

Flex Coalition Conference Call

6/21/13

Attachments

1. AAHRPP Tip Sheet: on Equivalent Protections
 2. Stanford IRB Chart Review Form
 3. Flex Coalition Checklist of Flexibility options
 4. Cedars Sinai poster on project for rapid IRB review
 5. USC Conflict of Interest Disclosure system training video
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Notes

Sarah Kiskaddon, AAHRPP

AAHRPP has produced a tip sheet 27 “Developing and Applying Equivalent Protections” (attachment 1) which advises institutions to consider flexibility with studies under the following circumstances:

- No federal funding
- Not FDA regulated
- No staff involved who receive fed funding
- Have an IRB system for tracking funding changes
- Policies include criteria of equivalent protections for anything approved under a flexibility policy

Areas to Consider Flexibility:

- Allow IRB staff (non-member) to conduct expedited review of flex studies
- Extended approval period
- Grace period before next continuing review (i.e., research activities may continue for x amount of days)
- Exempt some less-than-minimal-risk research that would normally require subpart D
- Dissertation/ theses research conducted by grad students can be exempted as long as it meets flex criteria (minimal-risk, no federal funding)
- IRB staff review of admin changes (e.g., changes to non-key personnel)
- Reporting requirements: some adverse events or participant complaints can be reported to IRB only, not FDA and OHRP
- AAHRPP does not limit flexibility to examples above

Celia Molvin, Stanford University

Stanford undertook “2013 Year of Streamlining” administrative burden on research.

Innovations include:

- An e-protocol helpline / email, online “suggestion box”, :
 - Researchers asked for a visual flag so that PI’s are alerted to studies nearing expiration (study listing appears with red text in electronic system until continuing review is started).
 - What if a study received federal funding but it ran out?
- Shortened the consent form from 16 to 6 pages
- Shorter form specifically for chart review research (see attachment #2)

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- 3-year extended approval

Implementation tips:

- Involve IRB staff in discussions because they know best which areas need improvement
- Collect ideas from education sessions
- Designate someone to document all suggestions on spreadsheet; ensure someone gets back to person who made suggestion
- Broadcast changes via listservs (HRPP's as well as those of other departments)
- Be prepared to initially receive lots of spam

Rebecca Flores-Stella, Cedars Sinai Medical Center

- Cedars explored reordering the workflow for clinical trial activation in order to maximize time for IRB review, MCA review, contract negotiation, etc. A calendar was developed to address the protocol approval-timeline; a publication on this project is forthcoming. (Abstract: <http://meetinglibrary.asco.org/content/109950-132>)
Also see attachment 4: Cedars IRB Rapid Activation process

Martin Koning-Bastiaan, USC

- USC implemented "flex" as a new approval categories in the IRB's electronic submission system; (flex exempt, flex expedited)
- Implemented system of flags to note whether a study is eligible for flex policy, was flexed but had funding, auto-reminders for extended approval expiration dates (eg: this involved exceptions to existing rules for 1-year approval only)
- Most common flex is an expedited activity that is exempted under flex
- Implemented more check-boxes overall in e-submission system instead of open textboxes. Investigators can choose from options and can learn how to do things correctly instead of trying to come up with an answer. However, additional checkboxes had to be added after implementation because some answers were not addressed in the original checkboxes.
- Implementing flex in IT systems:
 - Create mechanisms to note when a study is flexed: add "flex" field and have a way for reviewers to indicate and approve study is flexed
 - Inform investigators that something is flexed and automatically flag the funding status (e.g., if funded, funding information turns red)
 - Send periodic reminders regarding funding changes
 - Verify expiration dates: system had to be revised to implement two-year approval periods; implement way for system to catch if expiration date is incorrect
 - Created "flex exempt" study category so that if an expedited study is recategorized as flex exempt, information provided by investigator is still visible

Jeff Cooper, WIRB Copernicus

New ideas for flexibility:

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- Individual names of research staff need not be documented if IRB can verify that individual has appropriate/required credentials. Some institutions require person-specific, study-specific data/registration due to way Conflict of Interest is captured
- Personnel changes should not be treated as modifications to research
 - Note: at USC, the system has been automated so research staff can change the study personnel (excluding PI, Co-Investigator and Faculty Advisor) without an amendment
- UC model for HIPAA authorizations: set up so authorization is fill-in-the-blank, boilerplate. No need to review authorization.

Tip Sheet 27: Developing and Applying Equivalent Protections

Related Accreditation Elements: I.1.D., II.2.A., II.2.E., II.3.F., II.3.G., II.4.A. and Standard I-3.

Organizations must apply the applicable U.S. federal regulations for protecting research participants when research is sponsored by a federal agency. Research on drugs, biological products and medical devices that fall under the jurisdiction of the Food and Drug Administration (FDA) must also follow the regulations published in 21 CFR 50, 56, 312 and 812. Organizations with a federalwide assurance (FWA) may choose to apply the regulations in 45 CFR 46 subpart A, or subparts, A, B, C and D to research that is not federally funded as well.

AAHRPP's Evaluation Instrument for Accreditation states that: "Organizations that must follow a certain set of regulations (e.g., DHHS or FDA) must meet the regulatory requirements. Organizations that are not bound to follow a particular set of regulations are not required to meet them, but they should describe and provide equivalent protections, when applicable." AAHRPP requires accredited organizations that do not voluntarily apply each subpart of 45 CFR 46 to all human research to provide equivalent protections to participants in non-funded research. This pertains to all organizations, regardless of FWA status.

