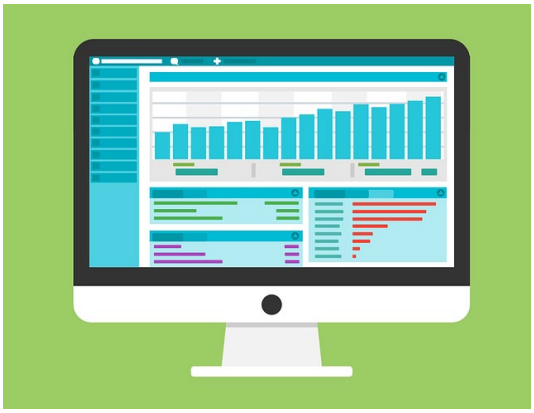
Harvard University Area

Harvard University Area IRB Monthly Newsletter

March 2023



NIH DMSP Survey to Assess Needs of the Harvard Research Community

It's been over a month since the NIH Data Monitoring and Safety Policy (DSMP has been in effect. How's it going?

The Harvard University NIH DMSP Working Group wants to know and has developed a survey to better understand the needs of the Harvard research community as they implement the NIH Data Monitoring and Safety Policy (DMSP) into their work. Although the survey has received a good deal of responses, now that we are more than one month into the policy, the Working Group is interested

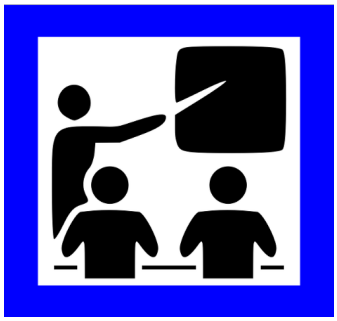
in seeing how things continue to go.

These responses will be used to understand the policy's effect on research at Harvard, and to develop additional resources and services. Please set aside 10 minutes to share your thoughts about the NIH policy and how the university can support data management and sharing.

Here is the link to the survey:
https://hms.az1.qualtrics.com/jfe/form/SV_cGxPhtJjj0TuKIm

If you have any questions about the survey, visit the Harvard NIH Data Management and Sharing Policy FAQ, or reach out directly to Julie Goldman, Harvard Library Research Data Services.

Harvard Medical School & Yale Symposium – Registration Now Open



Harvard Medical School and Yale University are hosting a symposium that will take place on Monday, April 3rd (Pre-Symposium) and Tuesday, April 4th at the Joseph

B. Martin Conference Center located on the Harvard Longwood Medical Campus.

Topics include Biosecurity in Healthcare Systems, Assessing Biosafety and Biosecurity Oversight of Dual Use Research of Concern and Pathogens of Pandemic Potential, Considerations and Best Practices for IRB/IBC Review of Gene Therapy Clinical Trials, From the Bench to the Cage: Operational Work Practices and Special Considerations When Working in High Containment Facilities, Emerging and Persistently Annoying Issues in Lab Design, among others.

To register, go to: https://secure.touchnet.net/C20832_ustores/web/store_main.jsp?STOREID=75&SINGLESTORE=true

Early bird registration ends on March 10th!

GAO Report on the Oversight and Effectiveness of IRBs

The U.S. Government Accountability Office (GAO) recently released the report "Institutional Review Boards: Actions Needed to Improve Federal Oversight and

Examine Effectiveness". According to the GAO, the office, "…was asked to examine independent IRBs, processes used to protect human subjects, and standards of IRB quality, among other things." This is the second report from GAO that concerns IRBs.

The current GAO report uncovered that while federal agencies such as the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA) do routinely inspect IRBs, "these inspections assess whether IRBs follow federal regulations when reviewing research; effectiveness of the IRB is not examined." Moreover, the number of IRBs that are inspected on an annual basis is relatively low.

The report found that "FDA data show these independent IRBs have reviewed an increasing share of investigational drug research: 25 percent of this research in 2012, and 48 percent in 2021." The use of independent IRBs has also increased in large part due to the single IRB (sIRB) requirement imposed by HHS and NIH. The GAO report also highlights that, "…the number of independent IRBs has decreased largely due to consolidation; this is, in part, related to private equity investment in IRBs."

The report mentions independent IRBs. Not sure what an independent IRB is? Most IRBs are found at universities to provide in-house reviews of research involving human subjects for their research community. However, not all research takes place in a university setting. For those researchers, Independent IRBs fill the gap. Independent IRBs are not affiliated with an institution. Independent IRBs provide IRB reviews for a fee.

For this report, the GAO used the following methodology:

- Conducted interviews or gather information from experts, stakeholder organizations, and organizations that operate IRBs.
- Reviewed OHRP's IRB Registry for IRBs to get a better idea of the IRB market.
- Conducted a literature review on recent news and scholarly articles with carious IRB search terms (e.g., IRB, ethics review committee, ethical review board).
- To gain a better sense of how the Department of Health and Human Services (HHS; which oversees OHRP) and FDA maintained oversight of IRBs, FDA and OHRP IRB inspection data were reviewed.

