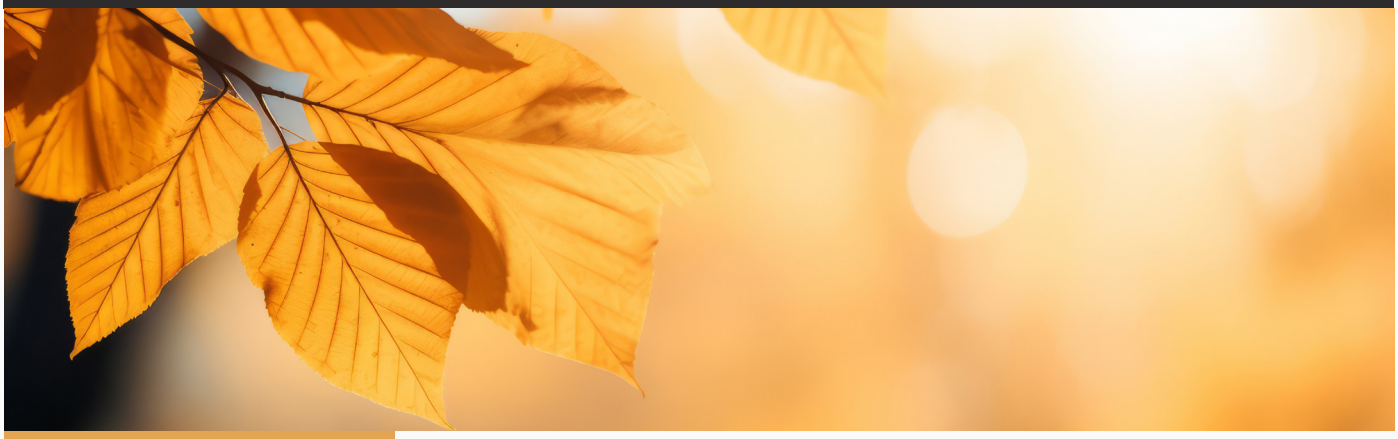
NIH Office of Intramural Research
*Office of Human Subjects Research Protections*

# OHSRP NEWSLETTER

Fall Edition October 2023



## IN THIS ISSUE



## LETTER FROM THE OHSRP DIRECTOR

Pretty much every day there is something in the newspaper about Artificial Intelligence/Machine Learning (AI/ML). Depending on which article you read, AI/ML is either going to be mankind's savior or an existential threat to our very existence. In the world of research oversight, there has also been a lively conversation about the potential benefits of AI/ML, along with a healthy dose of skepticism and concern. Many of the concerns stem from the "black box" nature of the algorithms, the potential for reinforcement of systematic biases as well as individual privacy. However, when used thoughtfully and intentionally, AI/ML has the potential to improve many aspects of medical care.

What you may not know about AI/ML is that when it is used in human subjects research, it may be considered an FDA regulated device. The FDA defines a medical device (in part) as "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals". Key to this definition is the intended use of the device. Software algorithms used to aid in the diagnosis or treatment of disease, referred to as Software as a Medical Device (SaMD) have been recognized by the FDA as devices for many years. AI/ML is essentially the next generation of SaMD.

To understand why AI/ML might be a device, let's compare to a more traditional device, such as an in vitro diagnostic assay. We are all

very familiar with blood tests that are used to detect and diagnose any number of diseases, ranging from biomarkers for cancer or heart attacks to routine clinical chemistry results. These take an input (a blood sample), perform an analysis (using a device), and provides an output (the lab result) which the clinician relies upon to guide diagnosis and treatment. Depending upon the significance of the underlying condition and the importance of the test in clinical decision making, the accuracy and reliability of that test result may have significant consequences for the patient. Hence, the FDA regulates such tests.

Now consider an AI algorithm that is used to detect potential neoplastic lesions present on radiographic imaging studies. In this case the input is the data from the imaging study, processed by a software algorithm (the device equivalent to the assay system in the blood test) and the output is the report to the clinician indicating whether or not a lesion is present. This would meet the definition of a medical device as it is a "contrivance" that is intended to be used to diagnose a disease. As with the blood test, the consequences of an incorrect test result can be significant. As with the blood test, this device is also subject to FDA regulation.

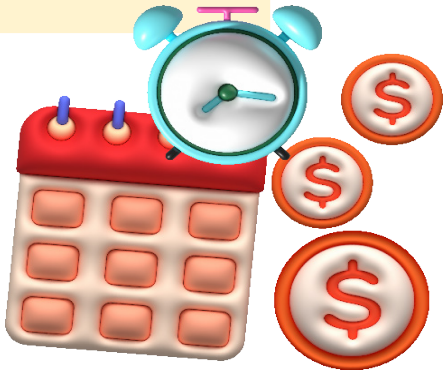
NIH researchers are increasingly involved in research protocols that use ML to develop AI algorithms that are intended to aid in the diagnosis of disease. Just like any other research protocol involving a device, the IRB will need to apply the applicable FDA regulatory framework when reviewing these protocols. It is important to understand that even during the development and training phase of the development, these protocols may be subject to FDA regulations. For example, when imaging data collected during routine clinical care is being used to develop and train an algorithm that is intended to be tested and ultimately used on patients to diagnose disease, that study is an FDA regulated device study that requires IRB review, even though it may not yet be being used or directly tested on actual patients. This is true even if the data used in the training sets is anonymized, as unlike the Common Rule, the FDA regulations do not consider identifiability as a threshold criterion.

