Comments from the Perspective of a Human Research Protections Program that Maximizes Opportunities to be Flexible and Innovative

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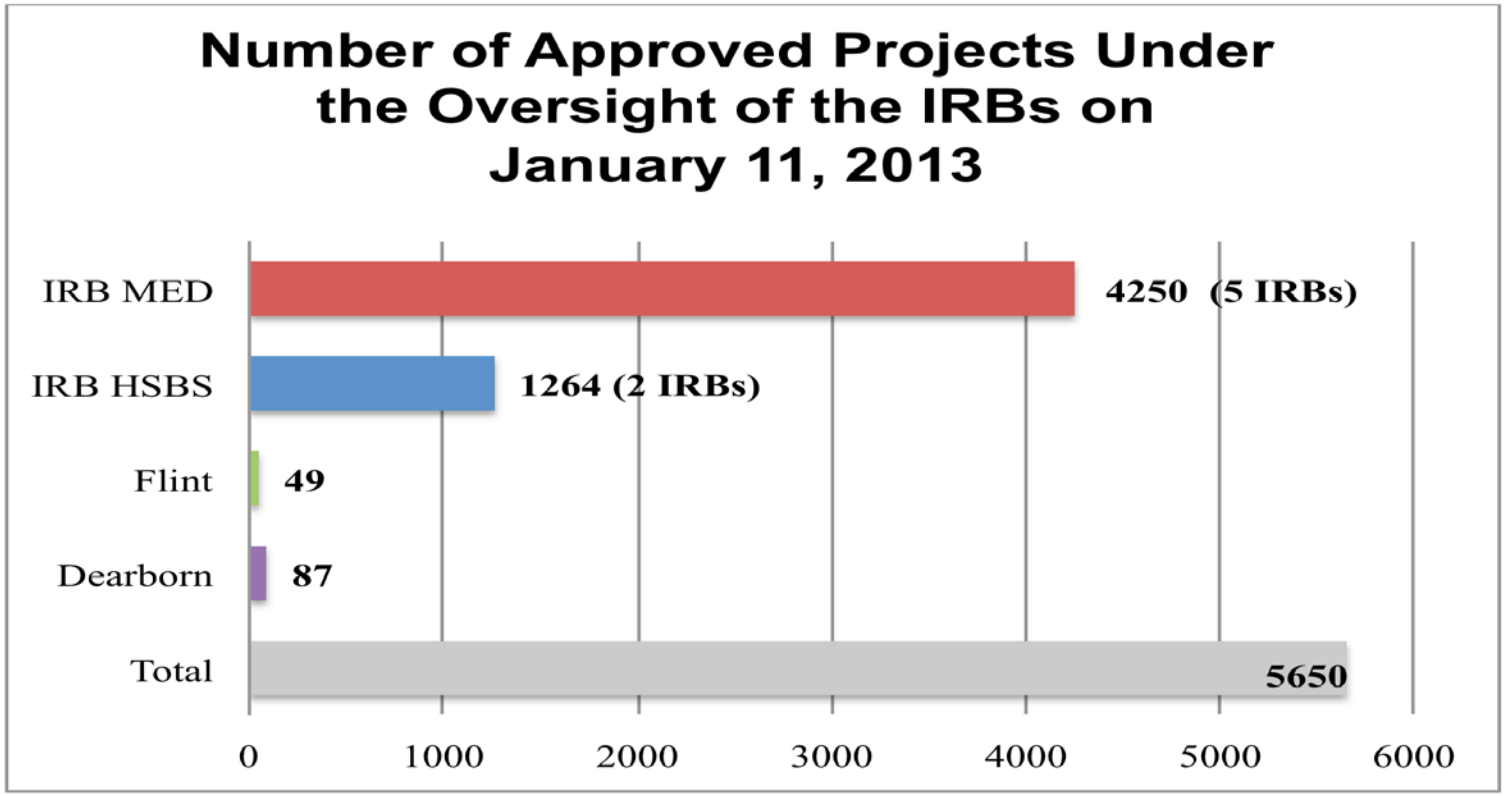
Background on the U-M HRPP

The University of Michigan is committed to continual improvement of its Human Research Protection Program (HRPP) and to utilizing the maximum amount of flexibility allowed under the current regulations.

Since 2005 we have been using an electronic application and information management system that allows us to track and monitor projects.

Within our HRPP we have a post-approval monitoring office that conducts routine and for-cause reviews of human research projects, provides reports on special topics we identify as needing improvements, and together with U-M's Survey Research Center, completed two IRB customer satisfaction surveys.