Here are some key conclusions from the report:

- "While inspections are a key mechanism through which OHRP and FDA help ensure that IRBs are following federal regulations for protecting human subjects, our review shows this oversight needs to be strengthened.
    - First, to the extent that OHRP and FDA rely on inaccurate data on the number of protocols that IRBs review, they are limited in their ability to appropriately select IRBs and to prioritize for selection the IRBs that are reviewing large volumes of research involving human subjects.
    - Second, both OHRP and FDA determine the number of IRBs to inspect each year based on available resources and not on whether the number of annual inspections is sufficient to help achieve the agencies' oversight objectives—protecting human subjects.
- Neither agency (HHS or FDA) has examined whether or to what extent IRB reviews themselves are effective in protecting human subjects, despite longstanding recommendations that the agencies do so."

And the report's recommendations:

- “Ensure that OHRP takes steps to ensure the accuracy of protocol data collected in OHRP's IRB registry. This could include updating instructions to IRBs and examining data accuracy for a sample of IRBs.
- Ensure that OHRP conducts an annual risk assessment to determine whether the agency is conducting an adequate number of routine IRB inspections and to optimize the use of IRB inspections in the oversight of IRBs and the protection of research participants.
- The Food and Drug Administration should conduct an annual risk assessment to determine whether the agency is conducting an adequate number of routine IRB inspections and to optimize the use of IRB inspections in the oversight of IRBs and the protection of research participants.
- Ensure that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects, and implement the approaches as appropriate. These could include effectiveness measures; peer audits of IRB meetings and decisions; mock protocols; surveys of IRB members, investigators, and human research participants; or other approaches.”

You can find more information about this report here.

Before the current report, the GAO conducted an investigation in 2009 that resulted in the report “Human Subjects Research: Undercover Tests Show the Institutional Review Board System Is Vulnerable to Unethical Manipulation”.

In this investigation, “GAO investigators created fictitious companies, used counterfeit documents, and invented a fictitious medical device to investigate three key aspects of the IRB system.” One of these key aspects was uncovering the process that medical research companies follow to get IRB approval for conducting

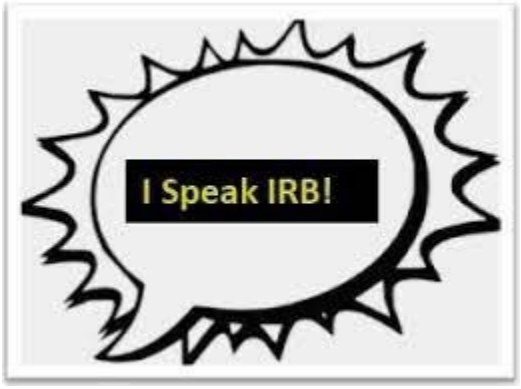
human subjects research. The GAO presented three independent IRBs with a fictitious submission for research on a new medical device.

And here is what they found:

"The IRB did not verify the information submitted by GAO, which included false information that FDA had already cleared GAO's device for marketing. Although records from this IRB indicated that it believed GAO's bogus device was "probably very safe," two other IRBs that rejected GAO's protocol cited safety concerns with GAO's device. No human interaction with these IRBs was necessary as the entire process was done through e-mail or fax. GAO's bogus IRB mentioned above also could have approved the fictitious protocol, which shows the potential for unethical manipulation in the IRB system."

You can find more information on the 2009 report here.

Do You Speak IRB?



Pilot studies - Do they require IRB oversight?

According to the NIH and defined in the Dictionary of Epidemiology (5th edition, 2008):

A pilot study is defined as "A small-scale test of the methods and procedures to be used on a larger scale" (Porta, Dictionary of Epidemiology, 5th edition, 2008). The goal of pilot work is not to test hypotheses about the effects of an intervention, but rather, to assess the feasibility and acceptability of an approach to be used in a larger-scale study. Thus, in a pilot study you are not answering the question "Does this intervention work?" Instead, you are gathering information to help you answer, "Can I do this?"

The definition of research, the type that requires IRB oversight, relies on two aspects: 1) That the activity involves a systematic investigation (i.e., methodical procedure and plan), and 2) that the information collected is expected to expand the knowledge base of a scientific discipline or other scholarly fields of study and yield one or both of the following:

- Results that apply to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

There is a great deal of variability in the IRB world regarding whether pilot studies meet the definition of "research". There is also a great deal of variability in what is considered a pilot study. Many pilot studies extend beyond feasibility and are used as a preliminary method to test the study hypothesis on a smaller scale.

How does one know the difference? Many (if not most) pilot studies can be completed without interacting or intervening with individuals. For example, conducting literature reviews, talking to experts, comparing other similar research studies, and the like.

What many call a “pilot study” is a preliminary assessment of the research; a first step in the conduct of a larger research investigation. In this case, the preliminary investigation and the larger investigation fall on a continuum rather than as discrete activities.

What we have seen at the HUA IRB is that most pilot studies are preliminary investigations rather than true pilot studies: the results will be used to inform the larger study, there is interaction or intervention with individuals, and that the activity is being conducted to test the hypothesis rather than the feasibility.

Unsure if the activity that you plan to undertake is a pilot study or preliminary investigation? Contact us! We’re here to help.

You can reach us at:
cuhs@harvard.edu or (617) 496-2847

Check out our website at:
https://cuhs.harvard.edu