As always, we encourage you to seek guidance from the IRB Office if you have questions as you prepare these types of protocols for submission. Our goal is to facilitate and support the ethical and compliant conduct of human subjects research and we are excited to work with the many thought leaders and cutting-edge researchers in the NIH community.

—Jonathan M. Green, MD, MBA
DIRECTOR

# IRB Member Meeting Payments

*Are you an unaffiliated IRB Member who receives an honorarium payment for attending IRB meetings? If you are, and you do not receive payment by 15th of the month after you've attended a meeting, please let us know. We will reach out to Guidehouse to get this corrected as soon as possible!*



# GOLD STAR AWARD

This issue's Gold Star award goes to Richard Wu, MD, PI; Katherine Brooks, MA Ed, MA, CIP, Protocol Navigator; and Dr. Wu's research team in the NIAID Vaccine Research Center. The PI submitted an Initial Review at the end of June called "A Phase I Open-Label Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Mosaic Hexavalent Influenza Vaccine VRC-FLUMOS0116-00-VP (FluMos-v2) in Healthy Adults" (IRB001614). It is a dose escalation study with the goal of evaluating the safety, tolerability, and immunogenicity of the mosaic hexavalent influenza vaccine, FluMos-v2. The protocol itself was very well put together and did not require any pre-review clarifications. The OHSRP analyst who conducted the Partnership for Informed Consent Optimization (PICO) review stated that the team did a nice job with the consent, used conversational language and included very little passive voice. The submission was returned to the team for only minor editorial/administrative revisions to the recruitment documents. The PI and Protocol Navigator were both very responsive in addressing questions as well as collaborating to ensure that any issues were appropriately addressed. At the Full Board meeting at the end of July, the IRB approved the action with no stipulations. **Congratulations to Dr. Wu, Ms. Brooks, and the other members of Dr. Wu's research team!**

## USING INVESTIGATIONAL MEDICAL DEVICES IN NIH IRP STUDIES

In this issue we want to focus on **investigational medical devices**. As a part of this article, we will explain some of the basics about the use of investigational medical devices in studies. We will also go over what information must be provided in the protocol, consent form, and PROTECT Smart Form, when your study involves the use of investigational medical devices. Many of us struggle to understand the FDA-regulated device regulations and how to apply them. A network of Southeast US research institutions, ReGARDD, have created a great website with resources about the FDA regulations which can be found on the ReGARDD website. They have created an excellent flow diagram to help investigators determine whether their study must comply with the FDA regulations (i.e. involves a significant risk or nonsignificant risk device) or is exempt from doing so, based on the type and planned use of the medical devices in their study. Another helpful guidance document is the Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors, Significant and Nonsignificant Risk Medical Device Studies (FDA, January 2006).

## ROLE OF YOUR IC (SPONSOR) AND THE REGULATORY SUPPORT TEAM

It is critical that any study teams, who are using investigational devices in their studies, identify and communicate with the regulatory support person(s) for their IC about each of these studies. The regulatory team needs to be alerted when a study may include a nonsignificant risk device (NSR) or significant risk (SR) device. These individuals' role is to represent the Sponsor (your IC) as referred

to in the FDA regulations. For studies that are not exempt, sponsors are responsible for making the initial risk determination (SR or NSR) and presenting it to the IRB. The FDA is also available to help the sponsor, the PI, and the IRB in making a risk determination. The regulatory team should assist the study team with addressing the use of investigational medical devices and providing a justification for the device-related determination in the protocol. It is also necessary for the regulatory team to be involved because there are FDA-reporting requirements associated with the use of NSR and SR devices in studies that they must adhere to.

## ROLE OF THE FDA VS. THE IRB

All studies that involve SR devices must be submitted to the FDA for approval of an IDE. The FDA is the final arbiter in deciding whether a device study poses a significant or nonsignificant risk. If the FDA has already made the SR or NSR determination, the agency's determination is final. The FDA generally only sees those studies that sponsors submit or those studies for which an IRB or PI asks for FDA's opinion.

It is important to clarify that a study involving an investigational medical device only has one device risk determination. This device risk determination is based on the highest risk determination associated with the use of all the investigational medical devices in the study. Accordingly, the study will be either a significant risk study, a nonsignificant risk study or an IDE exempt study. However, to get to this point, the IRB must consider the use of each investigational medical device in the study separately.

Unless the FDA has already made a risk determination for the study, the IRB must review the sponsor's proposed determination for the investigational medical device(s) and make a determination about the device risk for that study. Only the convened IRB can make a determination that the use of a device meets the criteria to be considered SR or NSR, while a designated IRB reviewer is allowed to make a determination that the use of a device meets the criteria to be considered IDE exempt.