Recommended Content:

I. Why might an organization choose to apply equivalent protections?

I.A. In some cases, organizations can improve their ability to protect participants by adapting policies and procedures to accommodate differences in types of research (e.g., biomedical, social science, behavioral science research) instead of applying the same regulatory requirements to all human research activities. Adopting equivalent protections can allow for greater flexibility in oversight of research for which federal regulations might not be appropriate and can reduce unnecessary administrative burdens on the HRPP.

II. When to apply equivalent protections rather than federal regulations

II.A. When any part of a research study receives funding from a federal agency that has adopted regulations for human research, the study must meet all applicable federal regulatory requirements. This includes when study personnel receive federal funding, even if the funding is not specifically intended to support research activities (i.e. scholarships, fellowships, training programs, etc.). It is important that the HRPP have procedures for tracking the funding sources associated with all studies to determine whether federal regulatory requirements apply. Policies and procedures providing protections that are different from, though equivalent to federal regulations can only be applied to studies that do not receive funding from a federal agency that has adopted regulations for human research.

II.B. IRB members, staff **and** researchers should be trained to determine whether federal regulations apply to a study.

II.C. IRB staff should be aware that a study that begins without federal funding may gain such funding or may add personnel with federal funding over the course of the study. If a previously approved study gains funding from a U.S. federal agency that has regulations for protecting research participants, the IRB that approved the research must apply the regulations to the study in reviewing and approving the funding as a modification of the protocol.

II.D. IRB members and staff should further consider that non-federally funded studies may be required to apply the federal regulations on the basis of agreements with sponsors or when the research is subject to FDA regulations.

III. Developing Policies and Procedures to Provide Equivalent Protections

III.A. When developing policies and procedures intended to provide protections equivalent to federal regulations, HRPPs might use the language of the federal regulations as a starting point and make clear where policies and procedures differ from the requirements of the federal regulations.

III.B. The language adopted in policies and procedures should define appropriate limits for the conduct of research not subject to federal regulations and should be consistent with the ethical principles described in the organization's policies.

IV. Areas to Consider Applying Equivalent Protections

Below are some examples of areas in which organizations might choose to apply policies and procedures developed by the organization, rather than federal regulations, to non-federally funded research. This is not an exhaustive list of policies and procedures that provide protections equivalent to the federal regulations, but suggested areas of review in which organizations have found it useful to apply equivalent protections. The suggestions offered below might or might not be relevant to a given organization, depending on the types of research conducted at the organization.

IV.A. Consent Procedures

1. Policies and procedures might modify or add additional elements of disclosure in order to clarify ethical requirements or account for ethical concerns not addressed by the federal regulations. For example, in clinical trials researchers might be required to disclose that by signing the consent document, participants agree to grant access to their original medical records to monitors, auditors and IRB members for the purpose of verifying clinical trial procedures and data. Researchers might also be required to inform prospective participants of the probability of random assignment to each treatment.

2. Policies and procedures might contain statements that elements of disclosure required under federal regulations, such as disclosure of alternative procedures or treatments and foreseeable risks or discomforts to participants, need not be included if they are not applicable. Multiple consent templates might be made available for types of research in which the relevant elements of consent differ.
3. Policies and procedures might describe conditions under which researchers will be required to obtain the re-consent of participants over the course of the study. For example, investigators might be required to obtain participants' re-consent after notifying them of an unanticipated problem involving risks to study participants or when the protocol undergoes significant modifications.
4. Policies and procedures might include additional categories of research for which the requirement to obtain participants' consent or to document consent may be waived. For example, they might permit waivers of consent documentation for all research involving no greater than minimal risk. They might also permit alternative forms of documentation of consent for certain types of research, such as completed survey forms in research involving only distribution of surveys, audio or video recordings of consent, documentation by a witness or having participants click "I Agree" on a website.

IV.B. *Criteria for Approval*

1. Policies and procedures might modify or add additional criteria for approval in order to account for ethical concerns not addressed by the regulations. For example, IRB members might be required to review terms for the distribution of compensation to participants according to specified criteria, such as the following:
 - a. The amount of compensation and the proposed method and timing of disbursement is neither coercive nor presents undue influence.
 - b. Credit for compensation accrues as the study progresses and cannot be contingent upon the subject completing the entire study.
 - c. Any amount provided as a bonus for completion cannot exceed 25% of the sum of the compensation for all visits, not including the completion bonus.
2. Policies and procedures might also suspend criteria for approval not relevant to certain types of research, or require different criteria for approval in minimal risk and greater than minimal risk research. For example, in studies that are not exempt from review but involve only analysis of existing medical data, the requirement that selection of participants be equitable might not apply, because the study data have already been collected for non-research purposes.

Furthermore, it might not be necessary to ensure that additional protections for populations vulnerable to coercion or undue influence have been considered, since their conditions do not put them at any additional risk of harm and consent may be waived when research involves only collecting and analyzing existing data (provided appropriate protections for participant confidentiality are maintained).

IV.C. *Exempt Research*

1. Policies and procedures might modify or include additional categories of exempt research beyond those approved in the federal regulations. For example, all studies that involve only review of existing data, even when the data are identifiable, might be designated as exempt provided no prior agreements (such as the terms of consent for obtaining the data) restrict the use of the data and the study does not involve interaction with participants.

IV.D. *Expedited Research*

1. Policies and procedures might modify or include additional categories of research that may be reviewed by the expedited procedure. For example, they might allow all research involving no greater than minimal risk that is not subject to federal regulatory requirements to be reviewed using the expedited procedure. Policies and procedures might also allow qualified IRB staff members who are not IRB members to conduct review by the expedited procedure.

