Town Hall Meeting

November 18, 2022
10:00 - 11:00 AM

We'll start shortly...
Covid-19 Update – 11/18/2022

David Strick, Ph.D.
Director of Safety & Emergency Management
Agenda

- Current Cases in Santa Clara County/Stanford
- Current Masking Guidance
- Notifications
- Testing
- What to do if you test positive
Current Cases:

Santa Clara County COVID-19 Cases Dashboard
Last updated on November 14, 2022.

Cumulative COVID-19 Cases: 441,477
7-Day Rolling Average of New Cases: 229

Cases by Specimen Collection Date

Stanford COVID Dashboard - Staff, Faculty and Postdocs
Last updated on 11/1/2022

Cumulative tests conducted: 519,550
Cumulative positive tests: 3,339
Positivity rate (%): 0.64

Data Filter
Last 6 months

Stanford Testing Metrics (Latest 6 months)

Weekly tests conducted vs. positive tests (as per week)

Timeline: Since Dec 3, 2021 (start of tracking *)

Metrics:
- BA.1 Omicron (PMV)
- BA.4 variant (PMV)
- BA.5 Omicron (PMV)
- BA.2.12.1 (PMV)
- BA.4.6 (PMV)
- BA.4.6.1 (PMV)
- BA.5.1 (PMV)
- BA.2.75 (PMV)

CODIGA (Stanford University)
Middle-Career Women (MCW), and race/ethnic-specific (e.g., BA.4 with Asian women)

Confidential
Masking

• Optional in our Research Laboratories
• Optional on Marguerite Busses
• Required as per the Instructor/School for the course
• Continue to required in Healthcare Facilities
Notifications

• AB685 is still in effect until January 1, 2023

• University is evaluating AB2693.

• Notices are sent to the OFPM building mailing list. If you are not receiving notifications, please use our mailman addition form at:

https://docs.google.com/forms/d/e/1FAIpQLScSaZ0zKQozM7jy84eVjY6WHvq uQDRBZSF23DH7EFp7M0jRQ/viewform
Thanksgiving Holiday Hours

EH&S, AFDC, and LKSC sites will be closed on Thu 11/25 and Fri 11/26.

Dropbox Schedule:

Wed 11/23: Drop samples by 10 am
Thu 11/24: No courier pickups
Fri 11/25: Courier pickup at 12 pm
Sat 11/26: Courier pickup at 5 pm
Sun 11/27: No courier pickups
I’m positive for Covid – what do I do

• Enter your positive test into healthcheck.stanford.edu
• Include the positive test date.
• Include your contacts in the 48 hours before you became symptomatic or 48 hours before testing positive if you are asymptomatic.
• Include what buildings you were present and the dates
• Include date your symptoms started.

• Healthcheck will issue you a return-to-work date.
• Medical support team may call.
• Return to work for individuals with hospital duties is different from the University. HRT
• All of this information applies to (My husband/wife/partner is positive with Covid)
Reporting requirements if you have clinical duties

If you have clinical duties at SHC

Positive Intake Questionnaire (smartsheet.com)
The NIH Data Management and Sharing Policy:
Updates and Services

John Borghi, PhD
Manager, Research and Instruction
Lane Medical Library

Scott Edmiston, JD, CIPP/US
Research Data Governance and Privacy Director
Vice Provost and Dean of Research

Contact John: jborghi@stanford.edu
Contact Scott: scotted@stanford.edu
Links and Resources

Online Resources

• NIH’s Data Sharing Page
• FORMS-H: Instructions, Forms, and a Handy Checklist
• Responding to the NIH Data Management & Sharing Policy (Library Guide)
• NIH Data Management and Sharing FAQs (VPDOR)

SPORR Colloquium and Help-a-thon (January 23rd)

Stanford DMP Service

Workshops and Discussion

• Bay Area Open Science Group – New Federal Open Science Policies (11/29)
• Understanding NIH Data Management and Sharing Requirements (12/6)
Today’s Agenda

The NIH DMS Policy
1. Policy Basics
2. Data Management and Sharing Services
3. Preparing for the Policy
4. Q&A
The 10,000 foot view

Proposals received by NIH after January 25\textsuperscript{th}, 2023 will require:

1. **Submission of a Data Management and Sharing Plan (DMSP)** outlining how scientific data and any accompanying metadata will be managed and shared while taking into account any potential restrictions or limitations.