## WHAT IS A MEDICAL DEVICE?

It is important to remember that the IRB only needs to make a risk determination based on the device(s) involved, when the device(s) meet the definition of a **medical device**. The FDA defines a medical device in section 513(a)(1) of the FD&C Act as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article or component part or accessory which:

- is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease
- is intended to affect the structure or any function of the body
- does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

## WHAT IS AN INVESTIGATIONAL MEDICAL DEVICE?

In addition, the IRB only needs consider the FDA-regulated status of the study related to the use of the medical devices when they are considered investigational in the context of the study. The IRB would consider the use of the devices to be investigational when 1) the use of the device is part of the object of the investigation, e.g. you are looking at the safety of the device or effectiveness of the device; using the device to answer one of the primary objectives; using non FDA-approved (or cleared) devices such as MRI scanners, MRI research pulse sequences, MRI research coils or MRI research image reconstruction and analysis software; or 2) you are returning results from the use of an unapproved device (or off label use) to the subject (e.g. conducting research assays in a CLIA-certified lab). In these situations, the medical device is considered **an investigational medical device**. Please note that an FDA-approved or cleared device can be considered an investigational medical device in the context of a specific study. An example of this is when an FDA-approved device is being used off label, i.e., for a use that is different than what the FDA has approved it to be used for, to answer one of the research questions. An FDA-approved medical device would also be considered investigational if its effectiveness is being compared to that of an unapproved medical device as part of the object of the study.

## WHAT IS MEANT BY IDE EXEMPT?

When an investigational device is being used in a study, the IRB needs to consider whether the use of the device is subject to the FDA IDE regulations or not. If the device is investigational in the context of a study but it is FDA-cleared or approved and is being used on label, the use of the device in the context of the study would be considered exempt from the IDE regulations. An unapproved device might also be considered IDE Exempt when the use of the device is diagnostic, and the testing meets the following criteria:

- Noninvasive
- Does not require invasive sampling that presents a significant risk
- Does not introduce energy (into the subject)
- [Results] are confirmed by another method [prior to using them to diagnose a patient]

Even if the use of the medical device is considered IDE exempt within the study, please note that study itself would still be considered FDA-regulated and would need to comply with the other FDA regulations for a clinical investigation.

## WHAT IS MEANT BY SIGNIFICANT RISK OR NONSIGNIFICANT RISK?

If the use of an investigational medical device on a study does not meet the criteria for IDE Exempt, it must either meet the criteria for significant risk (SR) or nonsignificant risk (NSR). Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

If the use of an investigational medical device neither meets the definition to be IDE Exempt nor Significant Risk in the context of a protocol, it would be considered Nonsignificant Risk.

When a study involves the use of a significant risk device, you must seek FDA approval of an IDE prior to receiving final IRB approval for the IR or MOD involving that device.

## WHAT MUST BE INCLUDED IN THE PROTOCOL?

If your study includes investigational medical devices, you should include an Investigational Devices section (or a Study Interventions section, if you are testing an intervention) within the protocol. Please review Section 6.1 of the **Interventional Protocol Template** for guidance. The protocol must include all of the following information:

- Device name(s), model(s), and manufacturer(s)
- Indicate whether the device is FDA-approved or cleared
    - Please note that just because a device is commercially available does not mean that it is FDA-approved/cleared.
    - If FDA-cleared, indicate if the device is being used in accordance with approved labeling (e.g., 510(k) clearance).
    - If the device is approved or cleared, please note if the device has been modified in any way for use in the study.
    - If a device has not been approved or cleared for the indications the study is designed to investigate, then a summary/report of test validation studies should be submitted with the protocol.
- Describe how the device is being used and its purpose in the study
- State how long and how frequent subjects will be exposed to the device (or how long the implant might be in place (if applicable))
- If the device(s) meets the criteria to be exempt from the FDA regulations, provide justification as to why the use of the investigational medical device(s) is IDE exempt in the context of this study.
- If a device study is being conducted under an IDE and is proposed to be non-significant risk (NSR), such that only abbreviated IDE requirements apply, provide a justification as to why the use of the device is NSR in the context of this study.
- If a device study is being conducted under an IDE and is significant risk, provide detail as to why the use of the device is SR in the context of the study.

## WHAT MUST BE INCLUDED IN THE CONSENT FORM?

For any investigational medical device being used in the protocol that is not FDA-approved or is being used off label, be sure that this is explained in the consent form. It is not necessary to provide the formal name of the device, however the consent form should make it clear that the study includes a device that is either not FDA-approved or is not being used per its FDA approval. For off label use of approved devices, please be sure to explain what indication the device is approved for. See example language under **WHY IS THIS STUDY BEING DONE?** in the Consent Templates. You should also address any potential risks of the devices under the **WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?** section.

If your study involves the use of Magnetic Resonance Imaging (MRI) devices (unapproved scanners, research pulse sequences, research coils or research image reconstruction and analysis software) or the use of Transcranial Magnetic Stimulation (TMS) devices in an investigational manner, please review and use the applicable language under MRI or TMS that is found in the Consent Library.

## WHAT MUST BE INCLUDED IN THE PROTECT SMART FORM (STUDY APPLICATION)?

**Under "Study Scope"**

**Question: Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**

If your study involves investigational medical devices, answer 'yes' if part of the intent is to determine the safety or effectiveness of a medical device or if the study uses a medical device that is not FDA-approved or is FDA-approved but is being used off label.