IV.E. *Approval Periods*

1. In order to decrease the administrative burden on the IRB, policies and procedures might extend the approval period to two to three years or indefinitely for certain categories of research that qualify for review using the expedited procedure provided doing so will not result in increased risk to participants. For example, continuing review might be required no more frequently than every two years for studies that involve no greater than minimal risk and do not involve clinical interventions or vulnerable populations. Proposed changes to studies granted an approval period of longer than one year should be reviewed and approved by the IRB before they are implemented.

2. Policies and procedures might allow a brief (for example, 30-day) grace period after expiration of the previous approval for processing of applications for continuing approval before study activities must stop.

IV.F. *Vulnerable Populations*

1. Prisoners

- a. On policies and procedures for review of research involving prisoners, see [Tip Sheet 18](#).

2. Children

- a. Policies and procedure might modify the categories of research involving children as participants that qualify for exemption from IRB review. For example, they might permit exempt determinations in non-federally funded research involving survey procedures, interview procedures or observation of public behavior (as described in paragraph 45 CFR 46.101 (b)(2)) when children are participants.
- b. Policies and procedures might clarify the meaning of minimal risk in the context of research involving children to describe the probability and magnitude of harm or discomfort as encountered by average, healthy, normal children, taking account of prospective participants' ages.
- c. Policies and procedures might describe requirements for the qualifications and expertise of IRBs who review research involving infants, children or adolescents.
- d. Policies and procedures might permit IRBs to waive the requirement to obtain parental permission in studies where:
 - i. procedures do not ordinarily require parental consent outside of the research context;
 - ii. the investigator has presented evidence that prospective participants who are children or adolescents can understand the study information and consent document on their own behalf; and
 - iii. appropriate safeguards are in place.
- e. For studies that extend over long periods of time, policies and procedures might include requirements that participants who are children be presented with more sophisticated information and re-assent or consent to participate as they mature
- f. Policies and procedures might establish criteria for approval of research not otherwise approvable under the criteria in paragraphs 46.404-406 of 45 CFR 46, for example, by:
 - i. establishing an expert panel affiliated with the organization who will review the research;
 - ii. establishing procedures for consulting with an external IRB to review the research; and
 - iii. outlining additional criteria for approval of such research.

3. Pregnant women and fetuses

- a. Policies and procedures might suspend additional criteria for IRB approval of research required by federal regulations in research involving no greater than minimal risk to pregnant women or fetuses.
- b. Policies and procedures might modify the criteria for approval described in paragraphs 45 CFR 46.204 (b) and (d) and 45 CFR 46.205 (b)(1)(ii) and (c)(4) to permit research involving pregnant women, fetuses or neonates that is intended to generate “generalizable” or “scientific” knowledge, rather than limiting permissible research under those criteria to that intended to generate “biomedical” knowledge.
- c. Policies and procedures might specify ethical requirements for review of research involving pregnant women that is not funded by federal agencies for political reasons, such as research involving in-vitro fertilization as a treatment for infertility.

IV.G. *Research Conducted by Students*

1. Policies and procedure might specify that students may only conduct research that meets the organizations' criteria for exemption or review using the expedited procedure. They might also designate as exempt from IRB review certain categories of research conducted by students that is intended to benefit their education and not to contribute to generalizable knowledge. For example, they might designate as exempt student research in which:
 - a. results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes;
 - b. results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.);
 - c. research procedures involve no more than minimal risk;
 - d. vulnerable populations are not targeted (e.g., children under age 18, prisoners, persons who are cognitively impaired);
 - e. data collected are recorded in such a manner that the participants are not identifiable (images in videotapes and photographs and voices on audiotape are identifiable); and
 - f. when appropriate, a consent process is in place.

2. Policies and procedures might also describe how students and instructors should treat student research which might or might not be subject to IRB review, including:
 - a. instructors' responsibilities pertaining to educating and advising students on requirements for submitting research protocols to the IRB;
 - b. the status of independent studies, theses and dissertations as research subject or not subject to IRB review;
 - c. conditions under which a student may serve as a principal investigator;
 - d. ethical requirements for student research not subject to IRB review.

IV.H. *Review of Modifications*

1. Policies and procedures might describe categories of minor changes to research protocols that do not require IRB approval. For example, IRB staff might be permitted to approve administrative changes such as:
 - a. translation of approved consent documents and recruitment materials;
 - b. minor changes to contact information;
 - c. changes to key study personnel who are not a principal or local site investigator.

IV.I. *Reporting Requirements*

1. Policies and procedures might specify that incidents such as adverse events and participant complaints must be reported to the IRB and organizational officials but not to the Office for Human Research Protections or FDA. In this way, they can improve participant protections by easing the administrative and institutional burden involved in reporting such incidents.

Chart Review Form

Creating the application:

*This form type may **only** be used for retrospective reviews of data, documents, or records that have been collected, or will be collected.*

***Do not** use this form if you plan on interaction or intervention with participants, if the chart review involves evaluating the safety and effectiveness of a drug or device, or if you are obtaining or analyzing specimens. Submit an expedited or regular form instead.*

Medical Application only
Expedited Category 5 only

Side Bar Menu:

Personnel Info - Same

Participant Population: Same

(If "Cancer Patients" checked, send auto email to CCTO)

Study Location – Same

(if VA checked, send auto email to VA)

Funding - Same

General Checklist

Collaborating Institutions

Yes No Are there any collaborating institution(s)?
(If yes: ADD button should appear and allow it/them to be listed.)