2. **Compliance with the awardee’s plan as approved by the NIH ICO.** The contents of the DMSP will be incorporated into the Terms and Conditions of the award. Compliance will be monitored as part of the RPPR process.

**Read the full NIH DMS Policy**

- Elements of an NIH Data Management and Sharing Plan
- Allowable Costs for Data Management and Sharing
- Selecting a Repository for Data Resulting from NIH-Supported Research
- Protecting Privacy When Sharing Human Research Participant Data
- Implementation Details
Defining our Terms

**Data Management** - The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

**Data Sharing** - The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.

The DMS Policy is NOT a blanket “open data” policy, but researchers will be asked to be specific about what restrictions on sharing pertain to their data and why.
Data Management

• An essential first step in effective data management is planning.

• Under the DMS Policy, NIH requires researchers to prospectively plan how they will manage and share their data. Then communicate their intended practices and strategies through the completion of a data management and sharing plan (DMSP).
  – DMSPs are short (2 pages or less) documents that outlines how data will be managed, preserved, and made available to others.
  – DMSPs will be evaluated by NIH program staff to ensure that all required elements have been addressed. Peer reviewers will generally not see the DMSP and it will generally not be factored into the impact score.
  – Make sure to carefully read the funding opportunity announcements for more information about what should be included in the DMSP and how they will be evaluated.
Writing a DMSP

- There are six required elements that must be covered in a DMSP
  - Data types
  - Related software and code
  - Standards
  - Data preservation
  - Use limitations
  - Roles and responsibilities

- NIH has provided a formatting guide for DMSPs, but researchers are not required to follow it.

- DMPTool can also be used to format effective plans
Stanford DMP Service

• Co-run by Lane Library and Stanford Libraries, the Stanford DMP Service is designed to provide a point of entry for researchers who want assistance with:
  1. Understanding data-related policies
  2. Writing effective data management and sharing plans
  3. Implementing data management and sharing-related practices and strategies

• This service is free of charge and open to all Stanford-affiliated researchers.

DMP Service Intake Form

Please enter your SUNet ID below:

We will only use this information to contact you and for internal tracking purposes.

If you have a preferred e-mail address other than your SUNet ID, please enter that below.

If applicable, please enter the name or the SUNet ID for the PI on the project related to your question.

Within which school at Stanford is your primary appointment?

- The Graduate School of Business
- Stanford Doerr School of Sustainability
- Graduate School of Education
- School of Engineering
- School of Humanities & Sciences
- School of Law
- School of Medicine
- Other (please enter) [ ]

What can we help you with?

- I need help understanding data management and sharing-related policies from a funding agency.
- I need help understanding data management and/or sharing-related policies from a scholarly publisher.
- I need help understanding what to include in my data management plan.
- I need help writing or reviewing my data management plan.
- I need help with data management and sharing more generally.
- Other (Please enter) [ ]
Stanford DMP Service

Members of the DMP service will:

• Provide their expertise in data management-related practices and strategies to help Stanford researchers create and implement data management plans that meet or exceed the expectations outlined by their funders.

• Refer clients to other campus services and offices for questions specific to those areas.

• Stay current on data-related requirements and changes to policies for major federal funding agencies.

• Provide self-service guidance.

• Share sample DMSPs (with permission, of course)
Stanford DMP Service

Members of the DMP service will NOT:

• Write data management and sharing plans on behalf of research teams of which they are not an active part.
• Provide technical support for setting up data management systems specified in data management plans, except as part of the technical support we already provide for library-related services.
• Create metadata.

• We request that you reach out to us in as early as possible so that we can provide you with the help you need well before your grant is due.
Data Sharing

• In terms of what data should be shared, the DMS policy does not give a specific answer. However, one can be inferred from how it defines “scientific data”

• “Scientific Data”
  – “The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."
  – Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
Data Sharing

• NIH expects that in drafting their plans, “researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared”.