**Under "Devices"**

**Question: Select each investigational device or HUD being used as part of the study:**

Click on "+ Add" to add each investigational medical device that is being used in the study as part of the object of the investigation (FDA-cleared and being used on label; not FDA-cleared; or FDA-cleared but being used off label in the study). In other words, any device that may be considered SR, NSR, HUD or IDE Exempt. Please note that a HUD is not the same as an FDA-approved medical device.

Medical devices that are approved and being used per labeling to collect research data (but not as the object of the investigation), do not need to be added in PROTECT. However, their use should be discussed in the protocol. When searching for your device, you will not be able to see any manufacturer names. If you see multiple devices with the same or similar names and you aren't sure if one might be your device, please initially select them all. You will then be able to see the associated manufacturers. Then go through and delete those devices which are not associated with your study. If you do not see the specific name of your device in the list, you should submit a ticket to the Help Desk to have the device added, so that you may select it.

## IRBO UPDATES, CONTINUED

Please attach documentation for each investigational device that you add into PROTECT. If it is an FDA-approved device, attach the FDA approval (e.g., 510K or PMA clearance letter). If it is not FDA-approved, attach a document with a description from the manufacturer. We only need about a one-page summary from the manufacturer which includes the make, model, etc. This information is uploaded/exchanged in the **"Attach files related to this device"** section. You do not need to add any documentation for the following types of devices: MRI scanners, pulse sequences, coils, or image reconstruction and analysis software.

**Question: Device exemptions applicable to this study:**

Be sure to select the category associated with the "highest risk" device being used in the study. The order from highest risk to lowest risk should be as follows: IDE (Significant Risk device), HDE number (Humanitarian Use device), Abbreviated IDE (Nonsignificant Risk device), and then Exempt from IDE requirements (IDE Exempt device).

**Question: Attach Files:**

Please attach any determinations or other communications from the FDA, when applicable, about any SR device (IDE) or HUD/HDE included in the study. If the sponsor (e.g., your IC) has done an initial assessment of the risk level or exemption status of the devices in your study, this documentation should also be attached in this section.

## FINAL DATE TO UPDATE PROTOCOLS BASED ON DOCUMENTATION IN IRIS

PROTECT went live in January of this year. As part of the migration only some of the existing Study Application content and attachments were migrated into PROTECT. Many of you have submitted a MOD to your protocol to update the PROTECT Smart Form (Study Application) & attachments as instructed when we first went live in the system—THANK YOU!

If you have not yet submitted a modification to update the PROTECT Smart Form for your protocol, please do so within the next few months. iRIS, our previous eIRB system, will be archived in 2024, and you will no longer be able to access iRIS to review and compare the information and documents for your study. The instructions for updating your study information after the migration, Notes to Researcher for PROTECT Migration, are posted on the **OHSRP website**. We provided even more detailed information about how to update the PROTECT Smart Form (Study Application) in the **Spring Issue** of this newsletter.

If you have not yet done this and you have a CR due before the end of the calendar year, please submit a MODCR so that you can update the Smart Form at the same time. If your protocol does not require a CR or you do not have an upcoming CR, please check in the history tab to ensure that your study has been updated; if not, please submit a MOD to address this by the end of December 2023.