Funding

Yes No Training Grant?
Yes No Federally Sponsored Project?

Veterans Affairs (VA) (If any are yes, auto email)

Yes No The research involves the use of VAPAHCS non-public information
Yes No The research is sponsored (e.g. funded) by VAPAHCS
Yes No The research is conducted by or under the direction of **any** employee or agent of VAPAHCS in connection with her/his VAPAHCS responsibilities
Yes No The research is conducted using any property or facility of VAPAHCS

Research done at or involving the VA must be reviewed and approved by the Research and Development Committee before any research is started. Contact the Research Administration Office at the VA at 650-493-5000 ext 65418.

Obligations - Add the highlighted bullet

The Protocol Director agrees to:

- Adhere to principles of [sound scientific research](#) designed to yield valid results.
- Conduct the study according to the protocol approved by the IRB
- Ensure adequate resources are available to conduct the study

Protocol Information

Expedited Section

Expedited Category 5 - Confirm that this project constitutes:

- Yes No Research involving materials (data, documents, records) that have been collected, or will be collected (such as medical treatment or diagnosis).
(If no: pop up to warn researcher to stop here and fill out a different application)

Section 1 Purpose

- a) In layperson's language, state the purpose of the study and what you hope to learn in 3-5 sentences.
- b) Estimate the approximate number of medical charts you expect to review for this study.
- c) Describe the source of the data that you will be studying, e.g., STRIDE, CERNER, EPIC, etc.

Section 2 Participant Population

- a) Indicate if you will target the medical records of any vulnerable populations not already listed in the Participant Population section, e.g., economically or educationally disadvantaged, or homeless people. Enter N/A if these populations are not targeted.
- b) Identify the inclusion criteria for which medical records you will study.
- c) If you intend to exclude a particular age group, ethnic group, or gender, provide a rationale for doing so, e.g., the disease only occurs in children.
- d) If children are involved in your research, confirm that the following regulation applies:
 Yes No 45 CFR 46.404: The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and

the permission of their parents or guardians. [Note: IRB Waivers of Assent and Consent are considered adequate provisions. See Section 5]

Section 3 Confidentiality Protections a-h

Before answering the following questions, [click here](#) to learn about HIPAA and the authorized use of identifiable protected health information (PHI). (Link to http://hipaa.stanford.edu/home_faq.html)

- a) Specify the PHI (protected health information) or other individually identifiable data you will obtain, use, or disclose to others. List ***both*** the ***type of health information*** you will obtain from the medical record (e.g., diagnosis, X-ray reports, H&P, lab reports, progress notes, billing records) ***and the HIPAA identifiers*** that are needed (e.g., name, Medical Record Number or MRN, SSN, dates of birth, death, admission, surgery, or treatment, geographic location smaller than a state.) Be very specific. (Note: this section must be consistent with the Waiver of HIPAA Authorization Section in Section 5.)
- b) Describe how the data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device).
- c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See <http://med.stanford.edu/datasecurity/> for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use a secure database such as STRIDE, RedCap, or Medrio. If you are unsure of the security of the system, check with your Department IT representative.

Please see [this link](#) for more information on IRT Information Security Services [link to <http://med.stanford.edu/irt/security/>] and [this link](#) [link to http://www.stanford.edu/group/security/securecomputing/mobile_devices.html] for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in a locked environment.

☺ By checking this button, you affirm that you will comply with the aforementioned.

- d) Indicate who will have access to the data (e.g., research team, sponsors, consultants).
- e) If data will be de-identified after it is collected, describe who will be responsible for the de-identification, and confirm that none of the [HIPAA identifiers](#) [link to http://hipaa.stanford.edu/home_faq.html] listed in this hyperlink will be linked to the data.

- f) If data will be coded, describe the code you will use so that the identity of the subjects cannot be readily ascertained from the code (e.g., the code should not contain initials, last 4 numbers of the SSN, date of birth, or dates of treatment). Indicate who will maintain the key to the code, and describe how the key will be protected.

Section 4 - COI – Same

Section 5 Waivers

Waiver of Consent

- Yes No The research involves no more than minimal risk to the participants because it involves materials (data, documents, records) that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained.
- Yes No The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.
- Yes No The research could not practicably be carried out without the waiver because it would require contacting patients, and contact information is not readily available.
- Yes No Whenever appropriate, the participants will be provided with additional pertinent information after participation. There is no plan to share information with participants as it is likely not to be pertinent.

If no to any of the above, please explain: [Do not include text box in CFC.]

Waiver of Assent

Complete only for children ages 7-17 or adults with limited decision-making capacity.

- Yes No The research involves no more than minimal risk to the participants because it involves materials (data, documents, records) that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained.
- Yes No The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.
- Yes No The research could not practicably be carried out without the waiver because it would require contacting patients, and contact information is not readily available.

- Yes No Whenever appropriate, the participants will be provided with additional pertinent information after participation. There is no plan to share information with participants as it is likely not to be pertinent.

If no to any of the above, please explain: [Do not include text box in CFC.]

Waiver of HIPAA Authorization

- a) Specify the PHI (protected health information) or other individually identifiable data you will obtain, use, or disclose to others. List ***both*** the ***type of health information*** you will obtain from the medical record (e.g., diagnosis, X-ray reports, H&P, lab reports, progress notes, billing records) ***and the HIPAA identifiers*** that are needed (e.g., name, Medical Record Number or MRN, SSN, dates of birth, death, admission, surgery, or treatment, geographic location smaller than a state.) Be very specific. Your answer should be consistent with information provided in 3a.
- b) Complete the following:
- Yes No Do you certify that the use or disclosure of the protected health information involves no more than a minimal risk to the privacy of individuals?
- Yes No Do you certify that the research could not practically be conducted without the waiver?
- Yes No Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?
- Yes No Do you certify that the research could not practically be conducted without access to and use of the protected health information?
- c) Describe an adequate plan to protect any identifiers from improper use and disclosure.
- d) Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

If no to any of the above, please explain: [Do not include text box in CFC.]

