NIH Office of Intramural Research
Office of Human Subjects Research Protections

OHSRP NEWSLETTER

Spring Edition JUNE 2023

IN THIS ISSUE

LETTER FROM THE OHSRP DIRECTOR

Consent Matters!

There has been a concerning increase in the number of reportable events related to obtaining informed consent. In particular, we are seeing an increase in non-compliance when consenting research participants that do not speak English.

Obtaining the fully informed, voluntary consent of all research participants is perhaps the most important and fundamental ethical aspect of human subjects research. Absent a waiver of informed consent, nothing else should happen until consent is obtained. The Belmont report identifies 3 aspects to the consent process: information, comprehension and voluntariness. Prospective participants must have all the necessary information needed to decide consistent with their own goals and values whether or not to participate. The information must be presented to them in a manner such that they can fully understand the implications of the decision, and their decision must be voluntary. There is nothing simple about this process, it requires time, effort and thoughtfulness on the part of the investigator and study team.

Enrollment of non-English speaking participants poses additional challenges. For many of our participants, they are facing a life altering illness. They are scared, stressed and in an unfamiliar environment. On top of this, not speaking or understanding English poses additional stresses and challenges to assure that consent is fully informed.

The regulations and NIH policies do allow the use of the "short form" process to document informed consent for participation in research. However, the short form is an extremely poor way to inform the participant of the important aspects of the research and should only be used when there truly is no other option.

The regulations and ethical research require that the information necessary to make an informed decision be provided to the prospective participant in a language understandable to them. The short form itself does not meet this requirement, as it contains no study specific information. The short form process relies upon an oral presentation of the information; however, the participant typically receives nothing in writing that is useful to them. They have nothing to look back on to help them understand what to expect, to understand what is or may be happening to them in the research. Nothing to refer to if they wish to discuss with their family or trusted friends or health care providers.

Respect for our research participants requires that we provide them with the informed consent translated into their own language. We enroll a lot of non-English speaking persons here. The NIH library will translate into Spanish for free and can translate for a fee most any other language. If you know you will likely encounter a non-English speaking person in your study, please translate your consent ahead of time and provide it (along with a certificate of translation) to the IRB for approval. The use of the short form should be reserved only for those situations in which enrollment is unanticipated and there is insufficient time to obtain a certified translation, and if it is in the participants best interest to enroll prior to obtaining the translation.

If the short form is used, although not a policy requirement, the consent should be translated as soon as possible afterwards and provided to the recently enrolled participant. Afterall, since they are placing themselves in harm's way to advance knowledge and help others, it is the very least we can do.

PROTECT UPDATE

We are now 4 months since going live with PROTECT. I wish I could say it has all been smooth sailing, however we have had our share of stormy weather. Perhaps this is not surprising with an IT project of this size. I am hopeful that we are approaching calmer waters now and that most of the major issues either have been or will very soon be resolved.

As you know, one of the major issues is that we are operating inside the NIH firewall, preventing our non-NIH sites and users from accessing the system. I am pleased to report that we are closer to being able to go outside of the NIH firewall. Upgraded software has been installed on our production server and the initial security scans were good. We have submitted the request to our ISSO and are awaiting that office's review and approval.

We realize there are some remaining workflow and software issues to be addressed, in particular, how the ancillary review activities are handled. We have many tickets in with Huron and expect 3 or 4 more patches to be developed and implemented over the next several weeks. Please visit the **PROTECT page** on our website for updated information and links as well as guidance on how to get help. Release notes that describe the issues addressed by each patch to the system are also posted here.

IRB METRICS

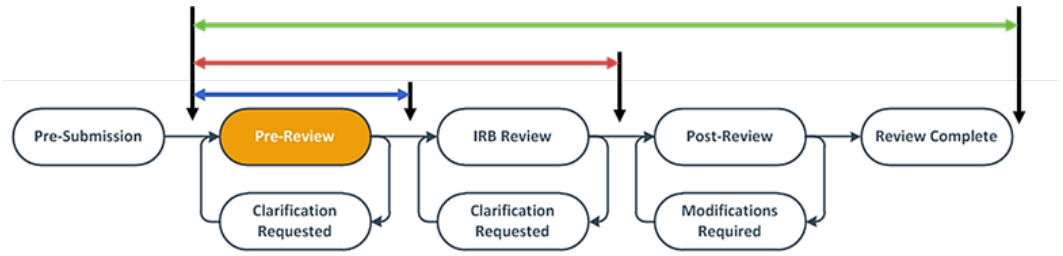
One of our goals with this system is to be able to reduce turnaround times by making the application easier to complete and simpler to submit. To that end, I wish to share with you some data on IRB review volumes and times. I am pleased that our turnaround times remain quite good, and am hopeful they will improve as we all get used to the new system.