U-M IRB Indicators

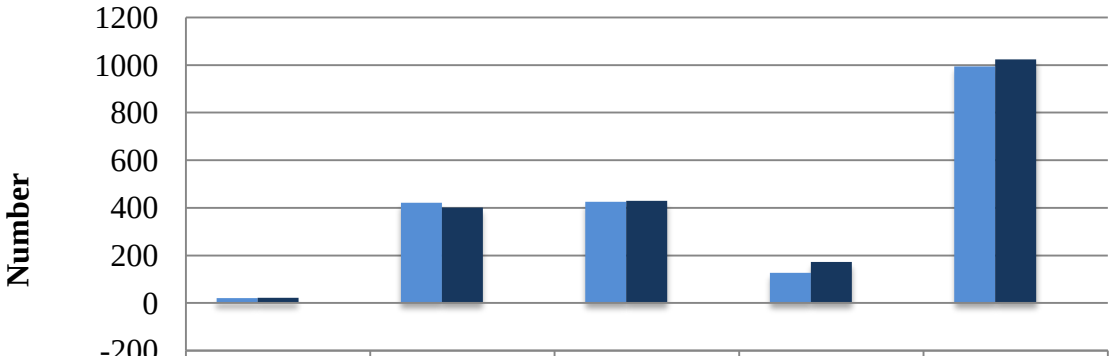


http://www.hrpp.umich.edu/Indicators_Report_January_2013_Final.pdf

IRB Health Sciences and Behavioral Sciences

IRB-HSBS: New Submission

Number of Decisions by Type



	Full Committee	Expedited	Exempt	Not Regulated	Total
2011	21	422	425	127	995
2012	22	401	429	172	1024
% Change	5%	-5%	1%	35%	3%

99% MR, 30% Student Research

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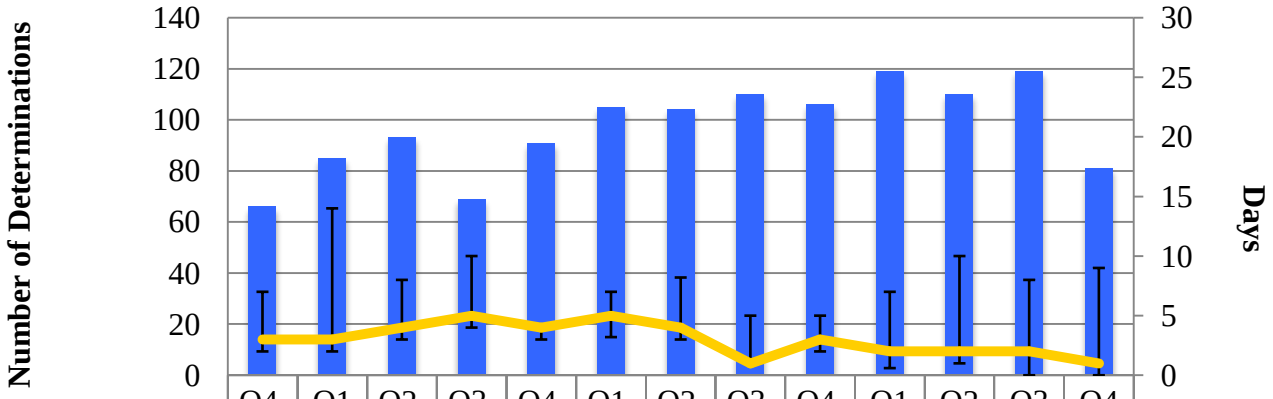
Flexibility Utilized by U-M's IRBs

U-M strives to take full advantage of the flexibility in the regulations, including:

- Limiting the scope of Federalwide Assurance ("unchecking the box")
- Only regulating research that meets the definition of human research (don't over-regulate)
- Granting exemptions by IRB staff reviewers
- Utilizing and streamlining expedited review
- Utilizing waivers or alteration of informed consent and waivers of documentation of informed consent
- Establishing cooperative research review arrangements to avoid duplicate review

U-M IRB-HSBS Exempt Turn Around Time

IRB-HSBS: New Submission Decisions
Exempt Determinations and Median Turn Around Time (TAT) in Days
with 80th/20th percentile I-bar for TAT



	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Q1 2012	Q2 2012	Q3 2012	Q4 2012
Determinations	66	85	93	69	91	105	104	110	106	119	110	119	81
TAT	3	3	4	5	4	5	4	1	3	2	2	2	1