Section 6 Attachments



Available Flexibility Initiatives – Checklist

This checklist is designed for institutions considering implementing flexibility initiatives. The first section provides mandatory components necessary to implement flexibility in an institution. The second section provides optional initiatives afforded by flexibility in the regulations. Optional items include checkboxes so institutions can follow-up on items of interest. An overview of the checklist items is included below.

Section I: Mandatory

- “Unchecked Box”
- Flex Policy
- Exclusions to Flexibility
- Standard Operating Procedures (SOPs)
- Audit/Monitor Flexed Studies

Section II: Optional Initiatives

- Consent Form/Process
- HIPAA
- IRB Staff
- Approval Criteria
- Subparts A-D
- Protocol Template
- Not Human Subjects Research
- Electronic Submission
- Review of Research
- Research Staff
- Engagement in Research



Available Flexibility Initiatives - Checklist



Section I: MANDATORY

<i>"Unchecked Box"</i>	<i>Notes</i>
<p>Uncheck all boxes on Federalwide Assurance (FWA) <u>or</u> check box for Subpart A but uncheck Subparts B, C, D (allows for different flexibilities)</p>	
<p><i>Flex Policy</i></p>	
<p>For studies that are no greater than minimal risk</p>	
<p>For studies with no federal funding</p>	
<p>Provide equivalent protections to subjects commensurate with risk level</p>	
<p><i>Exclusions to Flexibility</i></p>	
<p>Exclude greater than minimal risk studies</p>	
<p>Exclude no-cost extension studies</p>	
<p>Exclude projects in which a student is paid or supported from a federal training grant or otherwise paid or supported from the faculty advisors' federal funds</p>	
<p>Exclude federally-sponsored studies, including federal training grants</p>	
<p>Exclude studies with FDA-regulated components</p>	
<p>Exclude studies with contractual obligations or restrictions that preclude eligibility in this policy</p>	

Available Flexibility Initiatives - Checklist



	Notes
Exclude studies with clinical interventions	
Exclude studies using prisoners as subjects	
Exclude studies seeking or obtaining Certificates of Confidentiality	
<i>Standard Operating Procedures (SOPs)</i>	
Flex policy can be integrated in IRB Policies and Procedures (e.g., revise applicable sections) or be a stand-alone policy	
Implement campus-specific policy, if necessary (Socio-Behavioral Research vs. Biomedical)	
<i>Audit/Monitor Flexed Studies</i>	
Establish mechanisms and written metrics to routinely monitor and annually audit all flexed studies	



SECTION II: OPTIONAL FLEXIBILITY INITIATIVES

<i>Consent Form/Process (see handout on "Available Flexibility in the Informed Consent Process")</i>		Notes
<input type="checkbox"/>	Only require necessary signatures based on type of research (e.g., no translator or witness signature)	
<input type="checkbox"/>	Do not limit use of short forms to translations	
<input type="checkbox"/>	When written consent is normally not required (outside of research), grant waivers of documentation for studies approved using expedited procedure	
<input type="checkbox"/>	Make use of available waiver of elements (e.g., omit elements irrelevant to the research)	
<input type="checkbox"/>	Waiver of consent/assent or its documentation is allowed by the regulations	
<input type="checkbox"/>	Apply flexibility available in regulations for child assent (e.g., waivers)	
<i>Health Insurance Portability and Accountability Act (HIPAA)</i>		
<input type="checkbox"/>	Have IRB serve function of Privacy Board	
<input type="checkbox"/>	Use boilerplate, fill-in-the-blank HIPAA forms that require de minimus information	
<input type="checkbox"/>	Create short, smartform application for research using limited datasets	

Available Flexibility Initiatives - Checklist



IRB Staff		Notes
<input type="checkbox"/>	Can verify that minor contingencies are satisfied	
<input type="checkbox"/>	Can perform all non-committee functions	
<input type="checkbox"/>	Can handle all regulatory issues that do not require an IRB	
<input type="checkbox"/>	Appoint as member or alternate	
<input type="checkbox"/>	Designate as Expedited Reviewer	
<input type="checkbox"/>	Designate as Exempt Reviewer	
Approval Criteria (45CFR § 46.1 11)		
<input type="checkbox"/>	The following criteria are automatically met if study is flex policy eligible: <ul style="list-style-type: none"> - Risks to subjects are minimized (a)(1) - Risks to subjects are reasonable in relation to anticipated benefits (a)(2) - Selection of subjects is equitable (a)(3) - Research plan makes adequate provision for monitoring (a)(5) - When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights of vulnerable subjects (b) 	
<input type="checkbox"/>	Waive written documentation of consent for all minimal risk research (unless otherwise required by law) regardless of whether this is requested by the investigator (a)(5)	