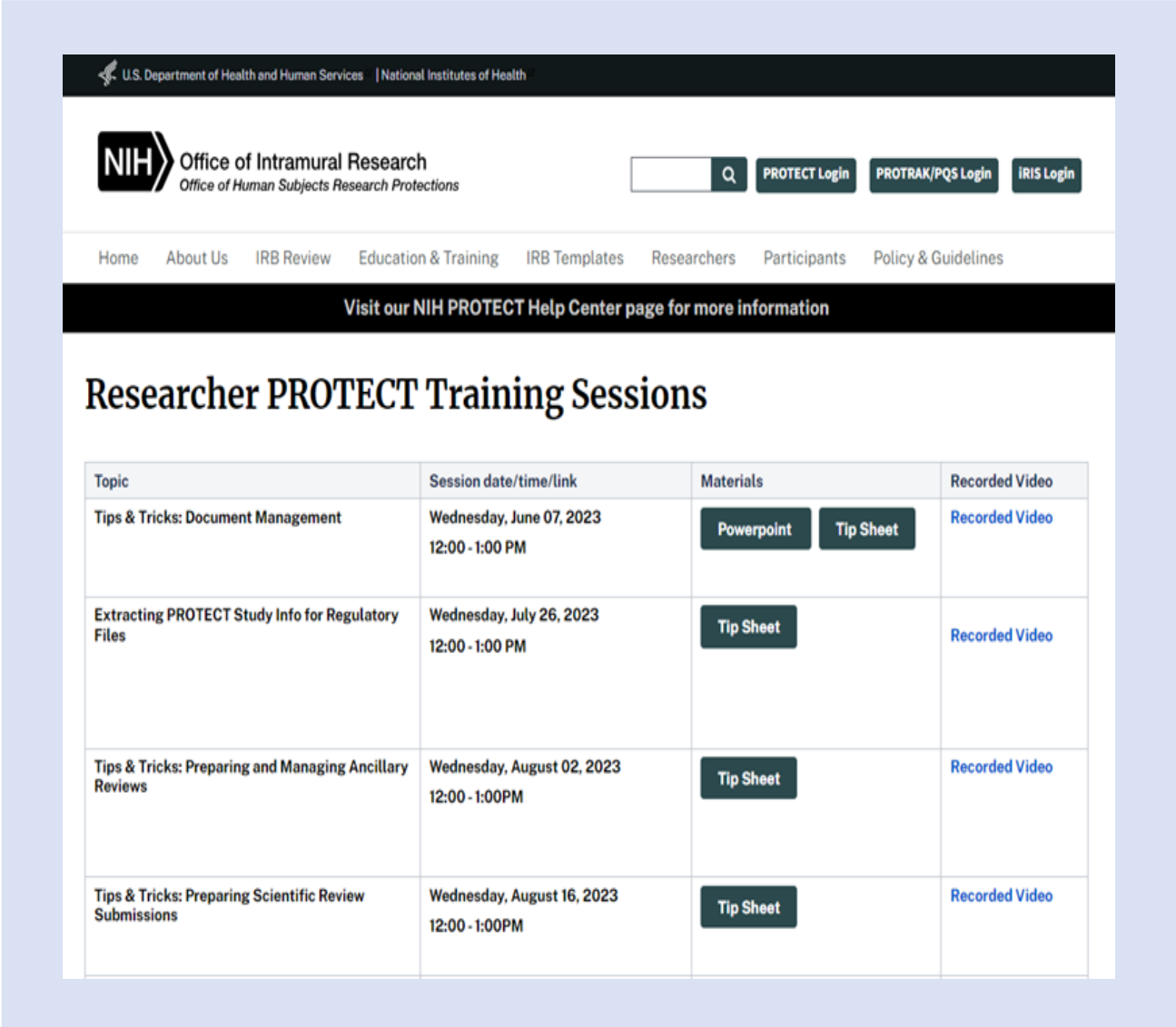
## PROTECT SYSTEM: SUPPORT & EDUCATION

We have added a new global [OHSRP Events Calendar] to our website that houses events, webinars and trainings available from our office and other human subjects protections organizations that may be of interest to our community . This calendar is updated regularly so check this often to remain current or to attend a class:

### Post Go-Live Education Series

Now that the PROTECT system has been live for over 6 months and users have gotten acquainted with basic system usage, we have created a post go-live PROTECT education series that dives into more specific class topics, such as Tips & Tricks for all the submission types, document management, etc. We hope that you find these topics useful. They have been heavily attended and appreciated by the community. Sessions are recorded and posted for later viewing or sharing with new hires as part of your orienting them. Each class is also accompanied by a Tip Sheet on the topic.

*Classes, recordings, and tip sheets can be found here:* Researcher PROTECT Training Sessions



## CHANGES TO PROTECT ACCOUNT REQUIREMENTS

The PROTECT system is compliant with the FDA regulations on Electronic Records/Electronic Signatures (21 CFR 11). The FDA provides guidance on this subpart of the regulations, describing that "persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks". To be compliant with this guidance, starting September 20, 2023, we will require all new PROTECT system users to complete a live virtual training class prior to getting an account.

***Who should take the new user training?***

Anyone requesting a new PROTECT account on or after September 20, 2023, must take the PROTECT: *New User Class*. If you are already a current system account user, you do not need to take the class as we provided training and overview on the system as part of our implementation strategy. Current users are welcome to attend, however!

***How can I request a PROTECT account and sign up for the new user training?***

Users will continue to request PROTECT accounts using our PROTECT Help Desk ticketing system. Beginning on September 20, 2023, when a new user requests an account, a trainer will reach out to you to follow up and ensure you are signed up for an upcoming training. The trainings will be offered on a recurring basis by our PROTECT trainers and can be found at: Researcher PROTECT Training Sessions. There, you can view and select the meeting invite and accept it so the class is added to your Outlook calendar.

***What will be covered in the class?***

Attendees will have their account provisioned in the TRAINING environment to use during the class. We will first provide a system overview. This will be followed by hands-on training, so users get the opportunity to practice using the system: navigate workspaces, create and submit submissions, and move through workflows. We will also review where to find resources/guides for various system tasks so users can locate these for future reference. Users will leave the class equipped with everything they need to get an account in the live PROTECT system so they can begin using it for their day-to-day roles. Who should I contact for questions about this new requirement or the training?

For additional questions, please submit a PROTECT Help Desk ticket and our PROTECT Training Staff will assist you.