• For some programs and data types, NIH ICOs may have specific data sharing expectations (e.g., scientific data to share, relevant standards, the use of specific repositories, timelines) that apply and should be reflected in a DMSP.
  – NIH encourages data management and sharing practices to be consistent with the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles and reflective of practices within specific research communities.
  – The current list of data sharing policies at NIH is available from Sharing.NIH.gov.
Sharing Human Subjects Data

In developing a Data Management and Sharing Plan for NIH-funded or supported research, it is paramount that researchers uphold the following principles.

1. Proactive assessment of protections
2. Clear communication of data sharing and use in consent forms
3. Consideration of justifiable limitations to sharing data
4. Institutional review of the conditions for data sharing
5. Protections for all data used in research
6. Remaining vigilant regarding data misuse

Allowable Costs for Data Management and Sharing
Sharing Human Subjects Data

NIH acknowledges there are multiple, effective strategies for achieving privacy protection in the context of the DMS Policy. The following represent best practices.

1. Apply appropriate de-identification.
2. Establish scientific data sharing and use agreements
3. Understand and communicate legal protections against disclosure and misuse
Data Repositories

• Whenever possible, NIH strongly encourages that data be shared through an established data repositories.
  • Discipline or data-type specific repositories are preferred when available.
  • NIH is supporting generalist repositories through the Generalist Repository Ecosystem Initiative (GREI)

• To find the right repository for your data, check Re3Data or NIH’s criteria for data repositories and follow the flowchart to the right.

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Do the groups that fund or publish your work specify where your data should be shared?

- YES: Put your data in the repository specified by the funding agency or publisher.
- NO: Put your data in the repository used by your research community.

Do researchers who work with similar data as you share it in a specific place?

- YES: We recommend sharing via: DRYAD
- NO: Contact Lane Library and we can direct you to the appropriate resources on or off campus.

Are there particular characteristics of your data that affect how it can be shared?

- YES: We recommend sharing via: DRYAD
- NO: Contact Lane Library and we can direct you to the appropriate resources on or off campus.
The Dryad Data Repository

Log in with your ORCID iD - https://datadryad.org/

For a first time login, select “Stanford” and enter your SUNet.

- Through Lane Library, Stanford is a member of the Dryad Community. This means Stanford researchers can deposit their data free of charge.

- Dryad is a member of the NIH Generalist Repository Ecosystem Initiative, which seeks to improve discoverability and usability for NIH funded datasets.

- Data is curated by experts to increase discoverability and ensure uploads do not contain sensitive information.

- Though Dryad has many excellent features it is not suitable for restricted data.
Preparing for the DMS Policy

Five Steps to Take as You Write Your Next NIH Proposal
1. Describe your data

The first step in understanding how to manage and share the data related to a particular project is to describe its characteristics.

- Be as thorough as possible in describing the size of the data you’ll be working with, its format (or formats), its contents, and what additional materials (documentation, code, etc) are necessary to make use of it.

- Probably many of these details will not make it into your DMSP, but they’ll help you decide how everything should be organized, stored, and described.
2. Determine what you can do

Whenever possible, the DMS policy recommends sharing data through an established data repository.

• However, if your data has particular characteristics (e.g. it is particularly large, contains sensitive information that can’t be deidentified without compromising utility, or is subject to IP-related concerns), how and what you share may look very different.

• Understanding if and how you will ultimately make data available at the latter stages of a project will help you choose the specific strategies, practices, and procedures you will need to implement at earlier stages.
3. Reach out to local expertise

Understanding the constellation of issues, practices, and technologies related to data management and sharing is not always easy.

• Reach out to the Stanford DMP Service.
• Schedule a consultation or join a free workshop with Lane Library.
• Come to the help-a-thon at the SPORR Colloquium in January.

• This is not at all an exhaustive list. Please reach out!
4. Write your DMSP

Once you have described your data, thought about how you might make it available, and connected with local resources, completing your data management and sharing plan should be more straightforward.

- Refer to related guidance and use the DMPTool, which is free and accessible using your Stanford credentials, to make this process as easy as possible.
- Lane Library also maintains a DMSP checklist for your reference.
- Please get in touch with the Stanford DMP Service as early as possible.
Creating a data management plan for a grant proposal is really just the beginning.