Available Flexibility Initiatives - Checklist



Subpart A	Notes
<p>Establish additional exempt categories for no greater than minimal risk activities not covered in regulations. Examples:</p> <ul style="list-style-type: none"> - Research that does not conform to a specific exempt category under 45 CFR 46 (USC Exempt 7) <ul style="list-style-type: none"> - <i>online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk</i> - <i>behavioral games</i> - <i>studies requiring performance of tasks that incur no risk</i> - Research where activity is limited to study of existing or prospective identifiable data (USC Exempt 8) <ul style="list-style-type: none"> - <i>medical record reviews where data is extracted from records</i> - <i>data analysis of information already collected from court records</i> 	
<p><input type="checkbox"/> Extend approval time for activities limited to data analysis-only</p>	
<p><input type="checkbox"/> Create short, smartform application for chart reviews</p>	
<p><input type="checkbox"/> Create short, smartform application for use of de-identified datasets</p>	
Subpart B	
<p><input type="checkbox"/> Exploit flexibility as FDA regulations have no Subpart B</p>	
<p><input type="checkbox"/> Obtain permission from the mother only (for neonates/fetuses)</p>	
<p><input type="checkbox"/> Consider flexibility for social-behavioral research</p>	

Available Flexibility Initiatives - Checklist



Subpart C		Notes
<input type="checkbox"/>	Exploit flexibility as FDA regulations have no Subpart C	
<input type="checkbox"/>	Consider flexibility for social-behavioral research	
<input type="checkbox"/>	Do not require IRB review or prisoner representative for types of research specific to institutional policies when individuals are incarcerated after study enrollment	
<input type="checkbox"/>	Expand definition of who is not a prisoner (house arrest, community service, parole, court-ordered treatment)	
Subpart D		
<input type="checkbox"/>	Only require signature of one parent for unfunded studies, regardless of risk	
<input type="checkbox"/>	Change assent requirements/eliminate written assent	
Protocol Template		
<input type="checkbox"/>	Allow investigators to write protocols in more general terms so that minor modifications to research are not necessary (e.g, change in sequence of intervention)	
<input type="checkbox"/>	Create generic protocols for common research activities where urgency exists	
NHSR ("Not Human Subjects Research")		
<input type="checkbox"/>	Establish policy to exclude projects that do not meet the federal definition of Human Subjects or Research	
<input type="checkbox"/>	Create brief online application to verify NHSR projects and provide documentation of NHSR decision to researchers	

Available Flexibility Initiatives - Checklist



		Notes
<input type="checkbox"/>	Publicize/make investigators aware of NHR, especially students	
Electronic Submission		
<input type="checkbox"/>	Make sure the electronic IRB submission system incorporates flex policies	
<input type="checkbox"/>	Ask funding question early on to identify flex-eligible projects to avoid unnecessary questions applicable to funded projects	
Review of Research		
<input type="checkbox"/>	Review each protocol at the least-restrictive level of review	
<input type="checkbox"/>	Evaluate risks in terms of probability and magnitude	
Research Staff		
<input type="checkbox"/>	Describe research staff generically so amendments to the study are not necessary (e.g., a registered pharmacist will dispense study drugs)	
<input type="checkbox"/>	Automate/simplify how education requirements are tracked (e.g., automatic uploading of human subjects research education)	
<input type="checkbox"/>	Automate a "personnel change" button (excluding Principal Investigator, Co-Investigator and Faculty Advisor) in place of amendment submissions	
Engagement in Research		
<input type="checkbox"/>	Do not consider "engagement" for exempt studies	
<input type="checkbox"/>	Relax engagement requirements	

Available Flexibility Initiatives - Checklist



		<i>Notes</i>
<input type="checkbox"/>	Do not require formal inter-institutional IRB agreements	

Available Flexibility in the Informed Consent Process

Developed by Office for the Protection of Research Subjects (OPRS), University of Southern California

Problem Statement on Informed Consent as Developed by SAS:

The goal of the informed consent process is to ensure an individual's voluntary informed decision to participate in research. Although the regulations that govern informed consent are designed to promote flexibility and the basic and additional elements of consent have remained unchanged, the level of detail provided in consent forms has grown steadily since the regulations were enacted.

Current approaches to consent forms and processes are falling short of the goal of promoting voluntary decision making based on adequate understanding. Anecdotal and empirical evidence indicates that potential participants may fail to understand critical aspects of the research, and that an overemphasis on the inclusion of detail has led to lengthy and complex documents, a lack of attention to process, and problems with comprehension.

Factors that contribute to the problem include:

- IRB review of consent documents that is increasingly focused on editorial review rather than a more meaningful review of the process by which consent will be obtained;
- Form has become the catch-all vehicle for related information that may not be central to the decision to participate (e.g. HIPAA; GINA; protocol registries; sponsor and institutional liability concerns);
- Over-interpretation of regulatory requirements combined with a fear of omitting important information;
- Current education on human subjects protections typically stops short of training investigators and their staff on how to promote and implement an effective informed consent process.

Opportunities for Flexibility

The following areas identified below provide opportunities for flexibility in the informed consent process that are often underused and/or misunderstood by IRBs. They are: **documentation of consent, use of short forms and alternatives, unnecessary elements of consent, waivers, child assent, administrative documentation, and consent for use of human tissues.**

Available Flexibility in the Informed Consent Process

Documentation of Consent (i.e. signatures)

- Waiver of documentation of consent is underused and allowed by the regsⁱ
- Waiver of written documentation is allowed in expedited research
 - In almost all cases, when written consent is normally not required, when procedures in categories (1)-(7) are performed outside of the research context therefore, consent documentation may be waived for almost all research approved using the expedited procedure.
 - IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- OHRP does allow electronic signaturesⁱⁱ on informed consent documents (as long as they are legally valid within the jurisdiction where the research is to be conducted)
- OHRP only requires a witness signature when the use of a short form is used. Otherwise, a witness/signature is not required on informed consent
- Faxed/mailed signed informed consents are acceptable by OHRP
- PI is not required to sign consent
- PI and subject need not sign on same day
- Signatures/initials of subject or witness are not required on every page
- Dating of consent recommended, but not required and date need not be date subject signs
- Use of legally authorized representative may be flexible in certain jurisdictions and allow LAR to consent
- Timing of consent signature need not be on day IC process initiated