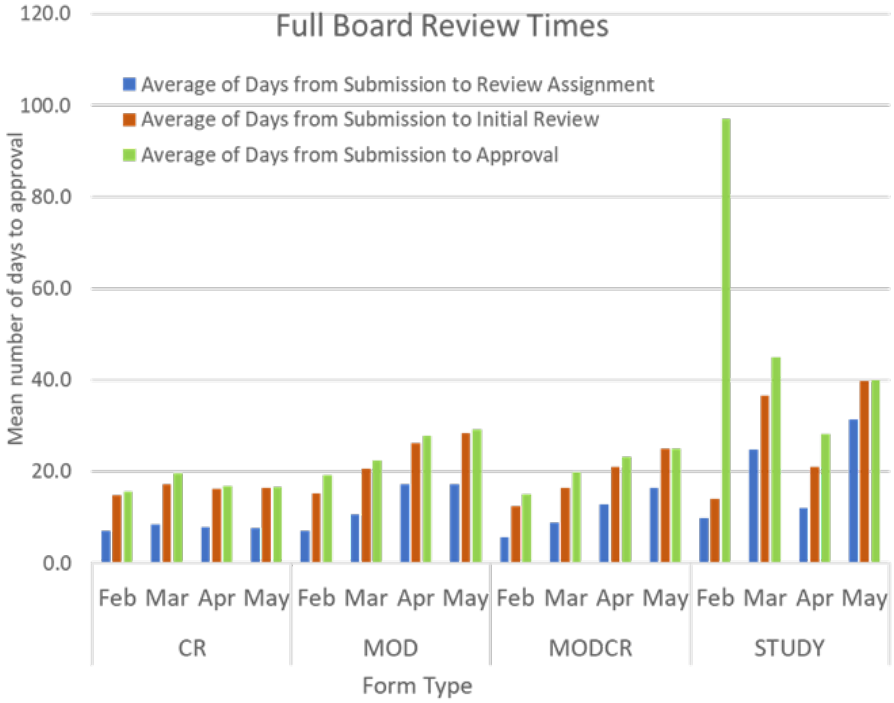
We knew that when we went live we would get flooded with submissions. I don't think we realized just how flooded. From January 17-January 31 we reviewed and approved 875 forms. All I can say is wow....and great job to the OHSRP staff in getting those 858 MODS processed on average in less than a day.

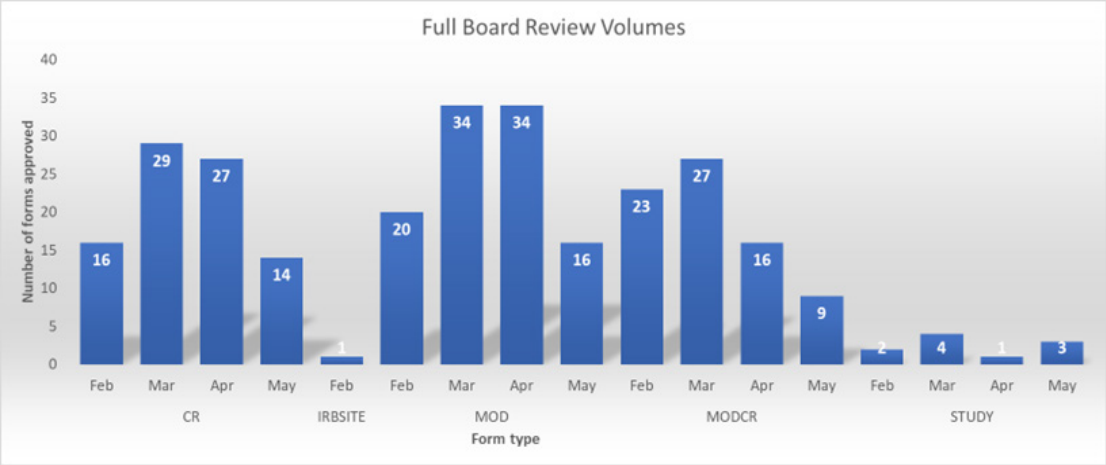
TYPE OF SUBMISSION	NUMBER OF SUBMISSIONS	MEAN TIME TO APPROVAL (DAYS)
CR	3	5.2
MOD	858	0.9
MOD/CR	6	7.5
INITIAL STUDY	8	55.4
TOTAL	875	1.4

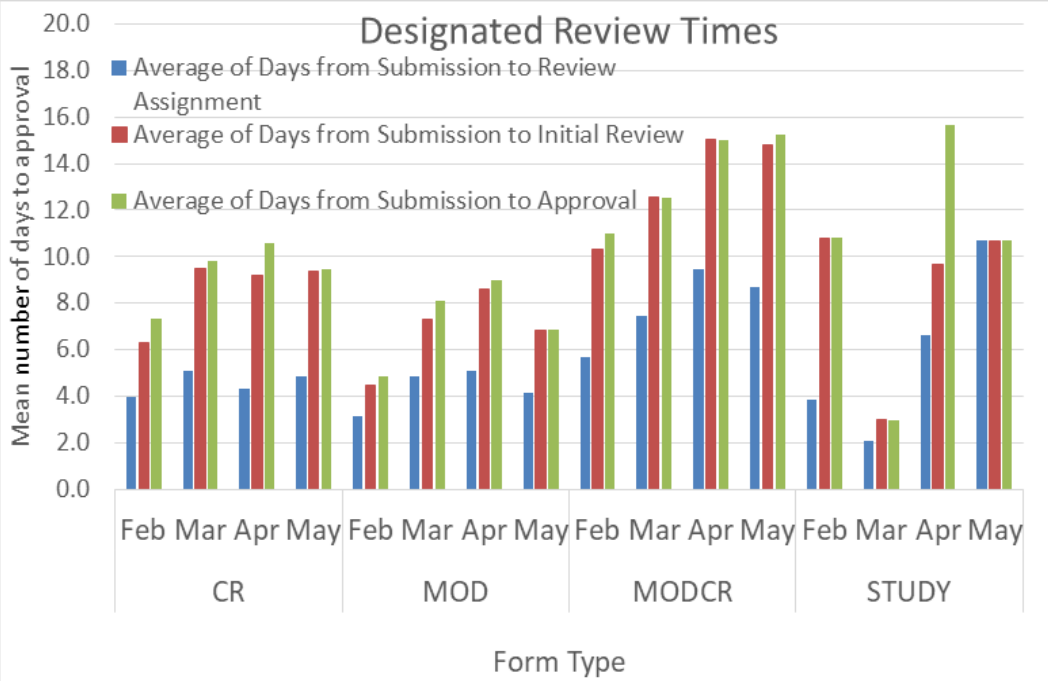
Turnaround times and volumes February 1 through May 19, 2023

