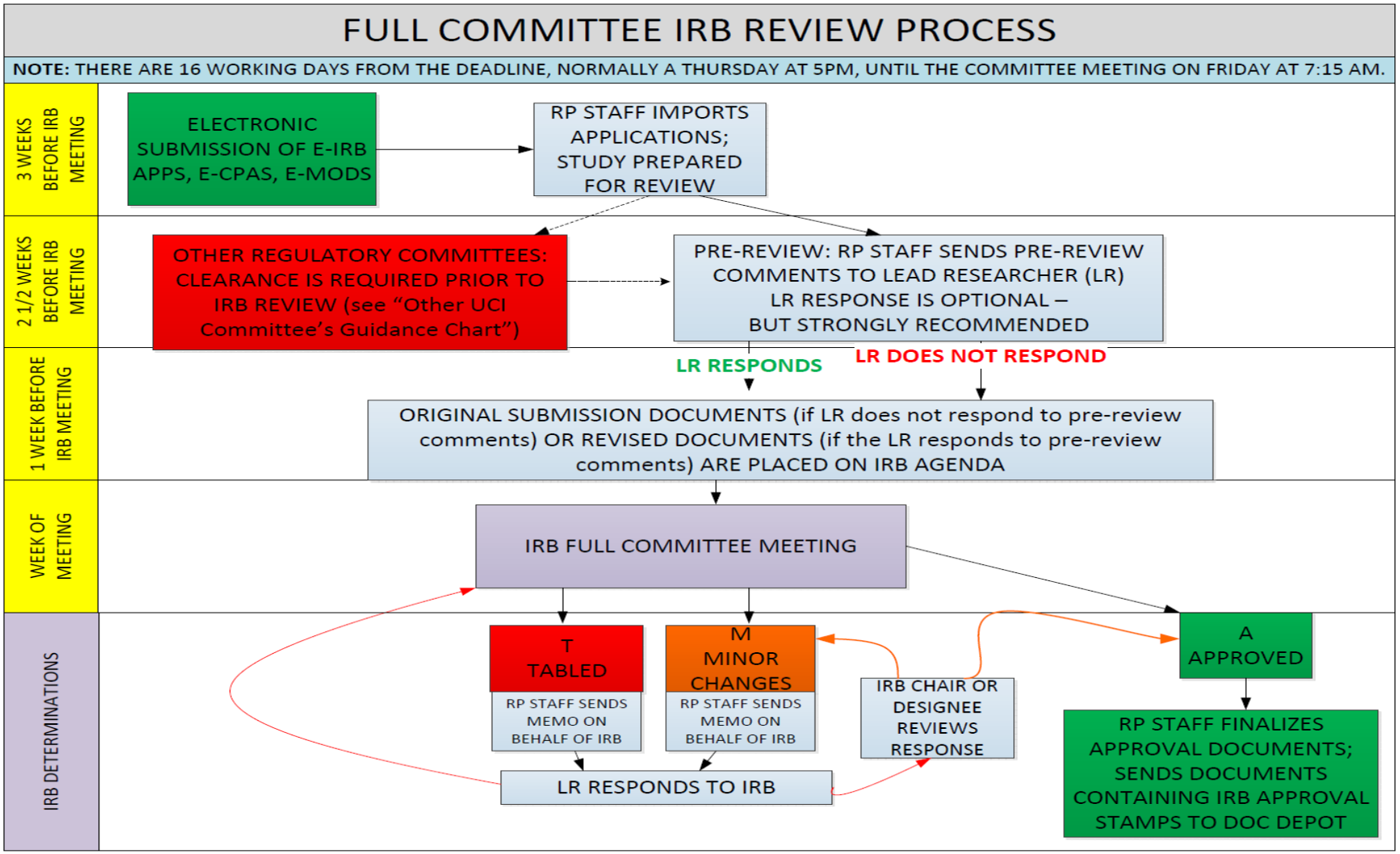
http://www.research.uci.edu/compliance/human-research-protections/researchers/common-irb-submission-errors.html

IRB Review Process



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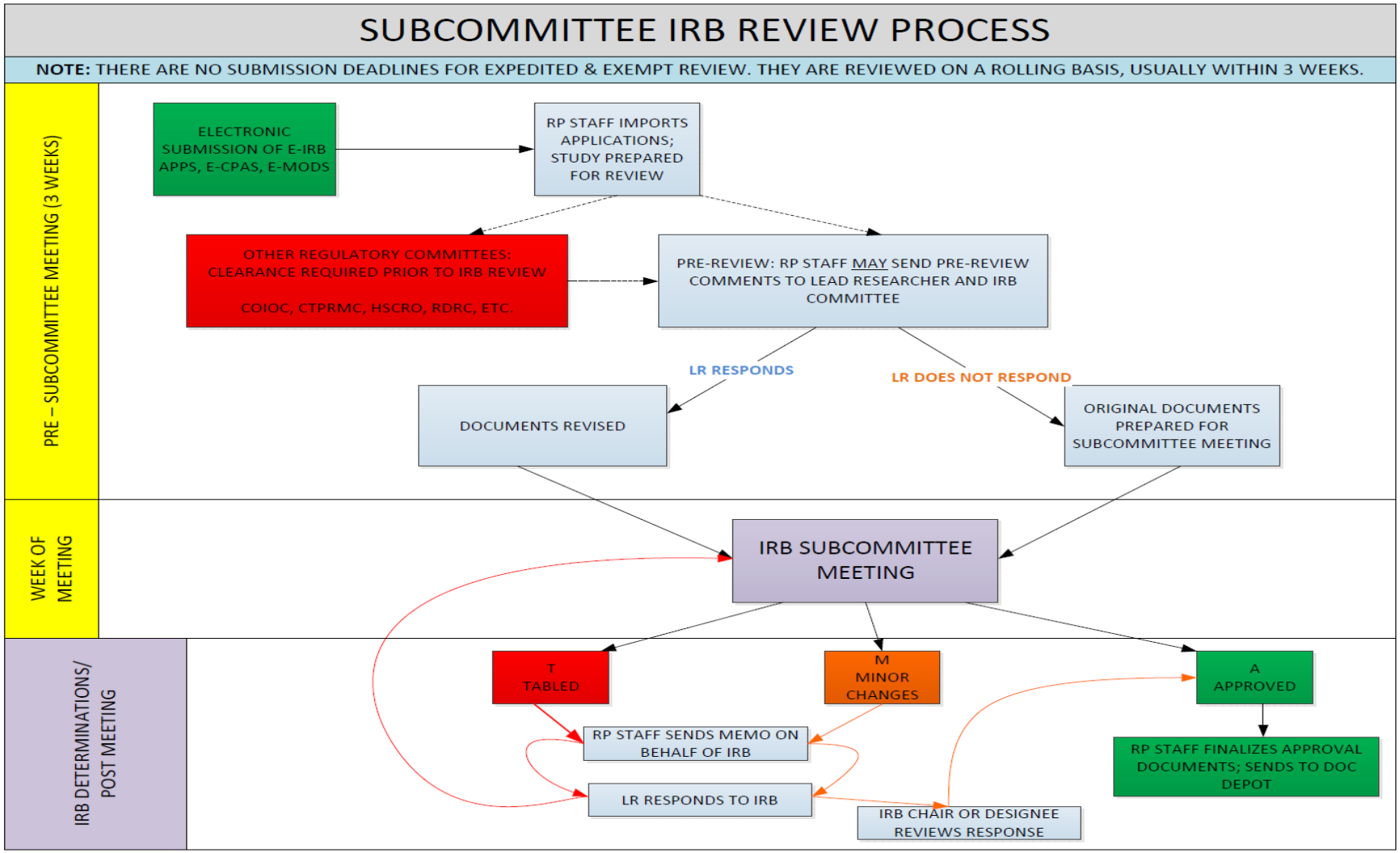
IRB Review Process



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After IRB Approval – Research Responsibilities

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http://www.research.uci.edu/compliance/human-research-protections/researchers/index.html

Lead Researcher Recordkeeping Responsibilities

Records to keep when a study is approved by the IRB

- ❑ Approved/Stamped **Protocol Narrative** (electronic and/or paper copy)
- ❑ Approved/Stamped **Consent Form**
- ❑ Approved **Modifcation Submissions**
- ❑ Approved **Continuing Protocol Submissions**

**** Maintain in a regulatory binder, and according to the privacy and confidentiality and data security plan (per protocol narrative)***