Short form/Alternatives

- Use of short forms is an option for any kind of research (very few know about this or that it is an option) regs do not limit use of short form to translations only
- Exempt research does not require informed consent (info/fact sheet can be recommended and is often more relevant to exempt research)
- Significant new information or findings (SNIFs) as required in the regs for transmittal to currently enrolled subjects should be provided in a separate, focused document as soon as possible and provided to enrolled subjects. Only new study subjects should get a full revised informed consent (approved by the IRB).
- Extraneous information and detailed study procedures may be placed in educational materials or study handouts, all do not have to be in the consent
- Screening Consent is an option prior to inclusion/study informed consent
 - University of Rochester RSRB investigator guidance:
- “Unless permission is obtained, identifiable data on individuals who do not pass the screening or who do not give consent to the study cannot be kept in study records”
 - “In studies where a screening/selection process is needed, it may be necessary to obtain consent for the screening in addition to or combined with the study consent”
- Situations allowing info/fact sheet (rather than consent) are under utilized
- OPRR Guidance (1995) “Obtaining and Documenting Informed Consent of Subjects who do not speak English”
 - “When a person obtaining consent is assisted by a translator, the translator may serve as the witness.”

Available Flexibility in the Informed Consent Process

Unnecessary Elements of Consent (those that are irrelevant to some types of research are allowed to be omitted)ⁱⁱⁱ

- Any experimental procedures.
- Any reasonably foreseeable risks or discomforts.
- Any reasonably expected benefits to participants or others.
- A disclosure of appropriate alternatives, *if any*.
- The extent, *if any*, to which confidentiality will be maintained.
- For research involving more than minimal risk, ...
- No requirement to disclose what is not part of the research, not a consequence of the research, or not related to the research.
- If disclosure element includes “any” and there is nothing that falls into the disclosure category, may consider this element not to apply.

Waivers

The following waivers are all available as requested by PI and justified by IRB:

- Waiver of signed/documented informed consent/parental permission/assent
- Waiver of informed consent/parental permission/assent entirely
- Waiver/alteration of certain elements of informed consent
- Emergency Research Consent Waiver must meet strictly limited but differing conditions when subject to FDA regulations or when not subject to FDA regulations (OPRR Reports 1996 *Informed Consent Requirements in Emergency Research*)
- Waiving the requirement for the investigator to obtain a signed consent form for some or all participants if the IRB finds:
 - That the research presents no more than minimal risk of harm to participants; and
 - Involves no procedures for which written consent is normally required outside of the research context.

[45 CFR 46.117(c)(2), 21 CFR 56.109]

Child Assent

- Minors who initially were enrolled under parental consent and reach the legal age of consent while enrolled in a study need to be consented as an adult (unless the IRB waives the consent requirements)
- Waiver of assent for minors is allowed if the conditions for waiver of consent with adults is met (46.116.(c),(d))
- Documenting of child of assent is not required by regs.

Available Flexibility in the Informed Consent Process

Administrative Documentation

- Informed consent stamping is not required
- Recruitment documents need not be stamped

Human Tissues, consent for use in In Vitro Device Studies Regulated by FDA

- Read recommendations provided in “Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff - Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” <http://www.fda.gov/RegulatoryInformation/Guidances/ucm127022.htm>

End Notes

ⁱ Documentation is completed via an IRB approved consent form or description of the consent procedure within the IRB approved study plan. If there is no signature line on the IRB approved consent form, the IRB has waived the requirement to obtain a signature. If there is no consent form approved, the default is that there is no consent form required. Minutes may reflect these decisions but this further documentation is not required

ⁱⁱ An electronic signature is any electronic means that indicates that a person adopts the contents of an electronic message. The U.S. Code defines an electronic signature for the purpose of US law as "an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record."^[1] It may be an electronic transmission of the document which contains the signature, as in the case of [facsimile](#) transmissions, or it may be encoded message, such as [telegraphy](#) using [morse code](#). Increasingly, encrypted [digital signatures](#) are used in [e-commerce](#) and in regulatory filings as digital signatures are more secure than a simple generic electronic signature.^{[2][3][4]} (http://en.wikipedia.org/wiki/Electronic_signature)

ⁱⁱⁱ For elements of consent that do not fit the research the IRB may approve the omission or can they just be left out of the consent

- The way the regs are worded (46.116(a)(4,5,7)): “if any” provides the out. Although the information regarding a research related injury is the exception as there is no “if any.”
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject



CEDARS-SINAI HEALTH SYSTEM
LOS ANGELES, CALIFORNIA

Meeting the Challenge: 42 Days from Concept to First Enrollment

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Office of Research Compliance and Quality Improvement/Samuel Oschin Comprehensive Cancer Institute

PROBLEM STATEMENT

Research oversight programs face new challenges in addressing the fast-track nature of translational research which pushes institutions to bring laboratory discoveries to the bedside as safely and efficiently as possible. The Samuel Oschin Comprehensive Cancer Institute (SOCCI) at Cedars-Sinai Medical Center developed the Rapid Activation Process (RAP) to meet an institutional mandate requiring that early phase oncology trials be activated for enrollment within a six-week timeline.