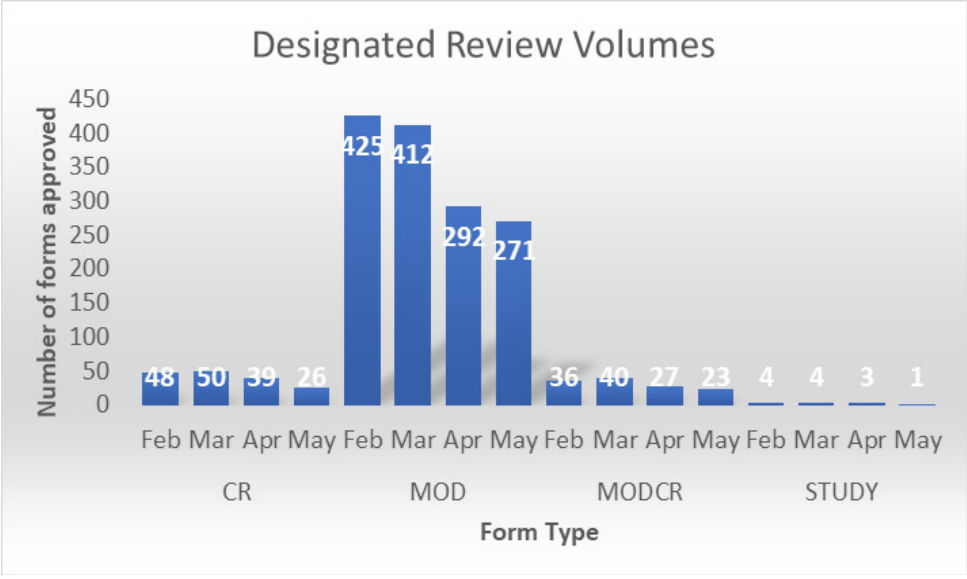
Below are graphs showing the number of submissions approved and the turnaround times for full board and expedited (also referred to as designated review) paths. To help you interpret the data, the time intervals presented in the graphs are represented on this workflow diagram. The blue is the pre-review time, which is the time from submission to the IRB to the time it is assigned either to committee review or to a designated reviewer (for expedited submissions). The red is the time from initial submission until the first review is complete, either committee review or designated review. The green is the time from initial submission to final approval. Note, that in PROTECT and on these graphs, an Initial Review form is called "study" and an amendment is a "mod"



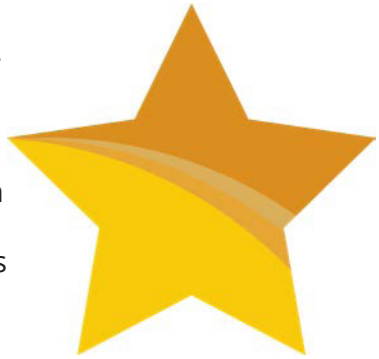

Full Board Review Times
Average of Days from Submission to Review Assignment
Average of Days from Submission to Initial Review
Average of Days from Submission to Approval
Mean number of days to approval
120.0
100.0
80.0
60.0
40.0
20.0
0.0
Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May
CR
MOD
MODCR
STUDY
Form Type


Full Board Review Volumes
Number of forms approved
40
35
30
25
20
15
10
5
0
16
29
27
14
1
20
34
34
16
23
27
16
9
2
4
1
3
Feb Mar Apr May Feb Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May
CR
IRBSITE
MOD
MODCR
STUDY
Form type


Designated Review Times
Average of Days from Submission to Review Assignment
Average of Days from Submission to Initial Review
Average of Days from Submission to Approval
Mean number of days to approval
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May
CR
MOD
MODCR
STUDY
Form Type


Designated Review Volumes
Number of forms approved
450
400
350
300
250
200
150
100
50
0
48
50
39
26
425
412
292
271
36
40
27
23
4
4
3
1
Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May Feb Mar Apr May
CR
MOD
MODCR
STUDY
Form Type