• Once funded, you will be held to the contents of your plan. This requires implementing strategies and practices throughout your entire research workflow.

• For more information, see Lane’s Data Management and Sharing Guide and our Data Management Checklist.

Contact John: jborghi@stanford.edu
Contact Scott: scotted@stanford.edu
Research Ethics Consultation Program

David Magnus, PhD
Thomas A Raffin Professor of Medicine and Biomedical Ethics and Professor of Pediatrics and Associate Dean of Research

Mildred Cho, Professor of Pediatrics and Associate Director for Research of the Stanford Center for Biomedical Ethics
DIAL ‘E’ FOR ETHICS

Facing a moral dilemma in the lab? No reason to panic. Helen Pellicer meets the academic troubleshooters who promise a quick answer to any ethical problem.

Sometimes, researchers find themselves in a research project before an ethical dilemma; simply, itself. This was the case for Helen Pellicer, a researcher at the Stanford School of Medicine in California. At some point during the study, she began recruiting children for a genetic study of autism, but realized that they couldn’t agree what to do with the parental consent. This is an example of the life that can be cruelly and suddenly thrown into a great, but one

Pellicer then turned to the Association for Research in Nuremberg, a group that provides advice on ethical issues that arise in research. But she found that the process was quite different from what she expected. "They were very helpful, but not in the way I had anticipated," she said.

"It’s sometimes difficult to know what information is dangerous," said Pellicer. The researchers at the Association for Research in Nuremberg helped Pellicer navigate through the ethical issues of her study. They advised her to have a clear protocol for handling any potential ethical issues, and to involve ethicists and other experts early in the process.

In the end, Pellicer was able to obtain ethics approval and move forward with her study. "We were able to do it in a way that was ethical and also beneficial to the participants," she said.

Pellicer is just one example of the work that these ethical resource centers do. They provide advice on a wide range of issues, from the use of animal models in research to the handling of sensitive data.

"We’re here to help researchers navigate the ethical landscape," said Pellicer. "Our goal is to help them make the best decisions for their studies and their participants."
History at Stanford

Began with funding as part of a P50 Center for Excellence in ELSI Genomics 2005

Became a core part of the CTSA funding of Spectrum since launch of the grant

Stanford an early pioneer and leader in development of research ethics consultation

Now over 60 consult services nationally and national group that meets regularly, publishes cases in *the American Journal of Bioethics*
Covers wide range of activities

**Assist in**
- Assist in research design (e.g., how to deal with incidental findings)

**Help**
- Help draft responses to funding agency with ethical questions

**Advise on**
- Advise on ethical literature on a topic

**Publish on**
- Publish on a difficult and controversial topic that requires extensive research (e.g., ethical issues in ambient intelligence research)
Strangers at the Benchside: Research Ethics Consultation

Mildred K. Cho, Stanford Center for Biomedical Ethics
Sara L. Tobin, Stanford Center for Biomedical Ethics
Henry T. Greely, Stanford Center for Biomedical Ethics
Jennifer McCormick, Stanford Center for Biomedical Ethics
Angie Boyce, Stanford Center for Biomedical Ethics
David Magnus, Stanford Center for Biomedical Ethics

In Strangers at the Benchside, David Rothman describes the social and technological changes in the practice of medicine in the United States (US) that have led to the involvement of beneficiaries, lawyers, judges, and others into the medical decision-making process that was once solely the domain of the physician (Rothman 1991). For instance, the introduction of new technologies or such as organ transplantation raised ethical and legal issues that seemed for the first time to require a broader community of physicians and other individuals with professional and lay backgrounds to address the needs of society. This has raised important ethical questions about the role of ethics consultation in helping to mediate the needs of patients, families, and society.

We are witnessing a similar phenomenon in biomedical research. New technologies, including cloning, stem cell research, and genetic engineering raise new issues and new concerns in the public, all of which are addressed by the inclusion of a wide range of voices.