## ONGOING PROTECT SUPPORT

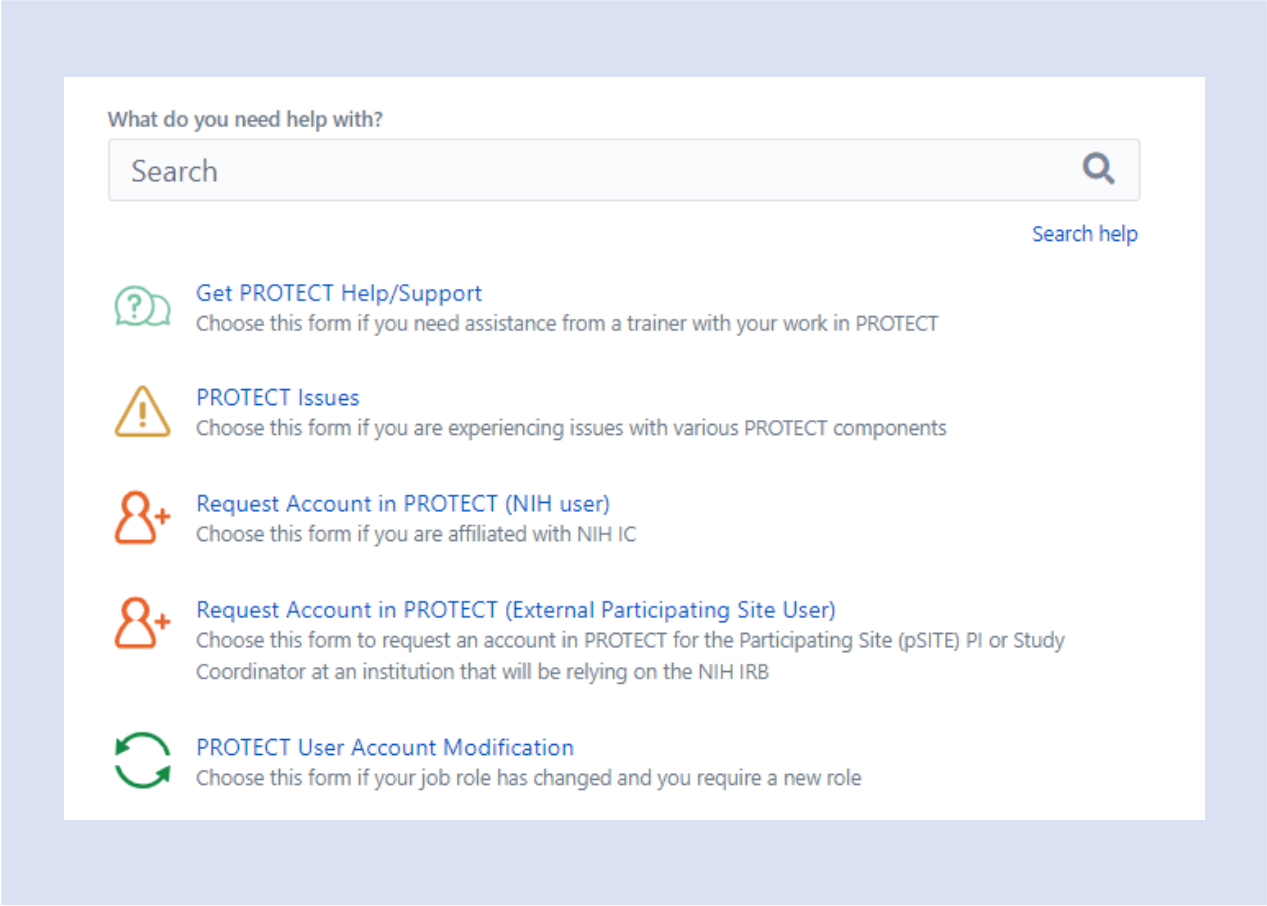
Our trainers continue to offer PROTECT support Monday to Friday 8-4:30 EST in a variety of ways so that users can get the help they need, when they need it, and in the way that works best for them. The best way to get help is either by attending our live help desk sessions, or via submitting a Help Desk Support ticket.

*(See below for how to get help in these two ways.)*

### PROTECT 'LIVE' HELP DESK HOURS

## PROTECT HELP DESK SUPPORT TICKETS

We continue to utilize the Protect Help Desk Support ticketing system for you to submit questions to. This can be found here: [OHSRP IRB PROTECT Help Desk Support](#).



As required by the 21st Century Cures Act and in in compliance with Section 301 of the Public Health Service Act (42 U.S.C. 241), the FDA is in the process of harmonizing relevant regulations at 21 CFR parts 50 and 56 to the greatest extent practicable, with the 2018 Common Rule (45 CFR 46). While the human subjects protections aspects of these regulations are already generally aligned, there are necessary differences based on the focus of the regulatory agencies who publish them (Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA)). When the revised 2018 Common Rule was published those differences in the regulations widened. Currently, the FDA has three (3) different harmonization efforts under way. The intent of all of these harmonization efforts is to alleviate regulatory burden on investigators, sponsors, and IRBs, to increase clarity, and to enhance both human subjects protection and the IRB review process.

As a federal agency we must already comply with the Common Rule and that is our baseline expectation for all NIH-conducted human subjects research regardless of whether it is FDA-regulated or not. FDA-regulated Intramural Research Program (IRP) studies must also comply with FDA requirements. When there is a difference between the regulations, we follow the stricter standard. This is the approach we already take with our policies and this approach will continue as we revise the policies in response to the harmonization efforts. The practical impact of these harmonization efforts is closer alignment of these regulations where feasible. We are in the process of revising our policies in anticipation of the proposed rulemakings. Because of this closer alignment of the FDA regulations with the 2018 Common Rule, many of the revisions will be subtle or minor. Where there are any new differences between the Common Rule and the revised FDA regulations, we will highlight what is different.