GOLD STAR AWARD



This issue's Gold Star award goes to Amy Janes, PhD, PI, and Carolina Smith, MS, Clinical Manager, in the NIDA Neuroimaging Research Branch. The research team submitted a Modification + Continuing Review for a study which aims to create an imaging biomarker to predict treatment outcomes in opioid use disorder and alcohol use disorder patients (18DAN053). This protocol was initially approved prior to implementation of the current OHSRP/IRBO/IRB, and Dr. Janes was named PI, when the former PI retired. As part of our review, the IRB requested many changes to update the protocol and consent form in accordance with current OHSRP policy and guidance. The research team re-submitted the action with the requested changes in just nine business days. The reviewer noted that the revised submission thoroughly satisfied all the requests of the IRB. The revisions to the protocol and consent were thoughtful and eloquently written. In some cases, the team changed other content (without even being asked) to ensure consistency or improve clarity. Finally, the response to stipulations carefully explained how each issue was resolved. The experience of conducting the review was painless and truly a pleasurable experience. We want to extend a big thank you to the team for their sincere efforts. **Congratulations to Dr. Janes, Ms. Smith and the other members of the research team!**

TIPS FOR COMPLETING THE STUDY FORM IN PROTECT

When completing or updating the Study Form in PROTECT (the SmartForm), you may have noticed that some questions are similar to those in the iRIS Study Application. However, there are differences in the wording, response choices and required information. For this reason, while we were able to migrate some of data from the iRIS Study Application for approved studies directly into each study's PROTECT Study Form, much of it could not be migrated. Given the differences between the questions in the two systems and the need to update the Study Info for migrated studies, some questions seem to trigger requests for clarification or stipulations more often than others. Accordingly, we thought it might be helpful to provide some guidance about what type of information is expected or required when responding to these questions in PROTECT.

BASIC STUDY INFORMATION

Question: [Add] Brief Description:

We are looking for either the study precis or a few paragraphs which summarizes the background & rationale, objectives, study population, methods, and analysis plan. Remember that this section of the protocol may be reviewed by different IRB members assigned to review a MOD or CR for your protocol. They will likely want to rely on this section to quickly understand the key aspects of your study.

NIH LOCAL REQUIREMENTS

Question: Does this protocol involve a CRADA or CTA?

When the question is answered "yes", the respondent must add the type of agreement, the name of the organization associated with the CRADA or the CTA ("Partner") and whether funding is being received from the partner.

While these questions may seem straightforward, it is critical that they are answered correctly. When answering these questions for an existing protocol, you should double check the answer to this question in the Study Application in iRIS and the protocol. For both old and new protocols, you should also confirm the answers with the PI. If a study involves a CRADA or CTA, this must be discussed in the protocol. There is also required language by policy that must be included in the COI section of the consent form (review the approved NIH consent form templates for more details). It is also critical that this section is updated when new CRADAs or CTAs are executed.

LOCAL STUDY TEAM MEMBERS

Question: Identify all NIH study team members who are engaged in this research project who are also listed in NED:

Question: [Add] Study team member:

Note: Protocol Navigators (who are not AIs) must be listed in this section to allow them access to complete and modify submissions in PROTECT. When the protocol is considered "covered", a statistician (who is not engaged*) should also be listed here, even if they will not have access to identifiable data, since they will need to be cleared by the DEC.

Otherwise, only investigators who are engaged in human subjects research (HSR) should be entered here.

*Examples of engagement in human subjects research include:

- Obtaining informed consent
- Interacting and/or intervening with human subjects for research purposes
- Obtaining, using, studying, analyzing, or generating identifiable private information or biospecimens for research purposes

Do not list any volunteers with a designation other than a Special Volunteer here, unless covered by the NIH's FWA via an IIA or FWA Coverage agreement or relying on the NIH IRB via a reliance agreement.

Question: [Select] Role in research:

When adding study team members, only select one role per study team member. Select the highest level of responsibility for each person. Refer to **Policy 300** for investigator role definitions. You should elect "Protocol Navigator" for any study team member who is only assisting the PI with regulatory

submissions and is not engaged in human subjects research (HSR). You should select "Statistician (who is not engaged)" only if a statistician is a member of the study team and is not engaged in HSR (otherwise they should be listed as an Associate Investigator).

Question: Is the team member involved in the consent process?

The default for any study team members who were migrated as a part of an existing study in iRIS will be "no". It is necessary to update this response based on who the PI expects to consent in the protocol.

When answering this question for fellows, please make sure that any fellows that have been designated to obtain consent have at least an MD/PhD/DDS/DMD per HRPP Policies 300 & 301.

STUDY SCOPE

Question: Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?

The answer should be 'yes' if the protocol is using a product as part of the focus of the research (mandated use as part of the protocol) or is using a drug or biologic that is not FDA-approved or is FDA-approved but is being used off label.

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

The answer should be '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. Please note that just because a device is commercially available, does not mean that it is FDA approved/cleared.

DRUGS

Question: List all drugs, biologics, foods, and dietary supplements to be used in the study:

You should list all the products that are being investigated as part of this study whether FDA approved or not, and if approved, whether being used on label or not (i.e., whether IND exempt or requiring an IND). Any product, which is mandated to be administered in a certain way at a specific time point in the protocol, needs to be included here. Please note that even if the use of the product is considered IND exempt within the study, the study would still be considered FDA-regulated.

Please be sure to attach the most recently approved IB or package insert for each product listed in this section. See "**Attach files related to this drug**" to add or update this documentation.

Question: Attach Files:

You should attach a communication from the FDA or the sponsor with the IND number for each IND included in the study.

DEVICES

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

You should add all medical devices that are not FDA-approved or are being used off label per the protocol (SR IDEs, HDEs, NSR IDEs, & IDE Exempt devices). Please note that a HUD/HDE is not the same as an FDA-approved medical device. Even if the use of the medical device would be considered IDE exempt within the study, the study would still be considered FDA-regulated.