Records Retention Requirements

- ❑ Retain all study records for a **minimum of three years** past the close of the study - approved IRB documents, as well as case-report forms, tapes or transcripts, and all other data-collection instruments and source documents
- ❑ UC General Counsel recommends longer retention periods for certain research records:
  - Records involving the generation, disclosure, and/or use of Protected Health Information **(PHI)** should be retained for **six years**
  - **Minors** in research: records retained for **seven years after all minors enrolled in the study reach the age of majority [age 18 in California]**
  - Records pertaining to **in vitro fertilization studies or** research involving **pregnant women** must be retained **25 years after study closure**
- ❑ In the case **of FDA-regulated studies**, investigators are required by regulation to retain records for periods which may be significantly longer than six years after study closure of the IRB protocol at UCI.
  - For **drugs with an approved marketing application**, the **retention period is two years after FDA approval**
  - For **drugs where the marketing application is not filed/not approved**, the **retention period is two years after the investigation is discontinued and FDA is notified**
  - ***Contractual obligations may require records to be maintained per the agreement with the trial sponsor***

Suggested templates for record-keeping documenetation

- ❑ NIH: http://www.nidcr.nih.gov/research/toolkit/#startup5
- ❑ UCSF: http://hub.ucsf.edu/virtual-regulatory-binder

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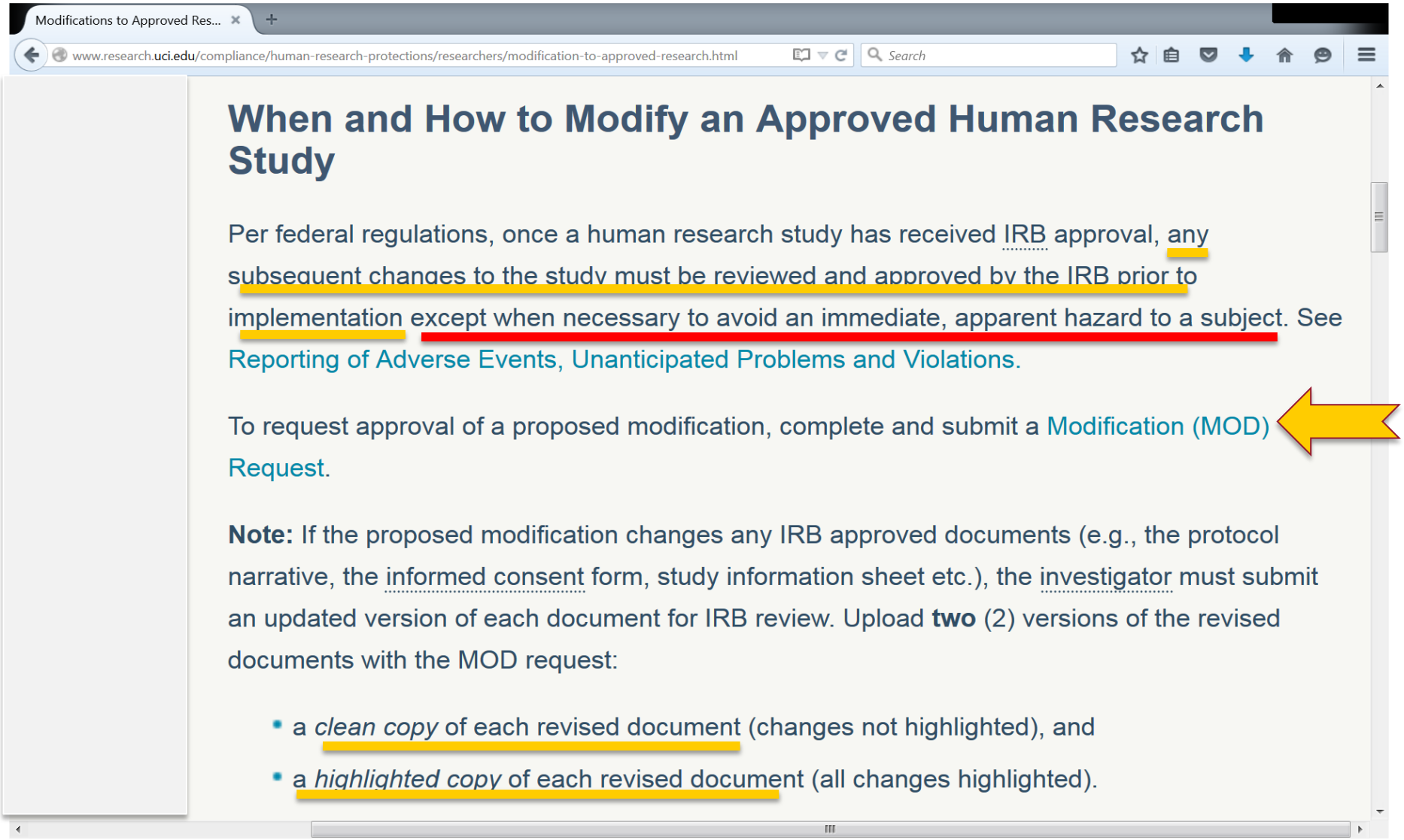
http://www.research.uci.edu/compliance/human-research-protections/researchers/lead-researcher-recordkeeping-responsibilities.html

Modifications to an approved protocol



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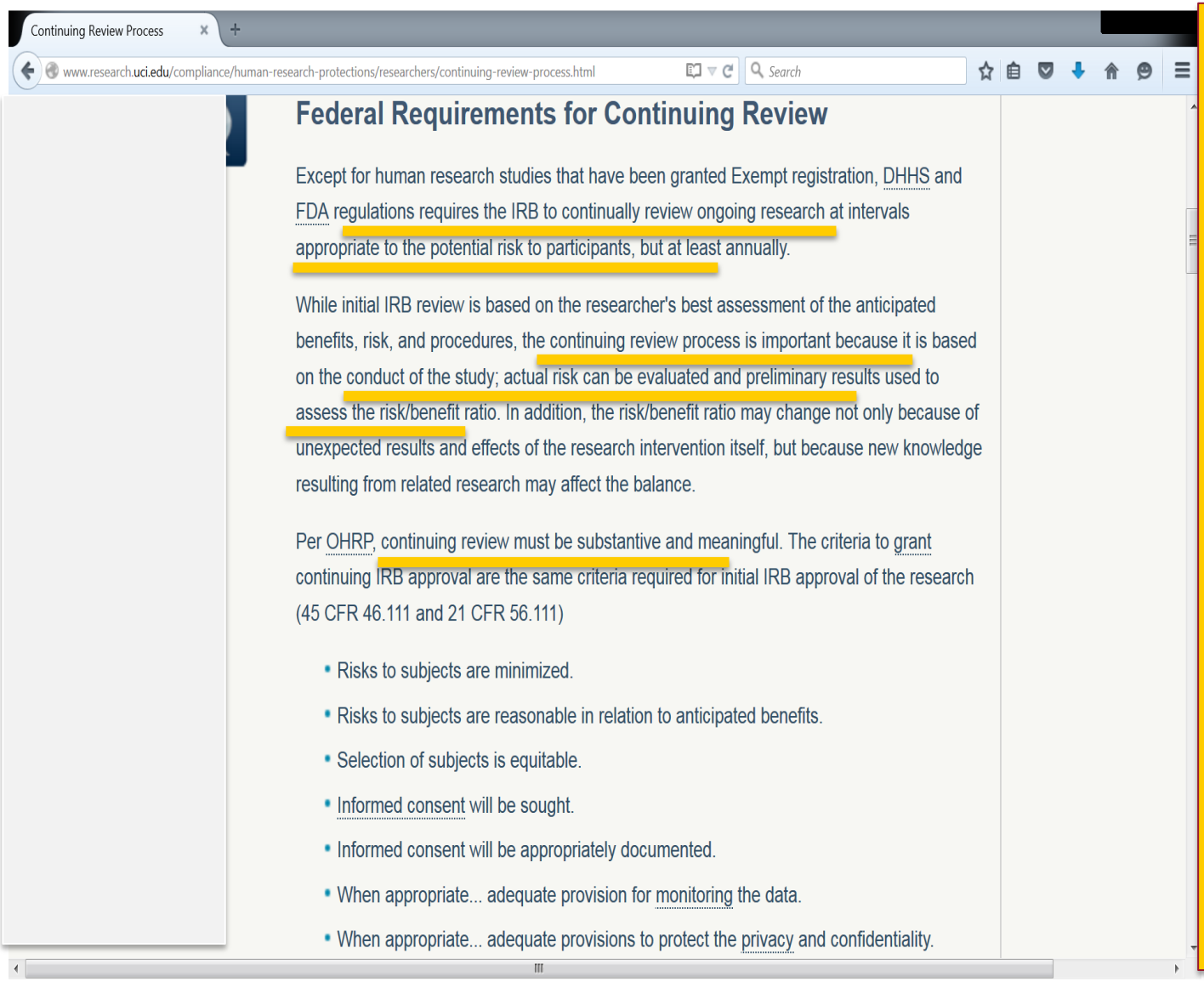
http://www.research.uci.edu/compliance/human-research-protections/researchers/modification-to-approved-research.html