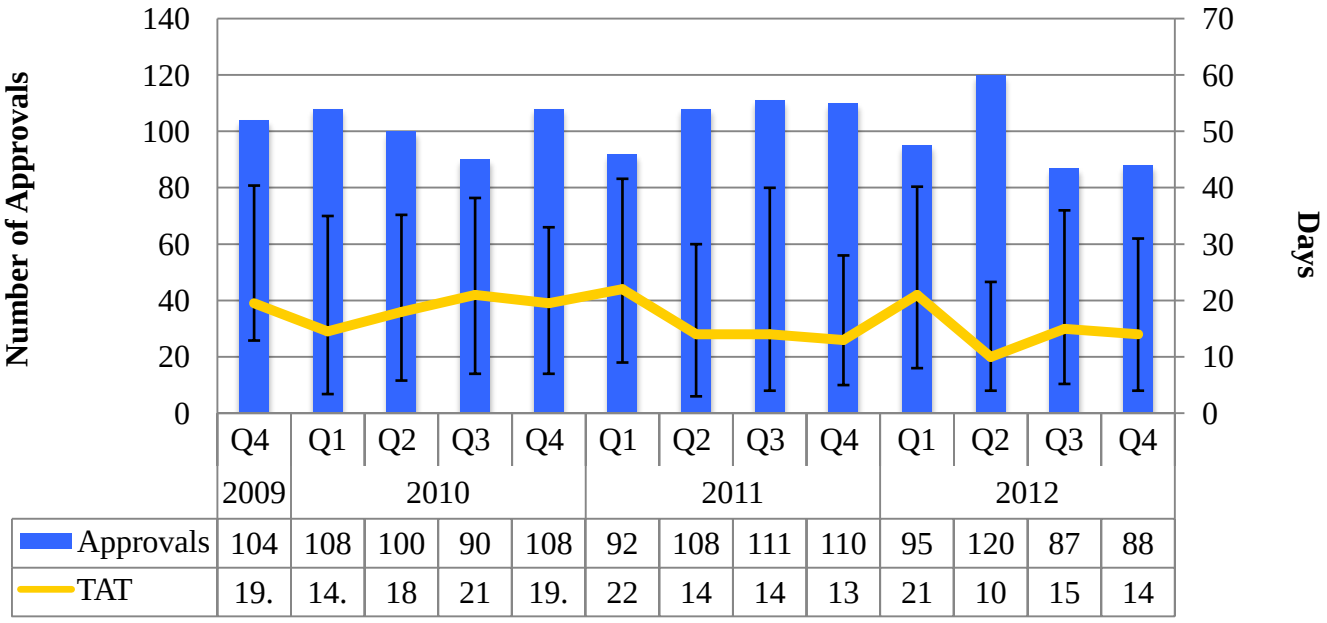
http://www.hrpp.umich.edu/Indicators_Report_January_2013_Final.pdf

U-M IRB-HSBS Expedited Turn Around Time

IRB-HSBS: New Submission Decisions

Expedited Approvals and Median Turn Around Time (TAT) in Days

with 80th and 20th percentile I-bar for TAT



	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Q1 2012	Q2 2012	Q3 2012	Q4 2012
Approvals	104	108	100	90	108	92	108	111	110	95	120	87	88
TAT	19.	14.	18	21	19.	22	14	14	13	21	10	15	14

http://
www.hrpp.umich.edu/Indicators_Report_January_2013_Final.pdf

Innovative Practices

Since 2007, U-M's IRB-HSBS has conducted demonstration projects to provide additional flexibility and reduced administrative burden for certain types of minimal risk research: http://www.hrpp.umich.edu/initiative/demonstrations.html

- Demonstrations:
  - 2-year approval
  - exemption for secondary data analysis with identifiers

These demonstrations have been adopted by a number of institutions, including members of the Flexibility Coalition.

http://www.usc.edu/admin/oprs/flex

Exempt vs. Excluded (or “Registered”)

“For most studies in which risks are primarily informational, research could begin immediately after the study is registered through a one-page form, accompanied by a commitment to observe data-security measures” *(Emanuel & Menikoff, NEJM, 2011)*

ANPRM proposal:

- Short “one page” application
- No review required before initiating research, but data security check
- Random audit to find problems

Current U-M exemption process:

- Short application
- Reviewed by a IRB staff specialist (No review of consent)
- One to 2-day turnaround time for approval

Exempt vs. Excluded (or “Registered”)

Recommendations:

- Use the term “Registered” rather than “Excluded”
- Allow investigators to self-determine exemption status through the use of standardized tools (e.g., decision trees, exemption wizards, smart forms) to automate the process
- Maintain an institutional screening process to validate exemption status prior to the initiation of research
- The IRB should continue to review ethical concerns related to the protection of privacy and confidentiality, but should be able to rely on institutional resources such as IT experts for the evaluation of data security

Exempt vs. Excluded (or “Registered”)

Suggestions for new exemption categories:

- Social networking
- Human testing of technology
- Analysis of secondary data with identifiers (Expedited # 5)
- Minimal risk deception research
- Collection of data from voice, videos, etc. (Expedited # 6)
- Group characteristics – surveys, interviews (Expedited # 7)

Expedited Review for Minimal Risk Projects

"The list of research activities qualifying for expedited review would be regularly updated as empirical data are accumulated."

(Emanuel & Menikoff, 2011)

Recommendations:

- New categories should be created by a panel of experts including researchers, particularly social scientists, IRB members and chairs, IRB administrators, and non-scientific IRB members, and updated frequently.

- Allow IRB to use expedited procedures for any additional activities determined by the IRB to be minimal risk.

Expedited Review for Minimal Risk Projects

Some suggestions for additional expedited categories listed in the CoGR response:

- Occupational health activities such as walking, deep breathing, mild exercise
- FMRI at standard exposure levels
- Studies of Internet behavior
- Establishment of registries for future research purposes

See SAS March 12-13, 2013 SACHRP presentation

http://www.hhs.gov/ohrp/sachrp/mtgings/index.html

Elimination of Annual Review

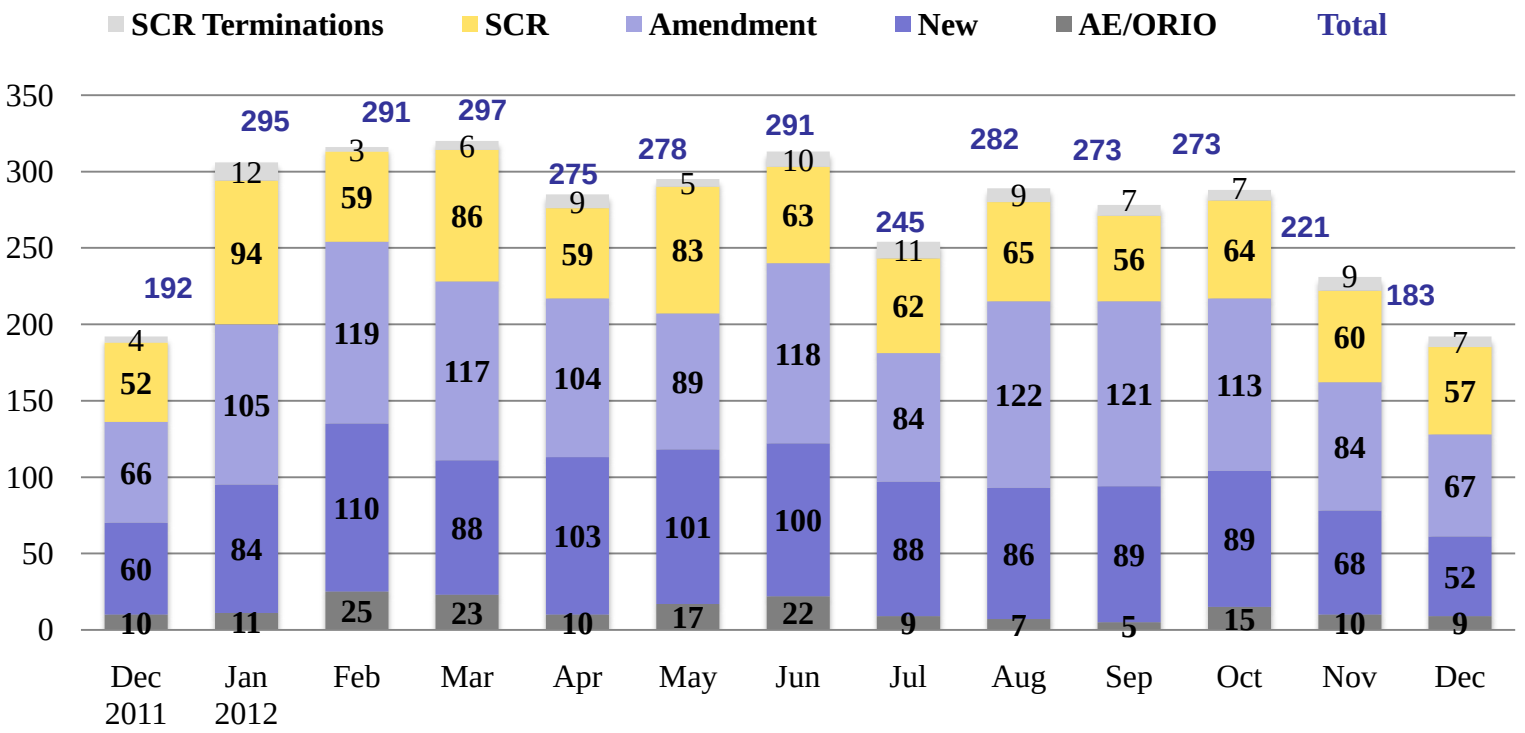
"For research posing minimal risk, no annual review would be required unless a reviewer explicitly justified the request for such a review." *(Emanuel & Menikoff, 2011)*