The interactions between science and society have long been a source of tension. Potential conflicts have been overcome generally through the scientific community and whether they should be evaluated strictly on the basis of a science-based risk assessment or whether other values should be taken into consideration. Prudent debates over such research raise a wide range of attitudes from proponents of research to those favoring bans. Even the recommended guidelines for human embryonic stem cell research issued by the National Academies (Washington, DC) explicitly consider both ethical and social concerns. The public response to the announcement of the cloning of Dolly the sheep created a new era in the relationship between science and the public, one in which the biomedical ethics community can provide commentary and mediation.

It is increasingly clear that a reactive biosafety that responds to scientific developments after they have taken place is not optimal to meet the needs of either the public or the scientific community (Cho et al. 1999). This article proposes a collaborative process in which the research community and society can work together to ensure ethical research. To date, the approach taken to ethical issues in scientific research has been largely ad hoc and reactive, with little in the way of systematic procedures for addressing the ethical implications of research. The article concludes with a discussion of the need for a more proactive and participatory approach to ethical research.

BACKGROUND: ETHICS IN RESEARCH

In the US, several methods have been tried to incorporate ethical concerns in research. In the 1980s, institutional review boards (IRBs) became the first major portion of formal ethics review into research. Other mechanisms have since been implemented that have brought in other "strangers" to the benchside, such as the National Institutes of Health (NIH), the Department of Health and Human Services (HHS), and the Office of Research Integrity (ORI). These mechanisms have been designed to address specific ethical issues in research.
Research Ethics Consultation: The Stanford Experience


Although bioethicists and institutions have long provided ethics consultations on an individual basis, research ethics consultation is still a relatively new concept as an institutionalized service and has been limited primarily to consultation for clinical researchers. With the recent initiation of the Clinical and Translational Science Award (CTSA) program by the National Institutes of Health (NIH), most of the 38 CTSA medical institutions are expected to establish some type of formal ethics consultation service designed to facilitate clinical and translational research. As more CTSA awards are made, a rapid increase in the institutionalization and use of research ethics consultation services is likely. Yet, while there is increasing recognition of the potential value of such services, little systematic analysis has been conducted on the few programs that currently exist. We present here baseline data covering nearly two years of research ethics consultations at our institution to provide an overview of how the Stanford model has evolved, what consultation teams have learned, and how core functions have been carried out and evaluated.

Background and Data Collection

In November 2005, the Stanford Center for Biomedical Ethics established the Benchside Ethics Consultation Service for clinical and basic scientists. The service has been funded in part by a CEER (Center for Excellence in Ethical and Social Implications Research) grant supported by the National Human Genome Research Institute (NHGRI) and the U.S. Department of Energy (DOE), which established the Center for Integration for Research on Genomics and Ethics (CIRCLE). CIRCLE is located within the Stanford Center for Biomedical Ethics (SCBE) and provides administrative support and partial salary support for consultants.

We envisioned the Benchside Ethics Consultation Service as a pilot program that was initially prompted by unanticipated research requests. We included the “benchside” descriptor to show that it was not limited to clinical researchers and to distinguish it from “deskside” ethics consultation in the hospital. The service’s goals are to integrate ethical consider-
Research Ethics Consultation: Ethical and Professional Practice Challenges and Recommendations

Richard S. Sheep, PhD, Holly A. Tabor, PhD, MH, Margaret A. Binotch, Mary M. Boyle, MH, Mildred Chiu, PhD, Marilyn Coors, PhD, Marlene Davis, MD, Molly Howard, MS, Chad Magnus, PhD, and Benjamin Whipple, MD

Abstract

The complexity of biomedical research has increased considerably in the last decades, as has the pace of translational research. This complexity has necessitated a number of novel ethical issues for clinical investigators, institutional review boards (IRBs), and other oversight committees. In response, many academic medical centers have created formal research ethics consultation (REC) services to help clinical investigators and IRBs navigate ethical issues in biomedical research. Key functions of a REC service include assisting with research design and implementation, providing a forum for deliberative exploration of ethical issues, and supplying regulatory oversight. As increasing numbers of academic research institutions establish REC services, there is a pressing need for consensus about the primary aims and policies that should guide these activities. Establishing clear expectations about the scope and policies of REC services is important if REC programs are to achieve their full potential. Drawing on the experiences of a Clinical and Translational Science Award Research Ethics Consultation-Working Group, this article describes three major ethical and professional practice challenges associated with the provision of REC: (1) managing multiple institutional roles and responsibilities, (2) managing sensitive interpersonal and communication challenges, and (3) communicating with consultation requestors about how these issues are managed. The paper also presents several practical strategies for addressing these challenges and improving the quality of REC services.