Continuing Review Process



Include the following information:

- ❑ # participants enrolled
- ❑ Summary of AEs/UPs
- ❑ # participants withdrawn + rationale
- ❑ Summary of complaints
- ❑ Summary of relevant recent literature, interim findings, and modifications since last review
- ❑ Current risk/benefit assessment based on existing study results
- ❑ Other relevant information (risks associated with the research)
- ❑ Copy of current consent form

Expedited Studies may qualify for an Extended IRB Approval period (continuing review every 3 years), when these conditions are met:

- ✓ Research is permanently closed to enrollment of new subjects
- ✓ All subjects completed research-related interventions
- ✓ Active only for long-term follow-up of subjects
- ✓ Remaining research activities limited to data analysis

In order to ensure that research protocols continue to meet current regulatory and institutional standards, every seven years, protocols will be required to undergo a **"Seven-Year De Novo Review."**

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http://www.research.uci.edu/compliance/human-research-protections/researchers/continuing-review-process.html

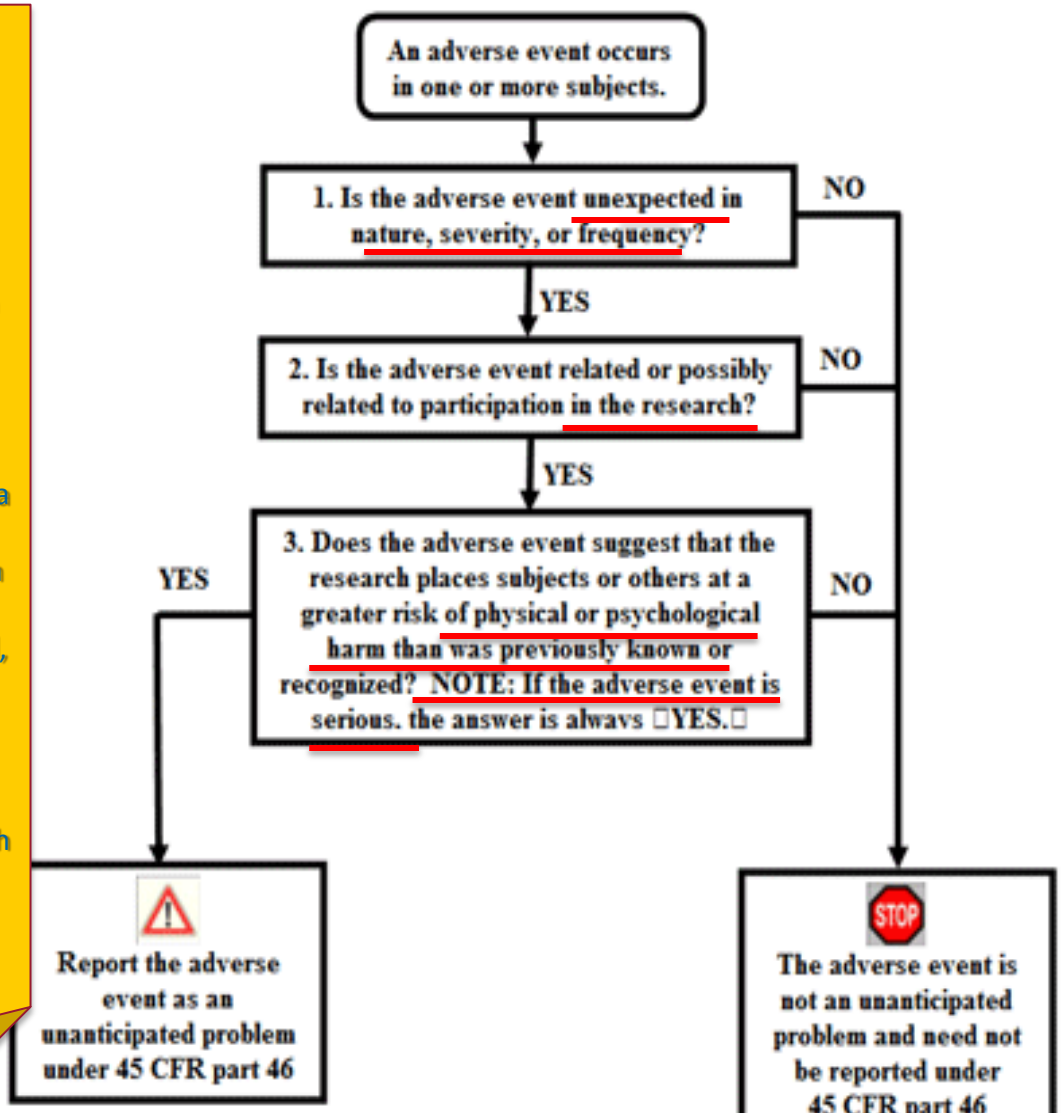
Adverse Events, Unanticipated Problems, Protocol Violations

Adverse Event
untoward or undesirable experiences associated with research

Unanticipated Problems Involving Risk to Participants or Others
any event, experience, or problem that is: **(1)** unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the IRB-approved documents, such as the protocol and informed consent document, and (b) the characteristics of the subject population being studied; **(2)** related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or problem may have been caused by the procedures involved in the research); and **(3)** suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

Protocol Violation
accidental or unintentional change to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data

* If an event does not meet this 3-criteria threshold, it can be reported at the time of continuing review



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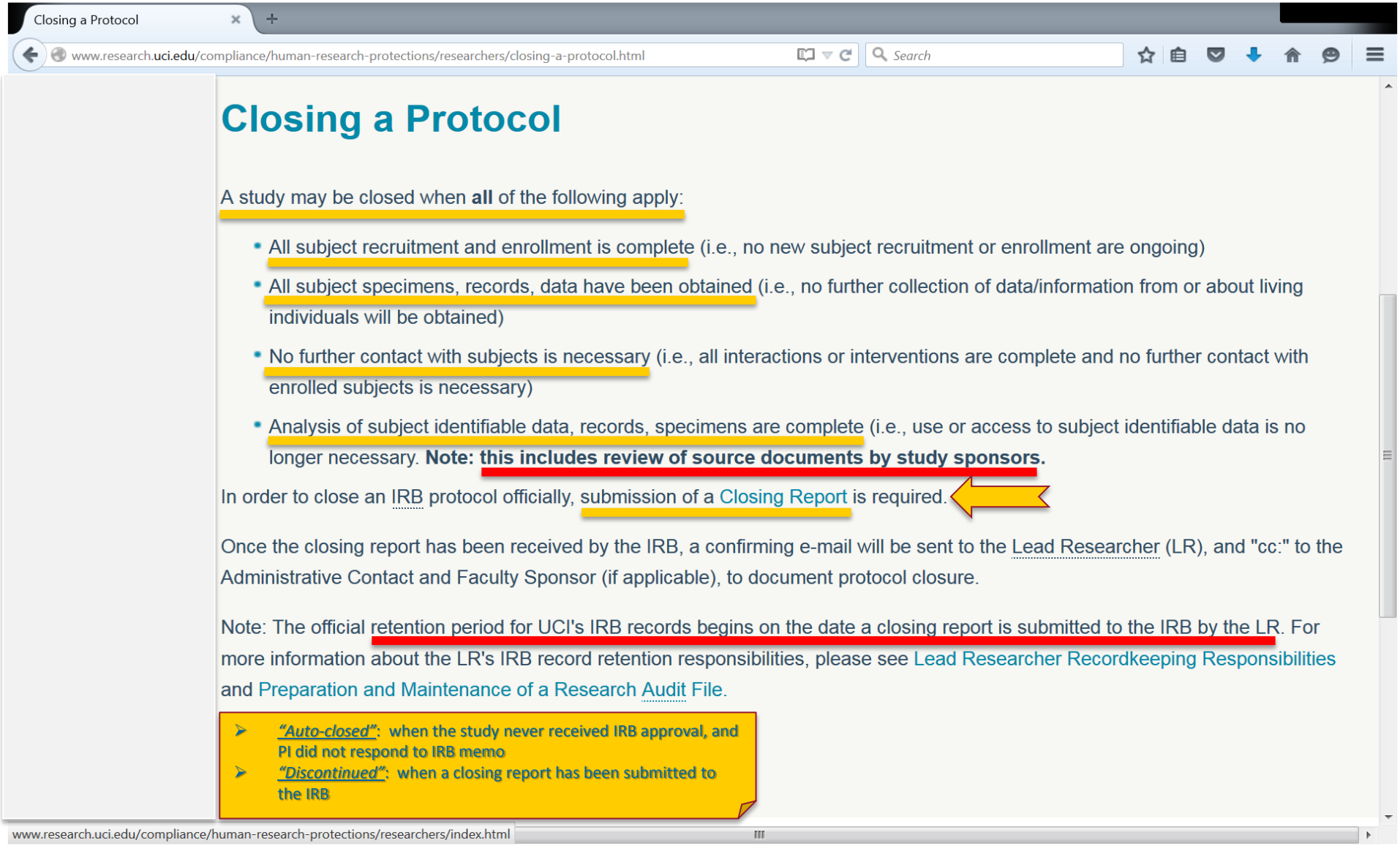
http://www.research.uci.edu/compliance/human-research-protections/researchers/reporting-of-adverse-events-unanticipated-problems-and-violations.html

