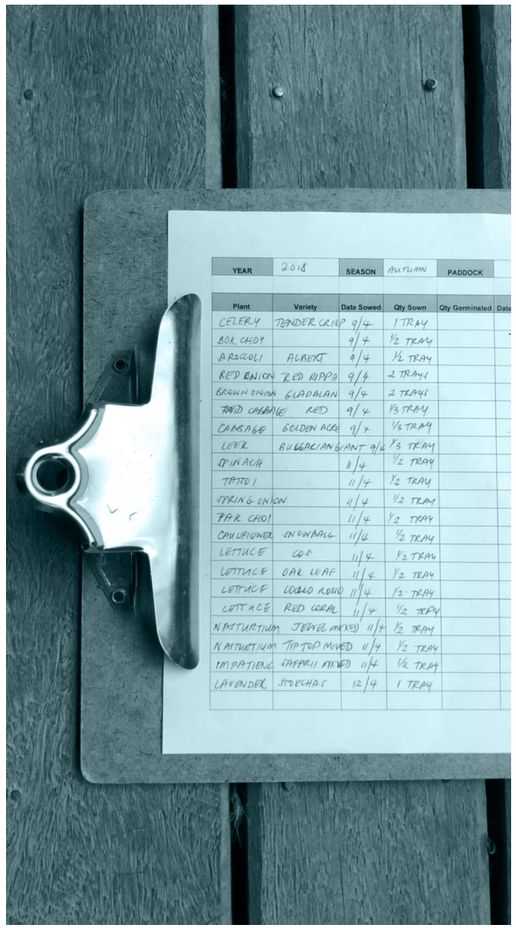
NIH
OHSRP

DECEMBER 2020

IRB MEMBER UPDATE

Happy Holidays!

We wish you all a very happy holiday season! We in OHSRP are so grateful for your participation as an IRB member over the past year, especially during these unusual times. We hope that you can take the time this holiday season to find peace and spend time with those that you love. And we all have much to look forward to in the new year!



New Reviewer Checklists in iRIS

We have revised the reviewer checklists in iRIS that you will complete when you are assigned as the primary or secondary reviewer for an action. The initial review and continuing review checklist have been revised, and the amendment checklist is new. We hope that these checklists will help guide your review and assist in your preparation for the meeting.

Please complete the checklist and your review in the system at least 24 hours prior to the meeting, so that the analyst and Chair can review your comments. In the past version of the checklists are required in the system. It is important that your review is documented in the system.

If you have questions about how to complete your review or need help navigating the system, please contact the iRIS training team at iris_training@od.nih.gov, and one of the trainers will be happy to set up time to work with you.

Voting against the Grain: Remember, it's okay to 'just say no'!

Given the complexity and variability in the nature and types of research that Institutional Review Boards (IRB) review, it is not unexpected for IRB members to occasionally find themselves feeling unsure of how to vote. This could stem from unfamiliarity with a given study objective, procedure or population, IRB inexperience, low quality IRB submissions, or simply the uncertainty of whether a minor concern is 'worth' voting no. The small group nature of IRBs can further put boards at risk of falling victim to conformity and 'groupthink'. Remember, consensus is not required for a review item to be approved. Research may be approved if a majority of those members present at the meeting vote to approve the review item (see 45 CFR 46.108, 21 CFR56.108, and Policy 204).

If you're struggling with how to vote, Robert Amdur, MD, author of "Institutional Review Board Member Handbook" indicates that board members should "vote 'no' unless they are convinced to vote 'yes'." Whether you are questioning a recruitment procedure in a new submission, a revision to the data and safety monitoring plan, or the board's response to an incident of noncompliance, don't be afraid to voice your opinion and vote against the majority.

If you have issues or concerns, be sure to raise them during the board discussion. Other board members may have the same question and discussion may help the board arrive at appropriate explanations or alternatives. In analyzing issues and raising concerns, Amdur also promotes referencing back to the basic ethical principles described in the Belmont Report: respect for persons, beneficence, and justice.

Utilizing these principles to frame concerns may help board members get to the core issues concerning the conduct of the research. Furthermore, while board

members may be hesitant to vote against the majority because the member's initials and a description of the reason for the vote are recorded in the meeting minutes (see Policy 204), it's important to note that access to meeting minutes is restricted to OHSRP staff, board members and IRB governing bodies (Office for Human Research Protections [OHRP] and Food & Drug Administration [FDA]) and to the entity that accredits the intramural research program's Human Research Protection Program (Association for the Accreditation of Human Research Protection Programs [AAHRPP]).