Unfortunately, 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 and delete those devices which are not associated with your protocol. If you do not see the specific name of the device in the list, you should submit a ticket to the **Help Desk** to have the device added, so that you may select it.

Please be sure to attach product information/documentation from each non-NIH manufacturer for each device listed in this section. This is not required for the following: CT or MRI scanners, pulse sequences, coils, image reconstruction and analysis software. See "**Attach files related to this device**" to add or update this documentation.

Question: Device exemptions applicable to this study:

Since you can only list one, be sure to list the exemption associated with the "highest risk" device being used in the study. The order would be as follows:

1. IDE (Significant Risk device)
2. HDE number (Humanitarian Use device)
3. Abbreviated IDE (Nonsignificant Risk device)
4. Exempt from IDE requirements (IDE Exempt device)

Question: Attach Files:

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

DOCUMENTS (STUDY-RELATED & LOCAL SITE)

For detailed information about adding, revising, stacking, and comparing documents and other

related information, please see "Tip Sheet for Document Management in PROTECT" here: **NIH PROTECT Help Center: Managing Your Documents in PROTECT**.

OTHER SOURCES OF INFORMATION

Please be sure to attend the monthly "ORSC Protocol Navigators Procedures Work Group Meeting" held the second Thursday of each month at 11 a.m. and the weekly "Ask the eIRB Training and Support Team" session at 12:30 p.m. on Wednesdays. These are additional venues that OHSRP is currently using to share helpful information about PROTECT. To sign up for emails from the PN Procedures Work Group, please contact Eugene Bond or Sara Sadeghi. To get access to the link for the eIRB Training Support sessions, please look for PROTECT Notifications in your email or email the NIH IRB mailbox at **irb@od.nih.gov**.

PARTNERSHIP FOR INFORMED CONSENT OPTIMIZATION (PICO)

Last Fall, IRBO quietly launched an informed consent readability pre-review as part of a new program, the *Partnership for Informed Consent Optimization (PICO).* This article introduces you to the program and describes our progress to date.

PICO seeks to improve the informed consent process at NIH. The first component of the program is a "readability" pre-review of informed consents submitted with certain Initial Reviews. PICO has conducted over 30 readability reviews so far.

Some readability pre-review concepts:

- Replacing scientific terms with plain language
- Active voice rather than passive voice ("We will take your temperature" vs. "Your temperature will be taken.")
- Conversational language
- Short words, short sentences
- Adding details to Key Information when they might impact the decision to participate (e.g., washout or birth control requirements)

How does the pre-review work? Generally, IRBO makes suggested edits through the first few pages of newly submitted consents, and requests the study team make similar changes throughout the rest of the consent document(s). Study teams receive this feedback with the Analyst's pre-review stips. IRBO expects PICO readability suggestions to be incorporated into the re-submitted consent.

What does this mean for IRB Reviewers? Fewer stips. Less editing, particularly during IRB meetings.

On occasion, the IRB has replaced simplified language recommended by PICO with complicated scientific language, which we would like to avoid moving forward. Our goal is to reach the 6th – 8th grade reading level, making consents more accessible – especially to our prospective participants with

limited or minimal health literacy.

According to the Milken Institute, "at least 88 percent of adults living in the US have health literacy inadequate to navigate the healthcare system and promote their well-being." The Belmont principle of Respect for Persons, the Common Rule, and AAHRPP, all expect – if not require - "language understandable to the subject."

PICO also strives to minimize the therapeutic misconception by replacing reference to "patients" with "participants," and avoiding the term "treatment" when referring to investigational study drugs or therapies.

Look for a future IRB Member Tip Sheet.

We will soon pilot an educational component of the program to educate investigators about their protocol-specific IRB-approved informed consent process. A third component will involve observation of informed consent discussions, and is under development.

eIRB PROJECT COMMUNICATIONS

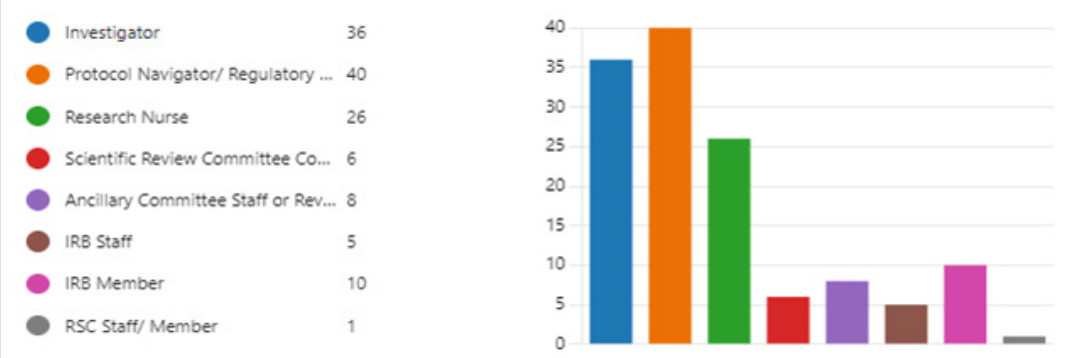
PROTECT SYSTEM: POST GO-LIVE SURVEY

Summary of Results & Responses

In mid-March, the OHSRP surveyed the NIH intramural research community on the training and go-live experience we delivered for the new PROTECT system. The purpose of this survey was to hear from you about what worked best and what could use some adjustment now that we are in the maintenance phase of our electronic IRB system implementation.