Closing a Protocol



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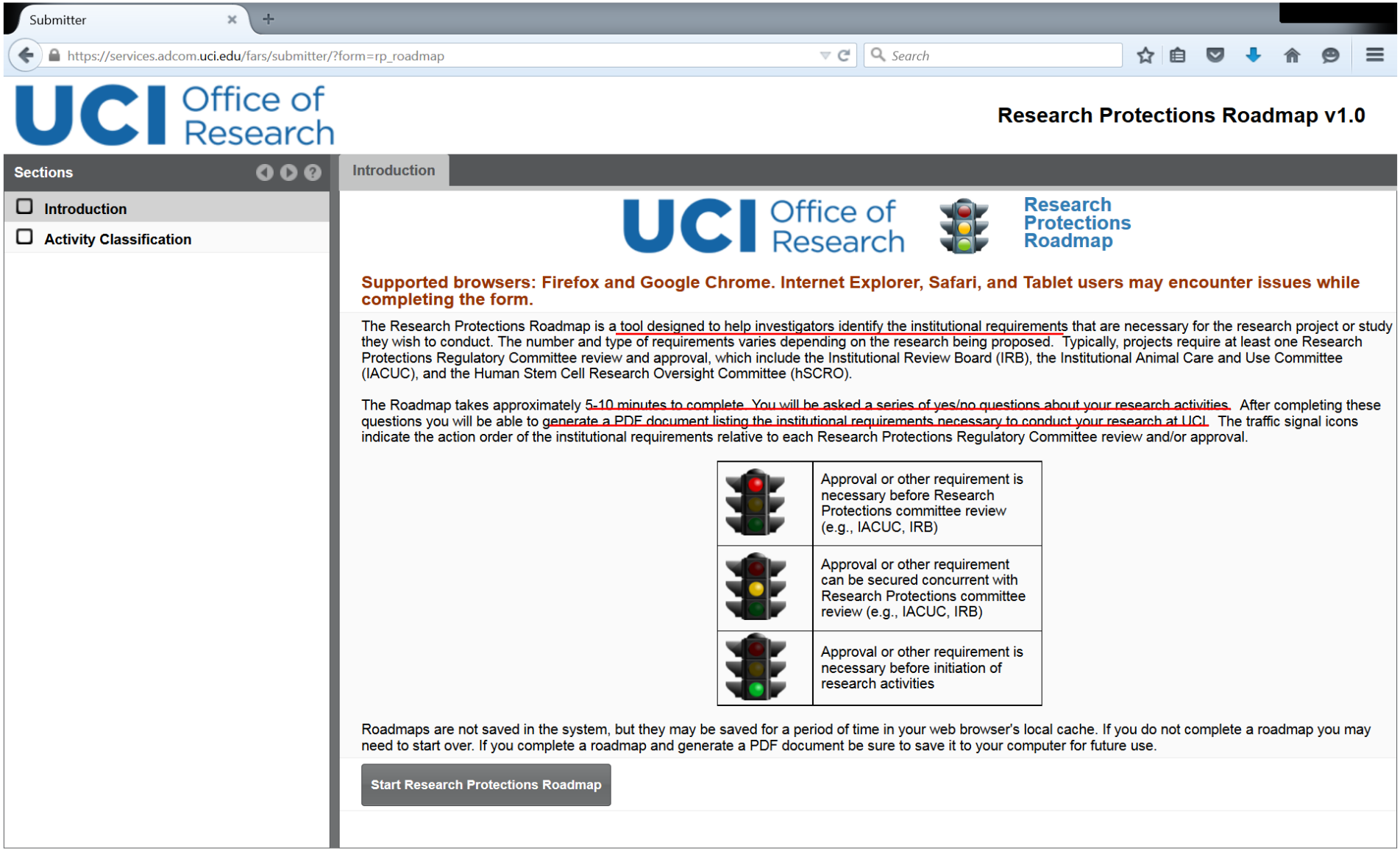
http://www.research.uci.edu/compliance/human-research-protections/researchers/closing-a-protocol.html

Research Protections Roadmap



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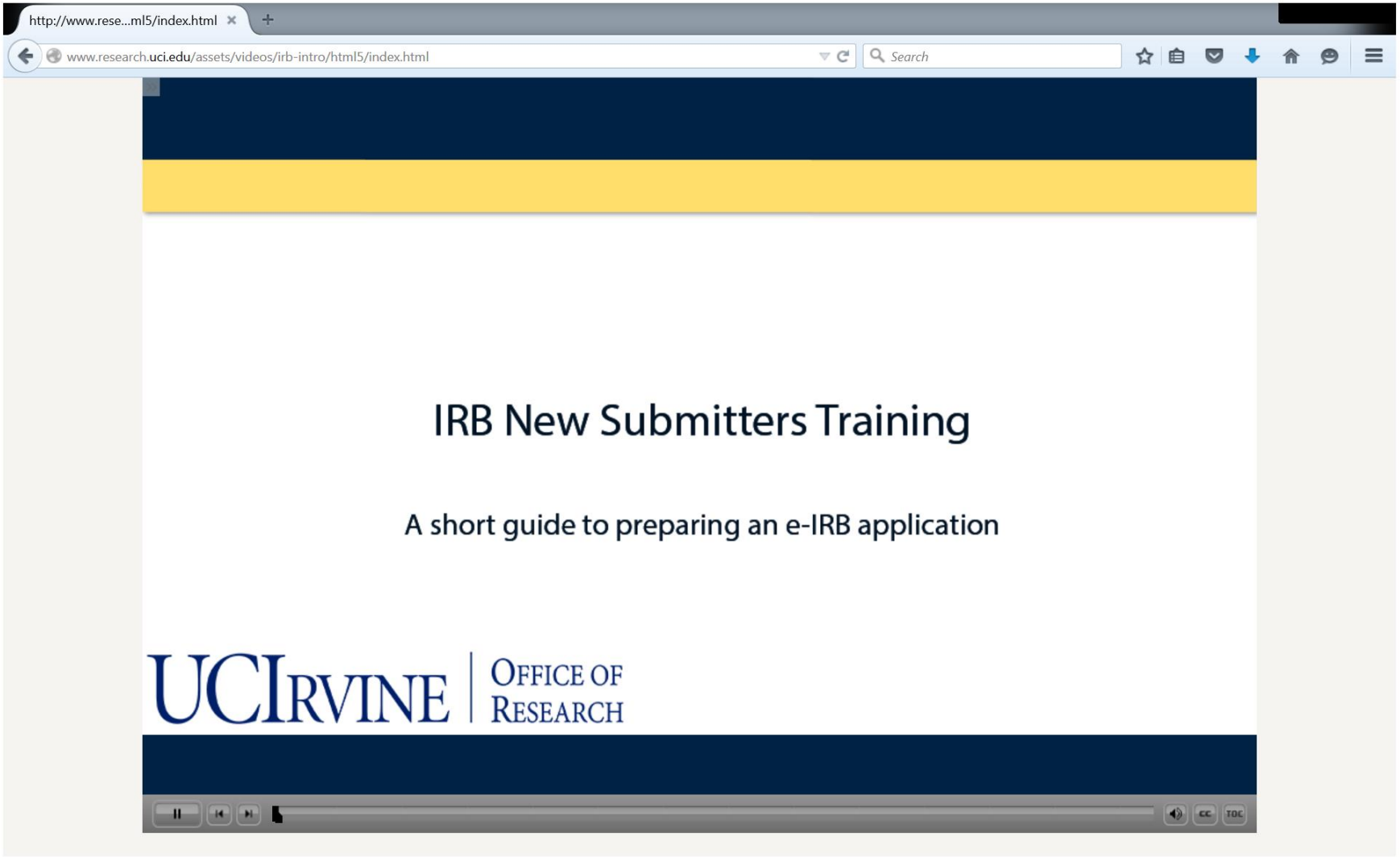
https://services.adcom.uci.edu/fars/submitter/?form=rp_roadmap