Should you have questions or concerns regarding this process, please contact Nicole Grant or Tiffany Gommel.

Reference: Amdur, R. J. (2003). Institutional review board: Member handbook. Sudbury, MA: Jones and Bartlett.

Tips for Reviewing Continuing Reviews

All full board approved research is required to undergo continuing review (CR) at least annually. This review provides the IRB the opportunity to monitor the research and ensures that the research continues to adequately protect subjects and meets the criteria for IRB approval, as defined by 45 CFR 46.111 and 21 CFR 56.111. The Office for Human Research Protection's Guidance on Continuing Review highlights the following key considerations to evaluate during continuing review:

- **Progress of the Research** – Is the study progressing in a manner that is compliant with what was originally approved? Reviewing information pertaining to study status and subject enrollment (including subject withdrawals) to ensure information is consistent with what was previously approved sheds light on how the research is being conducted.

- **Risk Assessment and Monitoring** – Is there new information that would change the risk/benefit assessment or how risks to subjects are minimized? This new information could stem from serious or unexpected events, toxicities or complications, data and safety monitoring reports or other related publications/reports.

- **Adequacy of the Informed Consent Process** – Are study teams providing accurate, up-to-date information during the consent process and following the approved consent process? The review of this process is two-fold in assessing: a) whether institutional requirements regarding documentation of the consent are being met (see 'How to Review the Last Signed Consent' box) and b) whether the information provided during the consent process requires updating.

- **Investigator and Institutional Issues** – Have there been any subject complaints or incidents of non-compliance that require additional information or further review by the board? Are there any institutional changes/issues that affect the conduct of the research? In tackling continuing reviews, keep the following in mind:

  - **Remember to Review Amendment & Reportable Event Information:** The continuing review form only includes progress report information and documents uploaded by the study team related to the re-approval (i.e., DSMB reports, last signed consent forms, publications, audit/monitoring reports, etc.). Amendment and reportable event information also needs to be reviewed and can only be accessed by going to the "miscellaneous" tab in the upper right corner, selecting "submission history", and then the "completed submissions" tab. From there, you can open and view all actions submitted to the IRB since the past review.

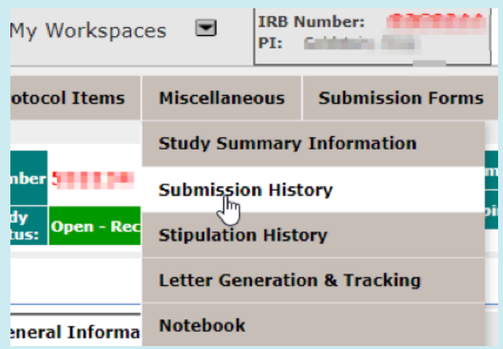
How to Review the Last Signed Consent

To meet institutional requirements, there are 4 key elements to assess when reviewing a last signed consent form:

1. Was the document current at the time of consent? This can be determined by cross-referencing the date the subject signed consent and the date the document was approved (see image of watermark). Note that this may require referencing amendments approved since the previous continuing review.

2. Did approved study personnel obtain consent? The study team member identified as the 'Investigator' can be cross-referenced with section 3 of the study application or under General Information

3. Are the dates the subject and the person obtaining consent consistent with the approved consent process? Typically, the date the subject signs the consent form and the date the person obtaining consent signs the consent form should be congruent. Occasionally signature dates may differ, e.g., the protocol identifies that consent is being obtained remotely, and the signed consent returned via mail.



- **Review the Previous Year's Report to Assess for 'Bigger Picture' Issues:** If applicable, compare the current continuing review to the previous year's continuing review. Assess whether enrollment information 'adds up,' and look for any trends in research events that may indicate 'bigger picture' issues in how the research is being conducted. If an initial trend is spotted, you may need to go back to older continuing reviews to further assess trends.

- **Don't Get Hung Up on Previously Approved Content:** Remember the protocol, recruitment and consent documentation reviewed during this process was previously approved by the board (or the board's designee). Revisions requested to these materials at the time of continuing review should be limited to those required based on a) any new information provided during the review process; or b) continuing need to meet the criteria for IRB approval.

The NIH IRB Welcomes New Board Members

The NIH IRB would like to welcome the following new board members:

Nicole Binder, PharmD, BCPPS

Michelle Egbuniwe-Paasch, BS, MPH

Jim Karousatos, BS

Pia Nierman, BA, BSN, MA

Killian Salerno, MD

Clevetta Drew, AA

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