Who we surveyed

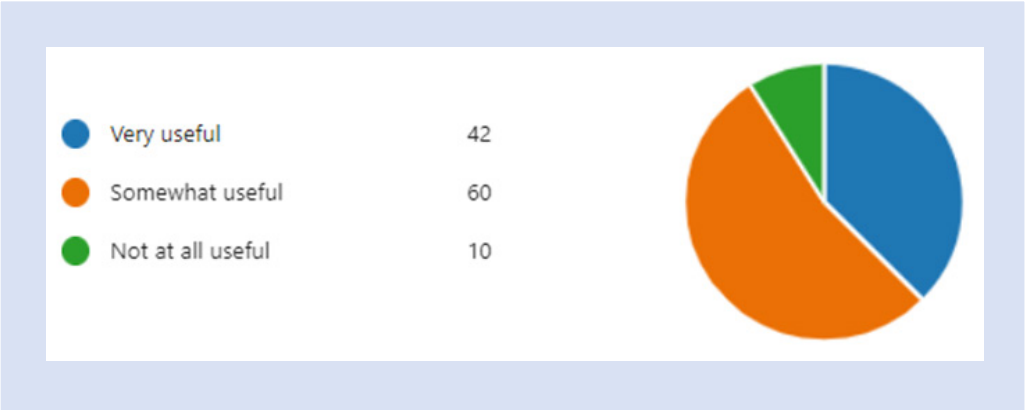
Majority of responders were investigators, protocol navigators/regulatory, and research nurses.



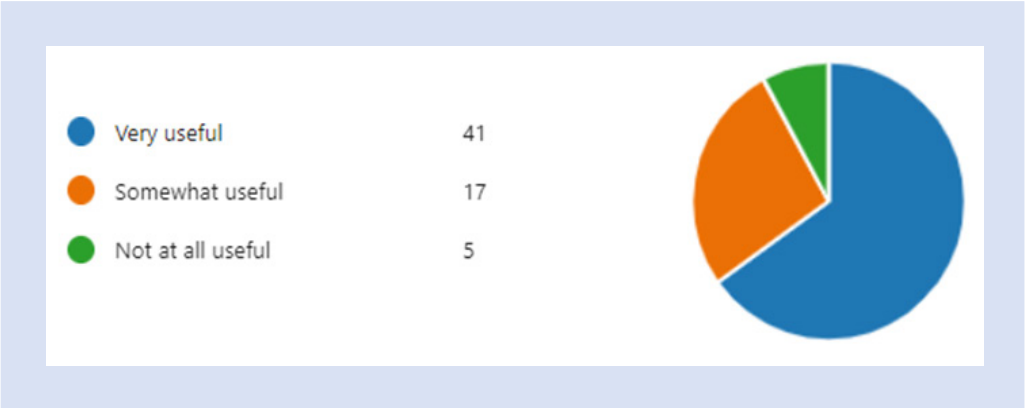
5888 system user accounts were targeted; 132 responses received (2.24% response rate).

What you found useful

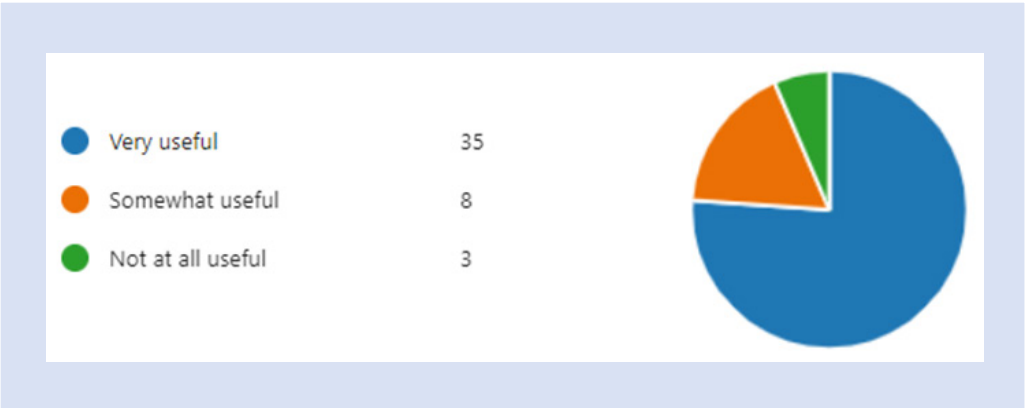
'Live PROTECT Trainings' before go-live were useful to most.



'Ask the Trainers' sessions have been useful to most.



'Live Help Desk Hours' have been useful to most.



General Feedback

TIMING
Trainings occurred too early before go-live date to be easily recalled.

SPECIFICITY
Trainings and guides/videos were more general and high level, less NIH/IC specific.

MODALITY
Preferred more hands-on trainings/interactive (not one directional) instruction. Recordings were helpful.

TOOLS
Desire more tools and aids to visualize timing of ancillaries (SRC, RSC, IBC, Rx, DEC, PRIA, PQS).

AUDIENCE
Desire more role-specific trainings, even by IC where needed (SRC, RSC, IBC, Rx, DEC, PRIA, etc.).