T he complexity of biomedical research has increased considerably in the last decades, as has the pace of translational research. This complexity has necessitated a number of novel ethical issues for clinical investigators, institutional review boards (IRBs), and other oversight committees. In response, many academic medical centers have created formal research ethics consultation (REC) services to help clinical investigators and IRBs navigate ethical issues in biomedical research. REC services are modeled on approaches in clinical ethics, in which specialists in ethics help to address challenging issues in patient care by (1) providing expert analysis of ethical issues and (2) facilitating discussion among health care providers and patients. REC services support clinical investigators and IRBs by analyzing ethical issues in research, offering recommendations and practical strategies for addressing these difficult issues.

Key functions of a REC service include assisting with research design and implementation, providing a forum for deliberative exploration of ethical issues, and supplying regulatory oversight. For example, in studies that involve the collection of biologically relevant materials for future genetic research on high-risk medical interventions for which the selection of an appropriate study population is uncertain, a REC service can assist investigators in navigating the multiple oversight committees that may be involved in clarifying ethical issues for which existing regulatory guidance is limited. Developing thoughtful approaches to ethical challenges in biomedical research can require a significant investment of time, particularly for investigators and IRB members who may not be familiar with recent advances in biomedical science or scholarship in bioethics. REC services provide clinical and translational researchers with access to ethics specialists with the knowledge and experience needed for addressing complex ethical issues in biomedical research.

The establishment of the Clinical and Translational Science Award (CTSA) Consortium created the impetus for more institutions to develop REC. A survey by McCormick and colleagues found that, of the 67 CTSA institutions supported at the time the survey was conducted, 55 (80%) had established REC services. Many of these academic medical centers are in the process of developing REC and are playing an important role in establishing and expanding their REC services.

As increasing numbers of academic research institutions establish REC services, there is a pressing need for consensus about the primary aims and policies that should guide these activities. For example, it may be unclear to institutional leadership how the work of REC services differs from the work of IRBs. Similarly, clinical investigators may not be clear about the types of questions that these services have established to protect the confidentiality of information provided as part of a consultation request.

Without shared expectations among investigators, consultation, and the institutions with which they are affiliated, REC services may be undermined. Alternatively, the advice of REC services may be sought when other institutional resources, such as an IRB or conflict of interest committee, may be more appropriate. Establishing clear expectations about the aims and policies of REC services is important if
COMMENTARY

POLICY

Triggers for Research Ethics Consultation

Molly Havard, Mildred K. Cho, David Magnus*

Research ethics consultation services are designed to help scientists address ethical and societal issues that may not be considered in the context of existing regulatory frameworks, such as institutional review boards. Here, we identify some types of biomedical research for which the research process can benefit from consultation with ethicists.
Triggers

- Is it human subjects research (vs innovative care or QA)?
- Issues in biobanking
- Incidental findings/return of results
- Stem Cell clinical trials
- Interpreting minimal risk in pediatric research
- Early-phase, first in human pediatric trials
- Community engagement (including EfIC)
- Research in Lower resourced settings
- Broad social acceptability issues
- Dual use research of concern
The Emergence of Clinical Research Ethics Consultation: Insights From a National Collaborative

Kathryn M. Porter, Seattle Children's Research Institute
Morlan Davis, National Institutes of Health
Holly A. Taylor, Johns Hopkins Bloomberg School of Public Health
Mildred K. Cho, Stanford University
Benjamin S. Wilford, Seattle Children's Research Institute

on behalf of the Clinical Research Ethics Consultation Collaborative Repository Group