IRB New Submitters Training Video



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http://www.research.uci.edu/assets/videos/irb-intro/html5/index.html

Reference

Human Research Protections: http://www.research.uci.edu/compliance/human-research-protections/index.html

Guidance for Researchers: http://www.research.uci.edu/compliance/human-research-protections/researchers/index.html

Applications & Forms: http://www.research.uci.edu/forms/index.html

IRB Calendar: http://www.research.uci.edu/compliance/human-research-protections/docs/2014-irb-meetings-and-deadlines.pdf

HRP Staff Directory: http://www.research.uci.edu/compliance/human-research-protections/about-the-irb/hrp-contact-list.html

Helpful Tips

- SBE research vs Biomedical Research
- Difference between NHSR, Exempt and Expedited Review for a minimal risk medical record chart revie study
- Exempt and Expedited Review criteria
- Waiver of Informed Consent criteria
- HIPAA/PHI
- Waiver of HIPAA Authorization criteria
- Device/IDE requirement
- Drugs/IND requirement
- Dietary Supplements/IND requirement
- Humanitarian Use Device criteria
- Scientific Review criteria
- IRB Chair's review/perspective
- QI vs Research
- Tips for completing the Protocol Narrative

Social Behavioral Research

Social Behavioral Research

Social behavioral research applies the behavioral and social sciences to the study of people's or animals' responses to certain stimuli (both external and internal). Such research is conducted by the following academic disciplines: sociology, psychology, anthropology, economics, political science, and history.

Types

NIH separates social behavioral research into two types, made up of several categories, as shown here:

Basic or Fundamental Research	Applied Research
• Research on behavioral and social processes • Biopsychosocial research • Research on methodology and measurement in the behavioral and social sciences	• Research on the identification and understanding of behavioral and social risk and protective factors associated with the onset and course of illness, and with health conditions • Research on the effects of illness or physical condition on behavioral and social functioning • Treatment outcomes research • Research on health promotion and disease prevention • Research on institutional and organizational influences on health

Methods

- Interviewing/Questions
  - Overt or covert
- Studies of existing records
- Experimental designs involving exposure to some type of stimulus or intervention
  - In person
  - Over the telephone
  - Via questionnaire
- Observation
  - With or without observer interaction
  - Includes public (*e.g.*, vital statistics, motor vehicle registrations, or court records) and/or non-public and sensitive (*e.g.*, medical or educational records in which the subjects are identified)
  - Conducted in public places, in private settings (*e.g.*, a clinic or therapist's office), or in laboratories
  - Interventions in such studies range from the innocuous, such as varying the package design of commercial products, to the potentially significant, such as varying behavior modification techniques in studying the treatment of alcoholism.

Risks/Harm

Risk is the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Most social behavioral research involves no physical intervention and therefore no physical risk, but the potential risks of social or psychological harm must still be considered. Researchers must consider the following risks when conducting their study.

- Social harm can occur when:
  - questions about illegal behaviors or immigration status may damage subjects' reputation or raise legal concerns
  - information about subjects' activities may place them at risk of harm or legal action
  - confidentiality is compromised, jeopardizing employment and/or insurance coverage
- Psychological harm can occur when:
  - the research involves deception
  - the research provides subjects with unwelcome and disturbing information about themselves
  - the research questions or procedures can cause stress, embarrassment or raise painful memories

Although most social and psychological risks are minimal and transitory, investigators must be aware of the potential for harm. The IRB will want to know how such outcomes will be minimized or addressed.

Biomedical Research

Biomedical Research

Biomedical scientists study human physiology and the treatment or understanding of disease. Biomedical research applies the principles of the physical sciences to medicine. Most biomedical research is conducted by physicians or biomedical scientists, but many studies are conducted by biologists, chemists, physicists, and other medical and scientific professionals.

Most biomedical research involves clinical trials, which are phased studies using human volunteers, designed to answer safety and efficacy questions about biologics, devices, pharmaceuticals, new therapies or new ways of using known treatments. Clinical trials are the fastest and safest way to find efficacious treatments for those who need the remedy. Trials are often conducted in stages to obtain useful and required information by testing in a small group initially but expanding greatly once safety and efficacy are demonstrated. Most clinical trials are FDA regulated, but there are some exceptions.

Risks/Harm

Risk is the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Biomedical researchers must consider the following risks when conducting their study:

- Social, psychological, or economic harm (See Social Behavioral Research for details)
- Physical harm
    - exercise-induced or repetition-exacerbated physical harm, such as carpal tunnel syndrome, stress fractures, asthma attacks, or heart attacks
    - exposure to minor pain, discomfort (e.g. dizziness), or injury from invasive medical procedures
    - possible side effects of drugs

Although most of the adverse effects that result from medical procedures or drugs are temporary, investigators must be aware of the potential for harm. The IRB will want to know how such outcomes will be minimized or addressed and is responsible for conducting a risk/benefit assessment.

Types and Methods

- Studies designed to evaluate the safety, effectiveness, or usefulness of an intervention:
    - research on therapies (*e.g.*, drugs, exercise, surgical interventions, or medical devices)
    - diagnostic procedures (*e.g.*, CAT scans, prenatal diagnosis through amniocentesis)
    - preventive measures (*e.g.*, vaccines, diet, or fluoridated toothpaste)
- Research on normal human functioning and development:
    - studies of the human body while exercising, fasting, feeding, sleeping, or learning
    - responding to such things as stress or sensory stimulation
- Studies comparing the functioning of a particular physiological system at different stages of development (*e.g.*, infancy, childhood, adolescence, adulthood, or old age)
- Studies defining normal childhood development so that deviations from normal can be identified
- Records research – often used to develop and refine hypotheses
- Research on specific disease processes is often needed before improved methods of prevention, diagnoses, and treatment can be developed, for example:
    - research on the biochemical changes associated with AIDS
    - research on the neurological changes associated with senile dementia
- Research on the human genome and genetic markers – for the purpose of creating new avenues for understanding disease processes and their eventual control
- Other biomedical studies that do not involve human subjects or are exempt from the human subjects regulations, and, therefore, do not require IRB review:
    - research with animals
    - research on preexisting samples of materials (tissue, blood, or urine) collected for other purposes, where the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
    - research based on records, when the data are recorded in such a manner that the individuals to whom the records pertain cannot be identified, either directly or through identifiers linked to them

NHSR, Exempt, and Expedited criteria for medical record chart review study

What Is the Difference Between Non-Human Subject, Exempt and Expedited Review for a Minimal Risk, Medical Record Chart Review Study?