Recommendation:

We support changing the regulations to eliminate the current processes of continuing review (e.g., eliminating annual review for qualifying minimal risk studies), but this should be accompanied by clear guidance and examples of what IRBs would no longer be required to do.

U-M IRB-HSBS Monthly Workload

IRB-HSBS: 2011-2012 Monthly Submissions by Submission Type



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Review of Multisite studies

"Only a single IRB of record would be allowed for the oversight of all domestic sites" (Emanuel & Menikoff, 2011)

Recommendation:

We support a movement to reduce duplicate review by multiple IRBs, but we do not support a mandate for requiring only single IRB review in all cases.

Clarifying and Harmonizing Regulatory Requirements and Agency Guidance

"*The need for a mechanism intended to harmonize guidance across federal agencies would be evaluated.*" *(Emanuel & Menikoff, 2011)*

Comments:

Inconsistencies in guidance from different agencies (e.g. FDA, DOD, DOJ, DOE, EPA, NSF, etc.) weaken human subject protection by distracting researchers and IRBs from more important considerations. These inconsistencies also inhibit research by slowing the IRB review process and by confusing and intimidating researchers.

However, we caution against an attempt to "harmonize" by applying a one-size-fits-all approach to differing types of research can often result in an unfavorable cost-benefit ratio. We advocate that due consideration be given to creating a single, multi-agency regulatory standard that calibrates its provisions to the nature and magnitude of each risk it addresses.

Proposed Changes that Would Increase Burden

- Requiring all human subjects research at institutions receiving Common Rule funding to be subject to federal oversight
- Mandating institutional data security and information protections whenever data are collected, generated, stored, or used
- Expanding the meaning of “human subjects” by including biospecimens without identifiers within the provisions related to information risk and requiring written consent for research use of de-identified biospecimens
- Requiring records of AEs and UaPs to be submitted and stored in a central database
- Adding data collection requirements to enhance system oversight

Informed Consent

"*The goals of the changes in the treatment of informed consent would be to specify more explicitly the content of consent documents, limit the length of the documents, simplify and streamline institutional boilerplate, promulgate the use of standardized consent documents, and permit the use of oral consent for survey, focus groups, and interviews conducted with competent adults, even if identifiers are retained.*" *(Emanuel & Menikoff, 2011)*

Comments:

We agree that the process of informed consent can be improved. Consent documents can be greatly simplified by focusing on the research activities, the risks imposed by the experimental component, potential benefits of the research, and burdens (financial, time commitments, alterations in medical care if any, etc.) imposed by participation in a research project.

Summary

We agree that the Common Rule is in need of revision.

We strongly support several proposed changes in the ANPRM that clearly reduce burden, including

- Less stringent review for low risk studies,
- Elimination of the requirement of annual review, and
- Harmonization of regulations across funding agencies, provided the harmonization does not increase burden.

We also believe that in some cases, clear and concise guidance, rather than changing the regulations, could accomplish more to assist investigators, institutions, and IRBs to better protect research participants.

We are particularly concerned about some proposed changes that seem to shift the burden rather than reduce burden. Before implementation of changes, clear delineation of the roles and responsibilities of the investigator, the IRB, and the institution are needed.

HRPP Change Agents at U-M

My colleagues who are the innovators and demonstrators:

Judy Nowack, now retired, former AVP and DIO for U-M's HRPP

Judy Birk, Director IRBMED, former Director IRB-HSBS

Cindy Shindledecker, Director IRB-HSBS

David Mulder, Assistant Director Research Administration Systems

Questions and Discussion