What you want more of

Some of you would like to select more classes (on ancillary reviews, document management, tips & tricks/common mistakes). The majority of you want better, more detailed guides and supplemental aids/visuals to help you understand and how the ancillary reviews tie into IRB workflow.

CONTINUING EDUCATION SERIES/TIP SHEETS/TOOLS

In the upcoming months, we will leverage some of our 'Ask the Trainers' sessions and offer a PROTECT Continuing Education Series that targets the topic areas you expressed that you would like more in-depth coverage on. These sessions are held on Wednesdays @ 12:30 p.m. EST on Teams and a reminder email goes out weekly with a meeting link. Topics we plan to include are below. We intend to send users back from each session with a related Tip Sheet on the topic. We also plan to revise the existing PROTECT User Guides in the context of NIH processes, and to produce visual aids/ workflow diagrams for each content area to assist with complementing our guides.

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FOR RESEARCH TEAMS

COURSE	DESCRIPTION
Tips & Tricks: Document Management	Audience: This class is intended for all system users. In this class, we will cover tips for managing your documents in your PROTECT submissions for both single and multisite studies. Document topics to be covered include: revising docs for MODs, comparing, naming and locating docs (both approved and clean), as well as formats that are accepted.
Tips & Tricks: Modifications	Audience: This class is intended for all system users. In this class, we will cover tips for preparing modifications (MODs) and updates for both single and multisite studies/pSites. Topcs to be covered include: types of MODs possible (study team only vs full application), how to revise docs as part of the MOD, and managing ancillaries on a MOD. Commonly asked Qs about the form data.
Tips & Tricks: Continuing Reviews/Closures	Audience: This class is intended for all system users. In this class, we will cover tips for preparing continuing reviews and closures for both single and multisite studies/pSites. Topics to be covered include: how you can submit a combo CR/MOD, CR, or study closure. Commonly asked Qs about the form data.
Tips & Tricks: Managing Ancillary Reviews	Audience: This class is intended for all system users. In this class, we will cover how to trigger and set up ancillary reviews (DEC, PRIA, IBC, Pharmacy). on various submissions (Initial, MODs, Scientific Reviews, etc). We will also cover the timing of these reviews relevant to IRB and Scientific Review, when the system checks for and blocks those reviews, and how to verify if those reviews are complete.
Tips & Tricks: Scientific Review Submissions	Audience: This class is intended for all system users. In this class, we will cover how to trigger and set up ancillary reviews on various scientific review submissions (Initial, MOD, Annual/Quad). We will also cover the timing of these reviews relevant to IRB and Scientific Review, when the system checks for and blocks those reviews, and how to verify if those reviews are complete.
Tips & Tricks: Radiation Safety Submissions	Audience: This class is intended for all system users. In this class, we will cover how to trigger and set up radiation safety reviews [Initial, Amendment, De Novo (triennial) Review, and Safety Incident]. We will also cover the timing of these reviews relevant to IRB Review, when the system checks for and blocks those reviews, and how to verify if those reviews are complete.

FOR ANCILLARY REVIEWERS AND SPECIALISTS

COURSE	DESCRIPTION (REVISE AS NEEDED)
Ancillary Reviews for Ancillary Reviewers	Audience: This class is intended for the ancillary reviewer users (DEC, PRIA, IBC, Pharmacy). In this class, we will cover how to find and complete your ancillary reviews (DEC, PRIA, IBC, Pharmacy). on various submissions (Initial, MODs, Scientific Reviews, etc). We will also cover the timing of these reviews relevant to IRB and Scientific Review, when the system checks for and blocks those reviews.
Scientific Review for SRC Coordinators	Audience: This class is intended for Scientific Review Coordinators. In this class we will cover how to find and review your SR submissions (Initial, MOD, Annual/Quad). We will also cover the workflow and processing for designated or committee review, as well as meeting management and sending for CSO review, and finally processing and sending the approval letter to the study team.

POLICY UPDATES

Only two minor technical revisions have occurred to Human Research Protection Program (HRPP) policies since the last newsletter. First, is a minor revision to the definition of a "Covered Research Protocol." This definition is used in **Manual Chapter 3014-102 Investigator Conflict of Interest and Government Royalties**. We have removed the parenthetical example at the end of the definition since it has caused some confusion. The definition now reads, "**Covered Research Protocol** – *Covered research protocols (and covered substudies) include: (1) studies of investigational drugs and devices, (2) studies with a research question about a commercially available drug or device, and (3) studies involving collaborations with a substantially affected organization (SAO) or another for-profit entity when the entity is receiving data or specimens from the NIH for the purpose of developing a product. Most interventional protocols will be Covered Research Protocols unless the intervention does not involve the criteria listed above."*

The second revision is a description in **MC 3014-301 Informed Consent** of what we expect of the witness to the short form consent process. The witness in the short form consent process is required by regulation (**46.117(b)(2)**). However, we continue to see confusion about the role of the witness during this process. We now explain that in addition to expecting the witness to be fluent in in the language of the subject and in English, that *"Generally, the purpose of the witness is to attest to the voluntariness of the subject's consent and the adequacy of the consent process (i.e., that the information was accurately conveyed and that the subject's questions were answered)."*

It is for this reason, in the very rare instance when the witness is not fluent in the language of the subject, that the policy already expects the following of the witness: *"... the witness should verify with the interpreter that the subject understands the information presented, that all questions have been satisfactorily addressed, and that the subject agrees to participate. The witness, or investigator obtaining informed consent, should document this as a note in the record documenting the short form consent procedure."*

We know that the short form consent process doesn't occur all that often for most study teams and that many technical issues may arise. So, when you are preparing to use this consent process it is always good to do a quick review of **MC 3014-301, Section E.2.h.VII**. In addition, we encourage you to look at the **consent FAQs** on our website to refresh your memory about other aspects of the short-form consent process you may have questions about.