	Definition	Can I view identifiers (direct or indirect)?	Can I record identifiers (direct or indirect) in my research record?
Non-Human Subjects (NHS)	Research obtaining individual private information from a living individual will be considered human subjects research and NOT fit within a NHS determination. *Private information* includes information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). 45 CFR 46.102(f)	 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.	
Exempt	Research can be exempt under 45 CFR 46.101(b)(4) if it involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens 1) from sources that are publicly available OR 2) if the information is **recorded** by the investigator **in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects**. 45 CFR 46.101(b)(4)		 *Unless using publically available sources
Expedited	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). 45 CFR 46.110 (Expedited Category 5)		

Eligibility for Exempt and Expedited Review

Exempt and Expedited Review

- ❑ Minimal Risk
- ❑ Identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal
- ❑ Not *classified* research

http://www.research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html

Waiver of Informed Consent

Waiver of written documentation of Informed Consent (verbal consent/Study Information Sheet)

- ❑ Minimal risk
- ❑ Verbal consent contains required elements of informed consent
- ❑ Involves no procedures for which written consent is normally required outside the research setting

OR

- ❑ Not FDA regulated
- ❑ Verbal consent contains required elements of informed consent
- ❑ The only record linking the subject and the research is the consent form
- ❑ The principal risk of a signed consent would be the potential harm from a breach of confidentiality

Waiver of Informed Consent (no consent)

- ❑ Not FDA-regulated
- ❑ Does not include non-viable neonates
- ❑ Minimal risk
- ❑ Does not adversely affect the rights and welfare of subjects
- ❑ Research could not practicably be done without the waiver
- ❑ If appropriate, subjects will be provided with pertinent information

OR

- ❑ Not FDA-regulated
- ❑ Does not involve non-viable neonates
- ❑ A research or demonstration project conducted by the state/local government
- ❑ Research could not practicably be conducted without the waiver

Use Appendix O or P

HIPAA/PHI

What is HIPAA?

HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The intention of HIPAA is to protect patients from inappropriate disclosures of "Protected Health Information" (PHI) that can cause harm to a person's insurability, employability, etc.

What Does the Privacy Rule Have To Do With Research?

HIPAA affects only that research which uses, creates, or discloses PHI. Researchers have legitimate needs to use, access, and disclose PHI to carry out a wide range of health research studies. The Privacy Rule protects PHI while providing ways for researchers to access and use PHI when necessary to conduct research. In general, there are two types of human research that would involve PHI:

- Studies involving review of existing medical records as a source of research information. Retrospective studies, such as chart reviews, often do this. Sometimes prospective studies do it also, for example, when they contact a participant's physician to obtain or verify some aspect of the participant's health history.
- Studies that create new medical information because a health care service is being performed as part of the research, such as testing of a new way of diagnosing a health condition or a new drug or device for treating a health condition. Virtually all sponsored clinical trials that submit data to the U.S. Food and Drug Administration (FDA) will involve PHI.

What is PHI?

PHI is information that can be linked to a particular person and that is created, used, or disclosed in the course of providing a health care service (i.e., diagnosis or treatment).

There are 18 PHI identifiers as follows:

Name	Address (all geographic subdivisions smaller than state, including street address, city, county, ZIP code)	All elements (except years) of dates related to an individual (including birth date, admission date, discharge date, date of death and exact age if over 89)
Telephone numbers	FAX number	E-mail address
Social Security number	Medical record number	Health plan beneficiary number
Account number	Certificate/license number	Any vehicle or other device serial number
Device identifiers or serial numbers	Web URL	Internet Protocol (IP) address numbers
Finger or voice prints	Photographic images	Any other characteristic that could uniquely identify the individual

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http://www.research.uci.edu/compliance/human-research-protections/researchers/protected-health-information-hipaa.html

Requesting a Waiver of HIPAA Authorization

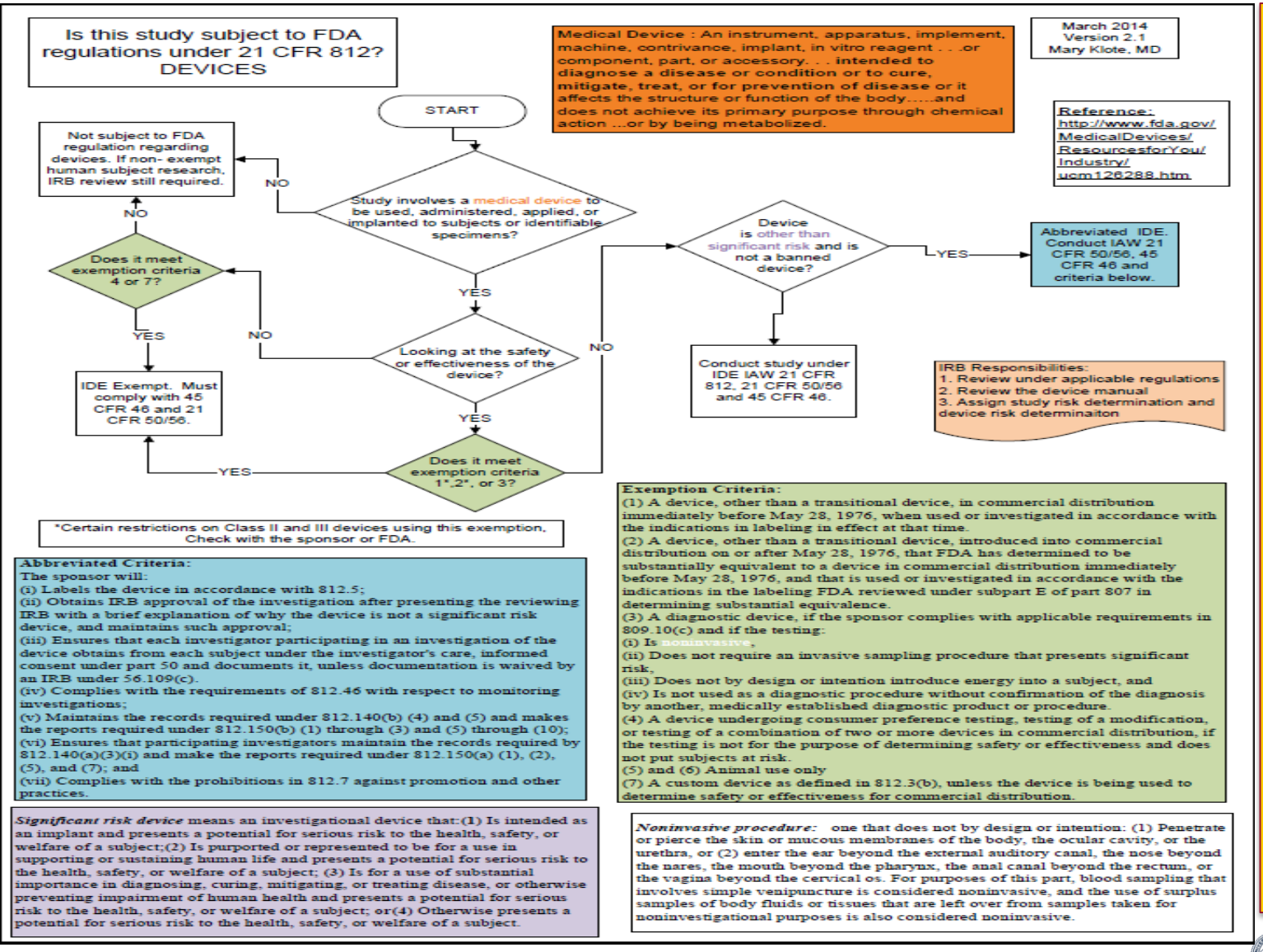
Requesting a Waiver of HIPAA Authorization

Although it is always preferred to get permission to use an individual's Protected Health Information, HIPAA permits research using PHI without obtaining permission (called "Authorization"). In order to waive HIPAA Authorization, the IRB must determine that the study meets all of the following criteria:

- The use or disclosure of PHI involves no more than minimal risk
- Granting of the waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used
- The project could not practicably be conducted without a waiver
- The project could not practicably be conducted without use of PHI
- The privacy risks are reasonable relative to the anticipated benefits of research
- An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal
- An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal
- The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Use Appendix T (Appendix O or P may also be applicable)

IDE requirement



Appendix K

- ✓ **Definition of Device**
- ✓ **Definition of Clinical Investigation: safety data collection**
- ✓ **Intent of study**
- ✓ **Categories:**
  - ❑ No IDE required: studies of physiology and practice of medicine
  - ❑ IDE required: studies of safety, effectiveness
    - – SR: support or sustain human life, serious risk
    - – NSR: not SR
  - ❑ Abbreviated IDE: NSR devices; only IRB review is required
  - ❑ Exempt from IDE: devices used according to label, non-invasive