The first harmonization effort is focused on aligning 21 CFR parts 50 and 56 with the 2018 Common Rule (e.g., informed consent requirements, eliminating continuing review for certain minimal risk research, sovereignty exceptions, and terminology changes). The FDA plans to implement this rulemaking within 180 days of publication of the final rule. The publication date has not been announced, so we are preparing for this harmonization but will not implement it until it comes into effect.

The second harmonization effort is focused on the cooperative research provisions requiring single IRB review. The FDA plans to implement this rulemaking within 1 year of publication of this final rule. The publication date of this rulemaking also has not been announced, so we are preparing for this harmonization but will not implement it until it comes into effect. That said, the existing NIH single IRB policy and 2018 Common Rule cooperative research provisions already apply to all Intramural Research Program research.

The third harmonization effort is formalizing the waiver of consent for certain minimal risk clinical investigations, which has been permitted by FDA guidance since 2017. The FDA hopes to implement this new waiver clause at 21 CFR 50.22 effective in December 2023. The FDA expects that this waiver or alteration will provide, *"benefits in the form of healthcare advances from minimal risk clinical investigations that would not be performed without a waiver or alteration of informed consent,"* such as studies involving clinical testing using identifiable biospecimens.

The effect of this waiver on Policy 3014-301 Informed Consent is minimal since 21 CFR 50.22 will align to the waiver already permitted by the 2018 Common Rule at 45 CFR 46116(f)(3). The IRB will no longer have to rely upon FDA guidance to exercise this flexibility. Upon publication of the final Rule, the FDA also intends to withdraw the guidance that previously allowed this waiver, titled, *"IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects."* The new clause at 21 CFR 50.22 will read:

"§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.

*The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in §50.25(a) and (b), or that waives the requirement to obtain informed consent, provided the IRB finds and documents the following:*

*(a) The clinical investigation involves no more than minimal risk to the subjects;*

*(b) The clinical investigation could not practicably be carried out without the requested waiver or alteration;*

*(c) If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;*

*(d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and*

*(e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation."*

Once the final rules are published, we will let you know. We will provide educational materials about how the harmonization will affect our policies, any process changes, and we will publish the revised policies to ensure compliance by the published implementation dates. We will highlight more harmonization details in coming newsletters so be sure to look out for these updates.

## ACCREDITATION UPDATES

As Fall returns and the fiscal year (FY) comes to a close we start planning to collect the Association for Accreditation of Human Research Protection Programs (AAHRPP) annual report data. We have reached out to AAHRPP liaisons and Institute/Center (IC) Clinical Directors to make sure that we have a point of contact to help us collect IC-specific data for FY '23 that we cannot get directly from PROTECT. We will also be coordinating with ORSC regarding the annual QA/QI data call. Unfortunately, AAHRPP does not put out changes to their annual questionnaire until the end of the calendar year which is always a challenge for us because our report is due in March 2024. We must collect and collate the data by no later than February 2024. Fortunately, we seem to collect fewer and fewer data points directly from the ICs as AAHRPP continues to refine its annual report. This is also our first year collecting information from PROTECT which may also affect what we collect from the ICs. AAHRPP has been developing an online data collection system which should further streamline future reports. We are looking forward to the implementation of their new system, particularly because in 2025 we must apply for re-accreditation again.

## EMERGENCY PLANNING FOR INVESTIGATORS

As has been discussed previously, OHSRP is becoming a Mission Essential Function (MEF) of the NIH Intramural Research Program (IRP). We are close to finalizing our Continuity of Operations Plan for submission to the OD Division of Emergency Management (DEM). We need these tools to ensure that the NIH IRB can continue to operate during and immediately following an emergency to be responsive to investigators, continue to protect our research participants and the needs of NIH scientific priorities. The September OHSRP Education Session was a panel discussion focused on a high-level overview of what investigators should think about to protect enrolled participants during and immediately following an emergency

that impacts the research enterprise. This panel discussion included staff of OD Division of Emergency Management, Clinical Center Pharmacy and staff of the Office of Clinical Research Support and Compliance as well as OHSRP. If you were unable to view this presentation a recording of the presentation and the slides will be posted to the presentation archive on the OHSRP website.

## 2023 NIH INVESTIGATOR SEMINAR SERIES

The monthly OHSRP Investigator Seminar Series covers topics relevant to investigators who conduct human subjects research. Links for slides and recordings of completed presentations can be found on the OHSRP Investigator Seminar Series Information webpage. During the past quarter of 2023, our June 12th session addressed *Investigator Responsibilities* and was presented by Liz Ness, Director of the NCI CCR Office of Education and Compliance. Her presentation dealt with the wide range of investigator responsibilities based on Good Clinical Practice guidelines as well as NIH HRPP policies.

The July session of this series addressed *What Investigators Need to Know About Scientific Review of New and Ongoing Protocols*. This July 10th session was presented by Leighton Chan, MD, Acting Chief Scientific Officer of the NIH Clinical Center (CC) and Captain Geri Hawks, RN, MSN who is Executive Secretary for CC Scientific Review Committee. Dr. Chan and Capt. Hawks described the purpose of the IRP scientific review process which varies among the ICs, the elements required for scientific review and the related processes required throughout the life of the protocol.