Acknowledging that it may not be possible to meet the deadlines set by the RAP with the existing IRB meeting schedule, an additional Rapid Activation IRB was established to meet on an ad-hoc basis.

BACKGROUND

The Rapid Activation Process was the identification of key milestones in the life of a protocol and identification of the players who are critical for achieving the milestones. Key milestones spanned from the execution of the Confidential Disclosure Agreement to the activation of enrollment. A leadership group, comprised of key personnel in contracting, IRB, Medicare coverage, budget development, study personnel, ancillary committees (e.g. Radiation Safety, etc.), and billing, developed a Study Calendar which assigned deadlines to each processing milestone and worked together to address any potential delays.

FEATURES OF RAPID ACTIVATION IRB

- Membership structured to address minimum regulatory requirements for IRB membership.
 - Five seats: three clinician researchers, one bioethicist, and one nonscientist and non-CSMC affiliated public member (dual role).
- Approved IRB roster includes all other CSMC IRB members as alternates.
 - Allows composition to be tailored to expertise in research being reviewed.
 - Maximizes the availability of members.
- Ad-hoc meetings can complete reviews outside available meeting schedule.
- Meetings are held when members concur that they have sufficient time to review the materials and may be conducted in person or via teleconference.
- Utilizes teleconferencing which allows for greater flexibility in scheduling ad-hoc meetings.
- Meeting Minutes are circulated and approved by electronic vote.

ELIGIBLE PROTOCOLS

- Compassionate Use requests
- Therapeutic protocols for which there is an urgent patient need
- Early phase protocols having a defined/limited study activation window
- Issues related to unanticipated problems or serious or continuing non-compliance

DISCUSSION

IRB staff processed two proposals using the Rapid Activation IRB in Q1, 2012. In comparison to the quarterly average for all submissions requiring Full Board review, use of the Rapid IRB process significantly reduced time for IRB review.

The biggest success of this endeavor has been the ability to meet review deadlines without having to add additional IRB staff resources. It must be recognized, however, that IRB review time is only one component of the protocol activation process.

SUGGESTIONS FOR IMPLEMENTATION

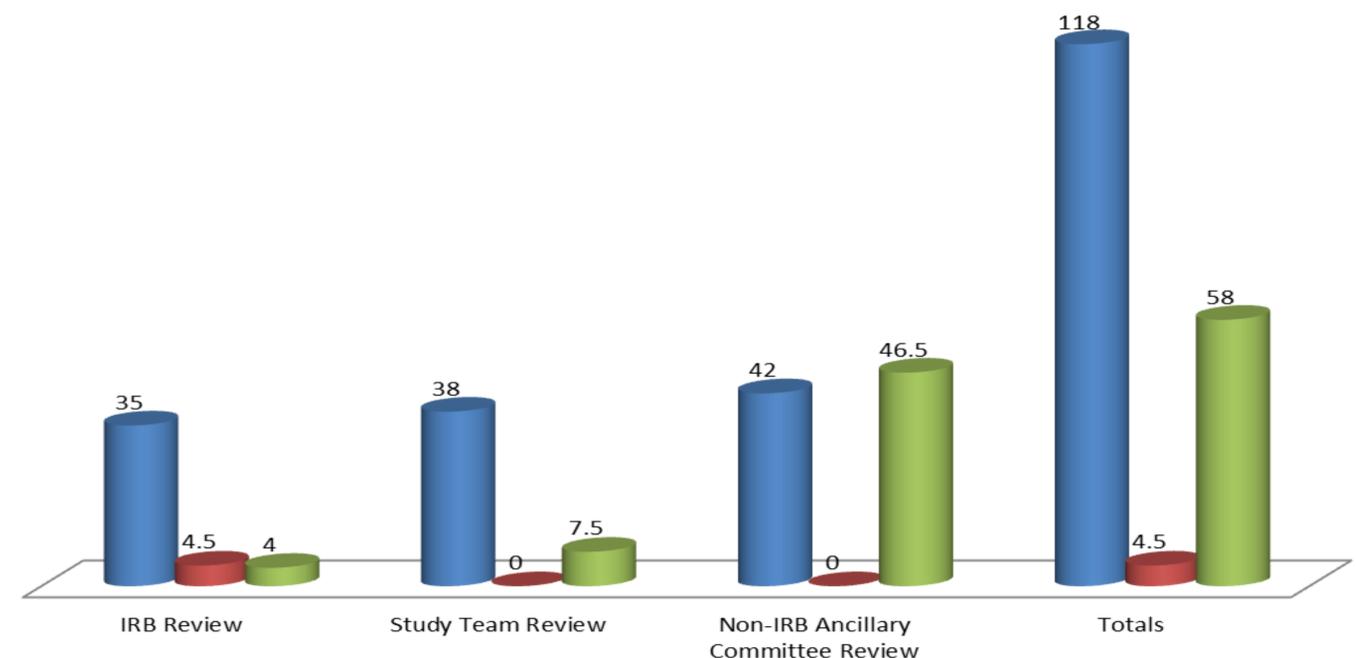
Implementing an ad-hoc IRB to support an Rapid Activation Process requires institutional leadership support and alignment with other entities involved in the protocol activation process. Ongoing communication, coordination of required tasks, and commitment from the Sponsor to provide timely response to inquiries, are required in order for the overall Rapid Activation Process to be successful.

STUDY ACTIVATION: RAPID IRB REVIEW vs. STANDARD PROCESSING

Turnaround Milestone in Calendar Days

(0 = <1 day)

Standard (avg Q1, 2012) Rapid Study 1 Rapid Study 2





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