* In Vitro Diagnostic (IVDs) and programs/softwares *may* also be a device

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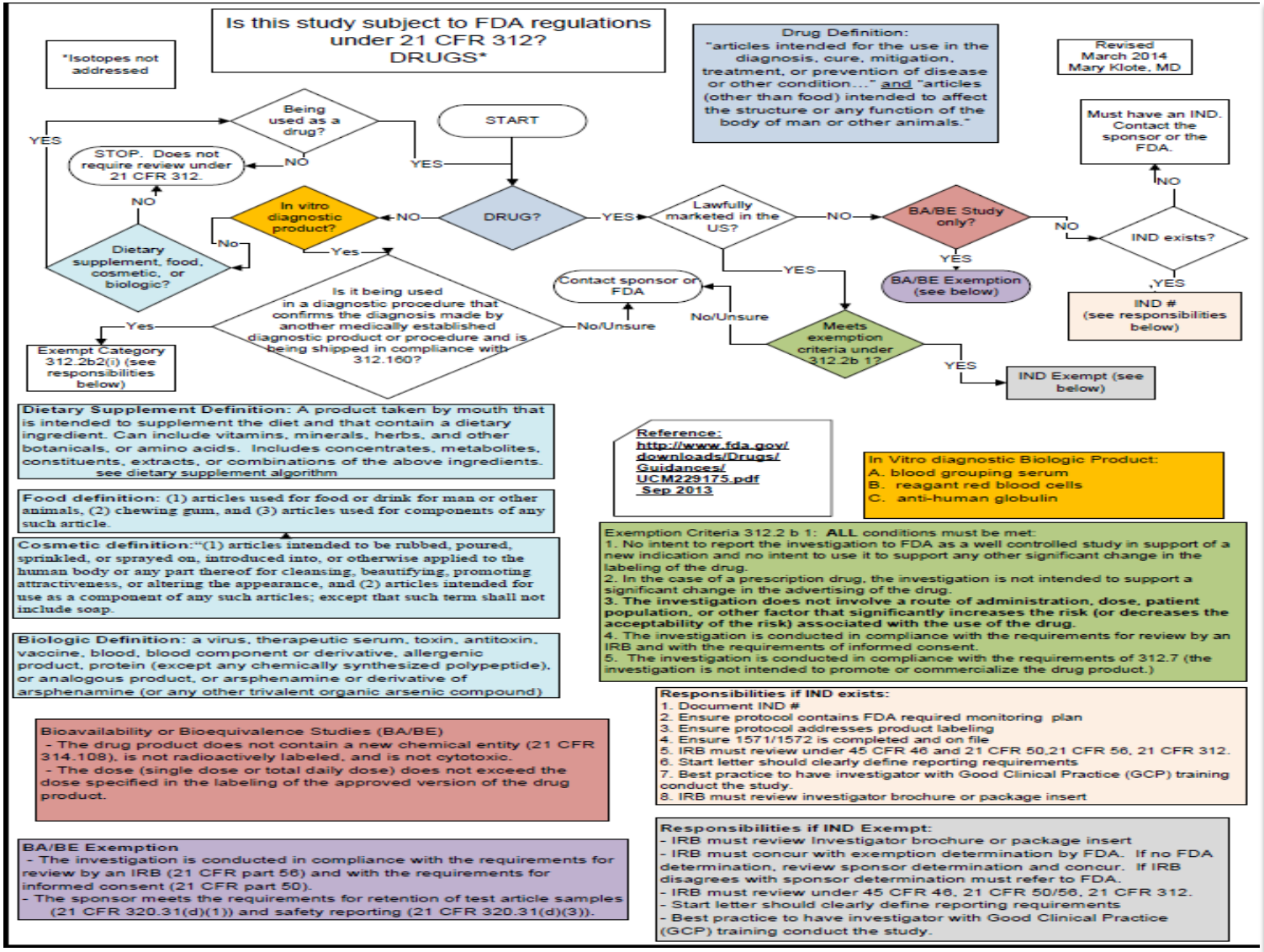
http://www.research.uci.edu/compliance/human-research-protections/researchers/drugs-biologics-and-devices-clinical-investigations.html

IND requirement



Appendix J

- ✓ **Definition of Drug**
- ✓ **Definition of Clinical Investigation:** an experiment using a drug for research purposes
- ✓ **Intent of study**
- ✓ **Categories:**
  - ❑ IND required: studies of a drug (approved or unapproved) for research
  - ❑ Exempt from IND:
    - marketed drug used according to label and study results are not reported to FDA
    - serological tests
    - placebos
    - BA/BE studies
    - radioactive drugs for research use
    - cold isotopes for research use

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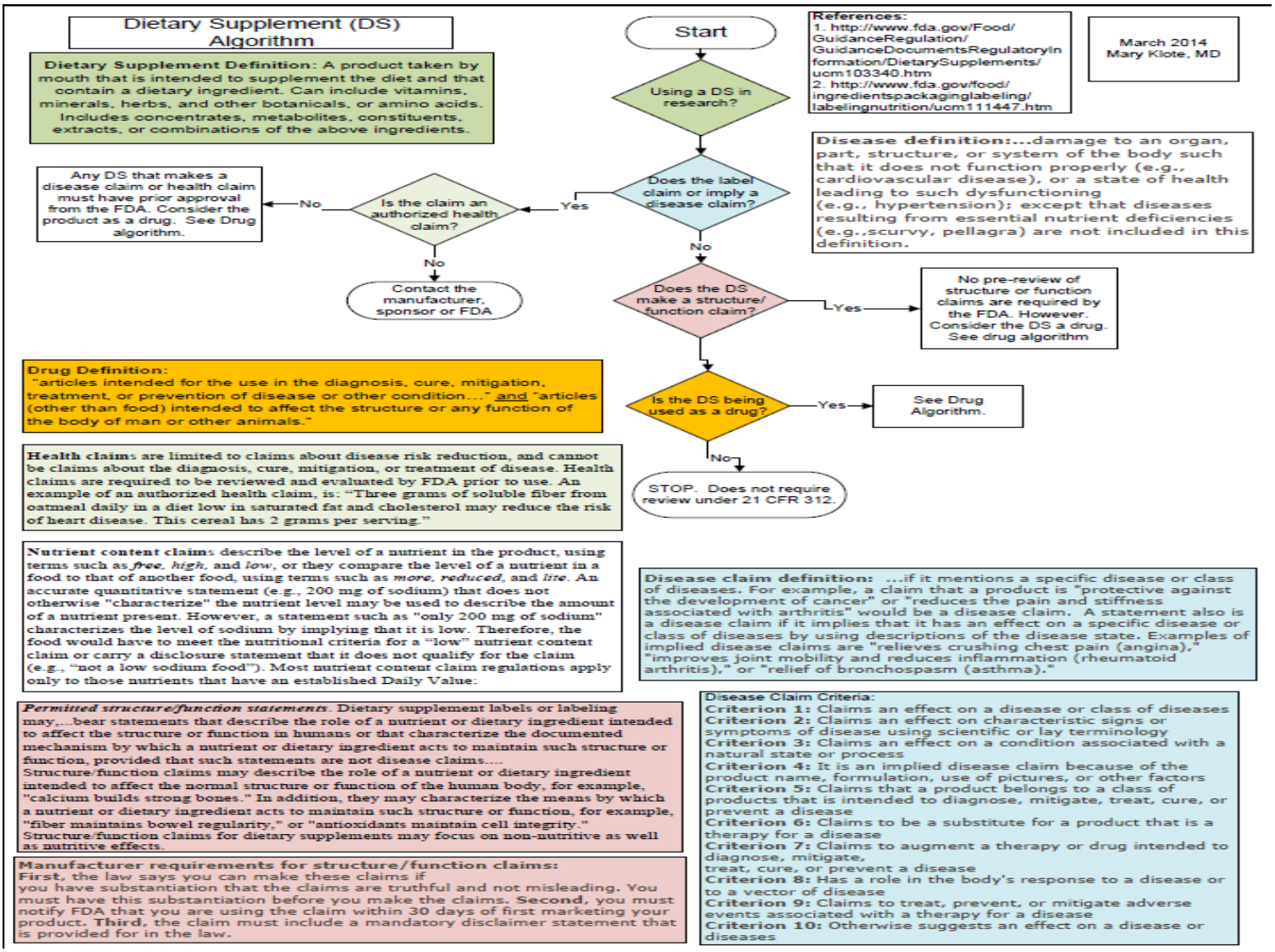
http://www.research.uci.edu/compliance/human-research-protections/researchers/drugs-biologics-and-devices-clinical-investigations.html