COMPLIANCE AND TRAINING UPDATES

UPDATES ON THE NIH INVESTIGATOR SEMINAR SERIES

The OHSRP Investigator Seminar Series was initiated earlier this year and targets investigators who conduct human subjects research. A list of topics, dates and links for upcoming sessions as well as links for slides and recordings of completed presentations can be found on the **OHSRP Investigator Seminar Series Information** webpage. So far this year, sessions have addressed the following topics: determining whether your project might require an exemption or IRB review, including submission of a secondary research protocol; IRB role, function, and authority; planning your protocol; and what investigators need to know about consent forms and processes. Our June 12th session will cover investigator responsibilities, and our July 10th presentation will address what investigators need to know about scientific review of new and ongoing protocols. Looking forward to later sessions in 2023, we will be discussing these topics: GDS policy and data safety and monitoring plans; Certificates of Confidentiality and the EU's General Data Protection Regulation; documentation and document management; reporting research related events; and post-approval monitoring/root cause analysis/ creating corrective and preventive action plans. We have additional issues to address in 2024 that will also be of interest to investigators. Please check back on the **OHSRP Investigator Seminar Series Information** webpage to obtain the most up to date information.

The sessions are presented by subject matter experts via Zoom and are usually held on the second Monday each month from 3-4 PM (though this may occasionally change based on speaker availability and federal holidays that fall on Monday). In addition to posting the topics and links on the webpage noted above, 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.

2023 OHSRP EDUCATION SERIES SESSIONS

The OHSRP Education Series sessions presented thus far in 2023 have covered a variety of topics of interest to the Intramural Research Program (IRP). Links to the videocasts and slides from these sessions are posted in the **Presentation Archive section** of the OHSRP website.

The January session covered T*he What, When and Why of Investigator Financial Conflict of Interest Review*. In this presentation, Tonia Awoniyi, Director of the NIH Ethics Office, discussed specific information about requirements and responsibilities for reporting COI within the NIH IRP. Jonathan Green and Heather Bridge from OHSRP also joined the presentation, and Heather provided COI tools available for study teams while Jonathan covered government royalty payments to NIH Investigators and the COI Review that occurs in these situations.

The updated NIH Policy Data Management and Sharing Policy became effective January 25, 2023, and our February OHSRP Education session was a timely one titled *Implementing the NIH Data Management and Sharing Policy within the NIH IRP*. Taunton Paine, Director of the Scientific Data Sharing Policy Division in the Office of Science Policy, and Dr. Chuck Dearolf, Director of Program Development and Support in the OIR, discussed the history of the policy as well as the important reasons why NIH supports data sharing. They discussed the scope and timelines related to the current policy as well as the Intramural Template and additional resources to which investigators can

refer when writing their Data Management and Sharing Plan (DMSP). The presentation also covered best practices for protecting privacy when sharing human research participant data and guiding principles for this process.

On a somewhat related note, the May session, *Ethics of Sharing Individual-level Data from Research with Human Subjects*, was presented by Dr. Saskia Hendriks from the NIH CC Department of Bioethics. She addressed the benefits and potential risks of data sharing and how these can differ across data types and contexts. Information related to investigators' and research participants' views on data sharing was also covered, and Dr. Hendriks discussed why ethically appropriate protections for sharing data may be proportional to the potential risks of data sharing.

Our March OHSRP Education session featured an outside guest speaker, Dr. Evan Myers, the Walter L. Thomas Distinguished Professor of Obstetrics and Gynecology in the Duke University School of Medicine as well as Vice-Chair for Reproductive Risks at the Duke Health System IRB. The title of his presentation was *Avoiding Unplanned Pregnancy in Clinical Research Balancing Science, Safety, and Ethics*. Among other topics, he spoke about common issues with sponsor protocol/consent language, pregnancy in the context of underlying disease, defining pregnancy "potential" and pregnancy testing. Some of the issues discussed have been incorporated into the updated language in the section related to pregnancy in the **Consent Library** on our OHSRP website.

As use of social media continues to expand within human subjects research, the April education session provided an opportune occasion to address this topic. Dr. Brenda Curtis, an investigator in the NIDA Translational Addiction Medicine Branch, presented *A How to Guide: The Use of Social Media in Research* and was joined by NIH IRBO Director, Tiffany Gommel, for the Q&A session. Dr. Curtis discussed various ways social media is used in research such as for recruitment, providing interventions, online support groups, health campaigns, and use of mobile apps. She also took a deep dive into the various human subjects protections issues and related ethical considerations that can arise when social media is used in this context .

We have a number of additional topics that will be covered as part of the monthly OHSRP Education Series over the remaining months of 2023 such as regulations and use of "big data," considerations for informed consent in cell and gene therapy trials, and requirements of our NIH HRPP's emergency preparedness and response plan which is under development. These sessions usually occur on the first Thursday of the month from 3-4 PM via **live NIH videocast**. 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. 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."