*Implementing the NIH Genomic Data Sharing Policy: What Intramural Investigators Need to Know* was the topic for the August 7th seminar presented by Drs. Cheryl Jacobs, Team Lead for the Genomic Data Sharing (GDS) Policy in the NIH Office of Science Policy, and Julia Slutsman, Director of Genomic Data Sharing Policy Implementation in Office of Extramural Research. Drs. Jacobs and Slutsman addressed the history, purpose, and scope of the GDS policy as well as how this policy is harmonized with the Data Management and Sharing (DMS) Policy. They also covered elements to be included when writing a DMS plan and related PI responsibilities.

The Investigator Seminar on September 11th titled, *Privacy and Confidentiality Requirements in Human Subjects Research - The Common Rule and Beyond* was given by Heather Bridge, OHSRP Director of HRPP Policy and Accreditation. Heather discussed investigator responsibilities related to Privacy and Confidentiality under the Privacy Act of 1974 and reviewed relevant information from NIH Policy 107, Privacy and Confidentiality. She explained information protected by Certificates of Confidentiality, and she also covered what investigators need to know about clinical research and HIPAA since, although NIH is not subject to HIPAA (the "Privacy Rule"), non-NIH investigators who collaborate with NIH investigators may be subject to HIPAA. Finally, she explained how the European Union General Data Protection Regulation (GDPR) can impact NIH researchers.

As we look forward to the last few months of 2023, the OHSRP Investigator Seminar Series will be addressing documentation and document management in clinical research (October 23rd), information that investigators need to know about reporting research related events (November 13th), and post approval monitoring and corrective action (December 11th). We hope you will join us for these sessions presented by subject matter experts via Zoom. A list of topics, dates and links for upcoming can be found on the OHSRP Investigator Seminar Series Information webpage. Additionally, prior to each session we will send additional information about the speaker and details about the presentation as well as a calendar invite with the Zoom link via the Protocol Navigation listserv. If you are not already on this listserv, please sign up because OHSRP uses this list to broadly communicate information to the NIH IRP community members who conduct human subjects research (including investigators as well as navigators). To sign up, scroll all the way down to the bottom of our OHSRP home page, and click the green box that says "Subscribe" below "Join the Protocol Navigation Listserv."

## 2023 OHSRP EDUCATION SERIES SESSIONS

OHSRP Education Series sessions are intended to present topics of interest to those individuals in the NIH IRP involved in human subjects research. These sessions usually occur on the first Thursday of the month from 3-4 PM via live NIH videocast.

Our June 1st session featured a guest speaker, Dr. Ivor Pritchard, Senior Advisor to the Director in the Office for Human Research Protections (OHRP) in the Department of Health and Human Services. His thought-provoking presentation was titled, *Regulations and the Secrets of Big Data: Public, Private, or What?* In this session, Dr. Pritchard reviewed the legal/court case history related to privacy issues and what our current day understanding of privacy may entail especially given social media and the technological ease of accessing information in a cyberworld environment.

Another guest speaker, Dr. Quincy Byrdsong, joined us for the August 3rd session, *More Ethics or More Compliance: What was Dr. Beecher Trying to Tell us?* Dr. Byrdsong is Vice President for Research Operations at Ballad Health, past President of the Society of Clinical Research Associates (SOCRA) and member of the Board of Directors for both the AAHRPP and Public Responsibility in Medicine and Research (PRIM&R). He discussed lessons learned from Henry Beecher's landmark article "Ethics and Clinical Research" published in 1966 and how these lessons have affected clinical research today.

The OHSRP Education Series session on September 7th addressed *Emergency Preparedness for Investigators* and featured a panel of NIH staff members who are continually involved in these preparations. Speakers included Heather Bridge (OHSRP HRPP Policy and Accreditation), Aaron Salter (NIH Division of Emergency Management), Paula Barton-Mann (Clinical Center Chief of the Clinical Pharmacy and Investigational Drug Research Services), Arman Sabet-Kashani (ORSC Protocol Monitoring Specialist), and Astrid Smith (ORSC Regulatory Affairs Specialist). The panel addressed how investigators can prepare for emergencies, how participants may be affected, and how to work with the IRB when emergencies arise.

Links to the videocasts and slides from these sessions are posted in the Presentation Archive section of the Education and Training page of the OHSRP website

Additional topics that will be covered as we finish out the 2023 OHSRP Education Series include *Considerations for Informed Consent in Cell and Gene Therapy Trials* (October 5th), an update on NIH involvement in multisite research (November 2nd), and use of artificial intelligence in human subjects research and associated ethical concerns (December 14th). Prior to each session, we will send additional information about the speaker and objectives to be covered during the session via the Protocol Navigation listserv.

**OHSRP Compliance and Training staff members are available to do in-person training for various groups within the NIH IRP. If your group (investigators in specific programs or labs, study coordinators, research staff, etc.) are interested in having us present on specific topics related to human subjects research, compliance or training, just email us at OHSRPCompliance@od.nih.gov, and we will contact you to set up the details.**