IND requirement – Dietary Supplement



Appendix J

- ✓ If a Dietary Supplement is being used as a drug, complete Appendix J

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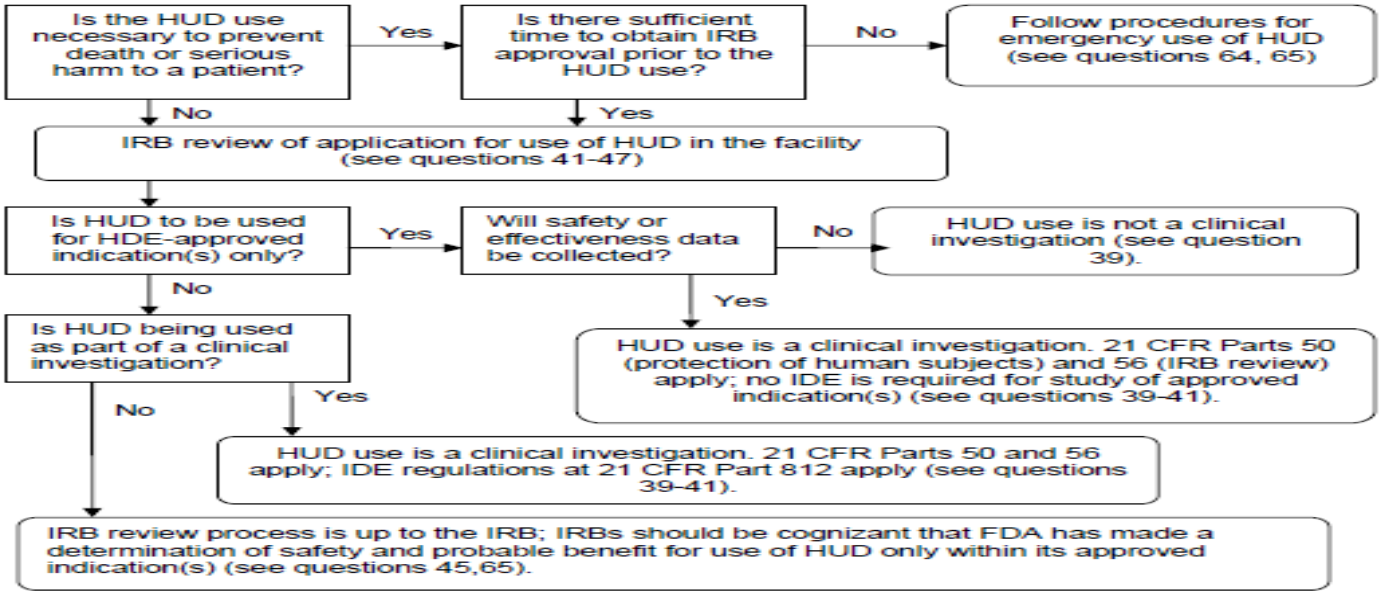
http://www.research.uci.edu/compliance/human-research-protections/researchers/drugs-biologics-and-devices-clinical-investigations.html

Humanitarian Use Device

Contains Nonbinding Recommendations

Figure 1: Decision Tree for IRB Review of HUDs



Note: Medical device reporting is required under 21 CFR Part 803 whenever the use of a HUD may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (see questions 30, 49, 65). For investigational use of a HUD under an IDE, reports of unanticipated adverse device effects must be reported under 21 CFR 812.150(a)(1) and 812.150(b)(1).

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http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf

Scientific Review of Human Subjects Research, David B. Resnik, JD, PhD Bioethicist and IRB Chair, NIHEHS

Figure 1. Scientific Review Form

The purpose of this form is to provide the IRB with information and analysis concerning the scientific aspects of the proposed study, which it can use to evaluate the ethical and regulatory aspects of the research. Answer each question from a scientific perspective and, where appropriate, provide commentary to explain your answer.

1. Does the proposed study address an important scientific, medical, public health, or social question or issue?
2. Does the study address questions not already addressed adequately by previous studies?
3. Is the study likely to make a significant contribution to the literature?
4. Are the aims, objectives and hypotheses clearly stated?
5. Is the study well-designed?
6. Are the methods and procedures appropriate?
7. Are the inclusion/exclusion criteria appropriate?
8. Are the statistical methods appropriate?
9. Is the study adequately powered?
10. Are study personnel qualified to perform the research?
11. Will any collaborating investigators or institutions provide scientific expertise, data, samples, or other help in conducting the research?
12. Are the personnel, facilities, funding and other resources adequate to conduct the research?
13. Does the proposal include an adequate review of prior research pertaining to the study?
14. Does the proposal include adequate plans to publish the research and share data, samples or results?
15. Is the proposal clearly written?
16. Have the investigators submitted all required documentation, such as radiation safety review and biohazard safety review?
17. Does the proposal clearly identify and describe risks to subjects or others?
18. Does the study use appropriate methods or procedures to minimize risks?
19. Does the study use any investigational drugs or devices? If so, has the investigator submitted adequate documentation from the FDA or other regulatory authority?
20. Does the study involve drug dosing? If so, are the dosing amounts, schedules, sites and routes appropriate to minimize risks?
21. Does the study need a data and safety monitoring board?
22. Does the proposal clearly identify and describe potential benefits to the subjects or others?
23. Are there any other issues that might affect the scientific validity of the study?
24. Should the study be approved as is, approved with modifications, disapproved or tabled due to lack of sufficient information?

https://firstclinical.com/journal/2015/1508_Scientific.pdf

Dennis J. Mazur, MD, PhD,

”Evaluating the Science and Ethics of Research on Humans, A Guide for IRB Members”

Will the study’s findings matter?

1. Assuming the investigator completes the study as planned, will it create generalizable knowledge of any significance?
2. Have previous (or current) studies addressed essentially the same hypothesis?
3. Is the study designed in such a way (e.g., with an appropriate study population and adequate statistical power) that the findings will be useful?
4. How likely is it that the study will have a material impact on medical practice?
5. How likely is it that the study will help create knowledge that will support future research that eventually could have a material impact on medical practice?
6. Would negative results be useful?

Do the benefits outweigh the risks?

7. Are the risks clearly much larger than can be justified by the potential benefits?
8. Are the risks too uncertain to even assess?

Is this the right team for the study?

9. Is the study proposal so poorly written that proper conduct of the study is questionable?
10. Has the investigator demonstrated the qualifications and experience necessary to conduct the study, given its risks and complexities?
11. Are the other personnel on the research team qualified?
12. Are support personnel and departments qualified?
13. Will everyone involved give the study adequate attention?
14. How will the study team hold up in the face of problems like serious adverse events or the loss of a team member?
15. How is the situation likely to change over the course of the study?
16. Can any weaknesses be addressed with supervision or assistance from more qualified people?

https://firstclinical.com/journal/2015/1509_Red_Flags.pdf

Distinguishing QI activities from research

RESEARCH

Systematic investigation **and** designed to develop or **CONTRIBUTE TO GENERALIZABLE KNOWLEDGE**

+

HUMAN SUBJECT

Research **about a living individual** either through **intervention/interaction** or **identifiable private information**

IRB REVIEW IS REQUIRED

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Publications: **DOI: 10.1177/1556264615575513 and DOI: 10.1177/1740774515597682**

Tips for completing the Protocol Narrative

Protocol Narrative	Tips
Non-Technical Summary	similar to a journal abstract format/outline (1-2 paragraphs)
Section 1	Answer each (applicable) item
Section 2	Answer each item; in the consent form, list only those that are involved in consenting subjects
Section 3	Include all subject populations
Section 4	Describe recruitment (passive, active) for all subject populations, and complete applicable waivers (ICF/HIPAA)
Section 5	Describe consent process for all subject populations, provide appropriate consent forms for all subject populations; if pre-screening is included, provide a verbal consent and screening scripts If the study involves secondary data analyses (use of existing data/specimens from a prior study), please include a copy of the prior consent form from the prior study
Section 6	Describe all research activities (may want to include a timeline/chart of activities) for all subject populations; helpful to correlate the research activities to (each) study aims; if study is industry-sponsored, you may refer to the master protocol/IB (include the page #s); this section should be similar to the Procedures-section in the consent form
Section 7	Describe all the risks (refer to each research activity described in section 6), for all subject populations; this section should be similar to the Risks-section in the consent form
Sections 8-10	Answer each (applicable) item
Section 11	Answer each (applicable) item for all subject populations; for most studies, identifiable data is necessary (multiple study visits, data quality assessment, etc), but the plan to protect the data needs to be described; this section should be similar to the Confidentiality-section in the consent form