The increasing complexity of human subjects research and its oversight has outrun traditional approaches, as well as institutional review boards (IRBs), to have a forum in which to discuss challenging or novel ethical issues not fully addressed by regulations. Research ethics consultation (REC) services provide such a forum. In this article, we rely on the experiences of a national repository and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Clinical Research Center at the National Institutes of Health to describe and summarize the published REC challenging cases with accompanying ethical commentaries to highlight four contexts in which REC can be a valuable resource. REC modestly (1) investigates broad and novel ethical issues, (2) investigations REC, and other research administrators (e.g., challenging and novel ethical issues, (3) engages and negotiates the increasing challenges of informed consent and risk/benefit analysis, and 4) provides collaborative assistance to create study studies, mitigate conflict within a team, or directly engage with research participants. Institutions that have established, or plan to establish, REC services should work to identify the need for their service and engage in open communication with existing clinical ethics consult services as well as the IRB. While the IRB remains the fulcrum for the ethical review of research, REC can be a valuable service for investigators, regulators, and research participants aligned with the goal of supporting ethical research.

Key words: research ethics, informed consent, Institutional Review Board (IRB), human subjects research, ethics consultation.

In the past five decades, a spate of review and oversight of human subjects research has been established that focuses primarily on institutional review boards (IRBs) and their interpretation and implementation of federal regulations. In 2017, the Department of Health and Human Services issued a revision to the Common Rule, thereby modifying the existing regulatory landscape (S.D. Department of Health and Human Services 2015). However, the new Common Rule will not fully address the increasing complexity of the ethical issues faced by researchers and researchers. Consensus is the number and size of multiple trials, investment in comparative effectiveness research, and advances in genomics and biologics have introduced novel ethical issues that will remain challenging.

Over the last decade, this complex research agenda has prompted researchers, as well as IRBs, to seek a forum in which to discuss novel and novel ethical issues (McCannick et al. 2008). More than three-dozen academic institutions in the United States provide research ethics consultation (McCannick et al. 2013). Cite more research related to ethical and regulatory and administrative, and sometimes research participants, in their navigation of ethical issues related to planning, conducting, interpreting, and disseminating results of research on a self-representing medical practice for managing their clients (Beckow et al. 2009).
Value Added

• As a resource for investigators before and after regulatory review
• As a resource for investigators and IRB’s facing challenging and novel ethical issues;
• To assist with increasing challenges of informed consent and risk/benefit analysis
• As a flexible resource that provides collaborative assistance
<table>
<thead>
<tr>
<th>Specific Research Context</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific context</td>
<td>185</td>
<td>52%</td>
</tr>
<tr>
<td>Pediatric population</td>
<td>63</td>
<td>18%</td>
</tr>
<tr>
<td>Human biological samples</td>
<td>40</td>
<td>11%</td>
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<tr>
<td>Innovative treatment</td>
<td>27</td>
<td>8%</td>
</tr>
<tr>
<td>Randomized control trials</td>
<td>22</td>
<td>6%</td>
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<tr>
<td>International research</td>
<td>14</td>
<td>4%</td>
</tr>
<tr>
<td>Community engaged research</td>
<td>11</td>
<td>3%</td>
</tr>
<tr>
<td>Human stem cells</td>
<td>10</td>
<td>3%</td>
</tr>
<tr>
<td>First-in-human trials</td>
<td>8</td>
<td>2%</td>
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<tr>
<td>Quality improvement research</td>
<td>7</td>
<td>2%</td>
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<tr>
<td>Emergency research</td>
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<td>1%</td>
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<tr>
<td>Issue</td>
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<td>Percentage</td>
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<tr>
<td>----------------------------------------------------------------------</td>
<td>-------</td>
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</tr>
<tr>
<td>Informed consent</td>
<td>175</td>
<td>49%</td>
</tr>
<tr>
<td>Research/clinical practice relationships</td>
<td>57</td>
<td>16%</td>
</tr>
<tr>
<td>Benefit/risk assessment</td>
<td>57</td>
<td>16%</td>
</tr>
<tr>
<td>Subject selection/recruitment</td>
<td>49</td>
<td>14%</td>
</tr>
<tr>
<td>Disclosure of incidental findings/research results</td>
<td>41</td>
<td>11%</td>
</tr>
<tr>
<td>Privacy/confidentiality</td>
<td>40</td>
<td>11%</td>
</tr>
<tr>
<td>Study design</td>
<td>39</td>
<td>11%</td>
</tr>
<tr>
<td>Research integrity</td>
<td>37</td>
<td>10%</td>
</tr>
<tr>
<td>Legal</td>
<td>36</td>
<td>10%</td>
</tr>
<tr>
<td>Undue influence/exploitation</td>
<td>30</td>
<td>8%</td>
</tr>
<tr>
<td>Socially or economically vulnerable subjects</td>
<td>28</td>
<td>8%</td>
</tr>
<tr>
<td>Conflict of interest</td>
<td>21</td>
<td>6%</td>
</tr>
<tr>
<td>Community considerations</td>
<td>21</td>
<td>6%</td>
</tr>
<tr>
<td>Communication of findings</td>
<td>19</td>
<td>5%</td>
</tr>
<tr>
<td>Broader social impact</td>
<td>13</td>
<td>4%</td>
</tr>
<tr>
<td>Ancillary care</td>
<td>11</td>
<td>3%</td>
</tr>
<tr>
<td>Study withdrawal/termination</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 2. Specific ethical concerns in research ethics consultations (N = 359).
Co-publishing
## Limitations of Regulation

<table>
<thead>
<tr>
<th>Origins of regulation</th>
<th>Focus on risks to subjects, not society</th>
<th>What IRB’s do</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Helsinki</td>
<td></td>
<td>• Risks to subjects are minimized</td>
</tr>
<tr>
<td>• Belmont</td>
<td></td>
<td>• Risks are reasonable in relation to anticipated benefits</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Informed Consent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Equitable subject selection (at least in principle)</td>
</tr>
</tbody>
</table>
What IRB’s don’t do

• Common Rule 45 CFR 46.111 (a)(2)
• “The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”
• Downstream impact of research is outside of the purview of the IRB (including dual use implications)
What IRB’s/Regulations don’t do

Regulations do not specify how to address long term societal impact

Regulations leave many issues unaddressed---e.g., what results from research should be returned

Issues of equity and justice often ignored by IRB’s
How to call a consult

• becs-spectrum@lists.stanford.edu
COVID-19 Fund to Retain Early-Career Scientists
Request for Application

Pooneh Fouladi
Manager, Office of the Senior Associate Dean for Research
COVID-19 Fund to Retain Early-Career Scientists

- Funding provided by the Doris Duke Foundation, Rita Allen Foundation, and Stanford School of Medicine.
- Supplemental “extra hands” research funding to support early-career faculty whose research productivity has been impacted by COVID-related caregiving responsibilities.
- Cannot be used to support experiments that utilize animals, or any tissues derived from them.
Eligibility Criteria

- School of Medicine assistant professors and new associate professors (within their first year of appointment) with UTL, UML, NTLR, or CE appointments.

- Funding from the Doris Duke Charitable Foundation and Rita Allen Foundation will support physician scientists who devote at least 50% of their effort to clinical research, while funding from Stanford School of Medicine will support early-career faculty engaged in research across the basic, translational, and clinical research spectrum.
Eligibility Criteria (continued)

- Compelling need for “extra hands” supplements that would boost productivity in light of increased pandemic-related caregiving. Caregiving is defined broadly as childcare, partner care, eldercare, caring for those with COVID-19 and/or other compelling instances of caregiving responsibilities.
- Must have an extant intra or extramural career development award or research project grant with annual direct costs sufficient to provide both research and salary support.
- We expect to award 8 to 10 research supplements.
- Research supplements will be between $35,000-$50,000 depending on need and will have a duration of one year.
- Funding must be used to support “extra hands” (Admin Support, Research Associate/Technician, Clinical Research Coordinator effort), grant-writing support, or buy out of required clinical time so that more time can be spent on research.
- Application Due Date is November 25, 2022 at 5:00 pm. No late applications will be accepted.
For questions please contact:
Pooneh Fouladi, Program Administrator, Office of the Senior Associate Dean for Research
pooneh.fouladi@stanford.edu