IRB News & Updates

Congruency, Consent, and Recruitment Materials

Dec 13th, 2024

In order to assure that subject injury language in the consent forms matches that in contracts, UNeHealth or SPA will begin conducting congruency checks. The congruency check is an institutional requirement and is a requirement for accreditation of our Human Research Protection Program.

Research teams should ensure a copy of the consent form is either developed or uploaded in RSS. The Office of Regulatory Affairs will notify SPA/UNeHealth of the requirement for a congruency check. If a discrepancy is found, SPA/UNeHealth will reach out to study teams directly to correct the consent form. Research teams will need to revise the consent developed in RSS or upload a copy of the revised consent (if relying on an external IRB) to RSS.

Congruency checks apply to studies that are conducted at UNMC, Nebraska Medicine, and Children's Nebraska that are:

- Commercially funded
- Grant/Foundation/Consortium (other than NIH) funded
- DoD funded

Congruency checks are NOT required for:

- NIH funded studies
- Cooperative Groups studies, such as the Children's Oncology Group
- Departmentally funded studies
- CCTR funded studies
- Studies conducted at UNO

CIRB Consent Forms

For studies relying on an external IRB for oversight (CIRB studies), the Office of Regulatory Affairs will be reviewing consent forms to verify the required UNMC local consent language has been appropriately inserted into the consent. The required language is available on the UNMC IRB

website. This review will also look for any consent language required by the UNMC Conflict of Interest Committee, as applicable.

CIRB Recruitment Materials

For studies relying on an external IRB for oversight (CIRB studies), the Office of Regulatory Affairs will begin reviewing recruitment to verify the materials conform to UNMC HRPP policies 3.5 and 3.6 . For existing studies, any new recruitment materials should be submitted as a change request. For new studies, recruitment materials should be uploaded to RSS at the time of initial submission.

Fee Increase

July 31st, 2024

To align with other academic medical centers and universities, effective September 1, 2024, the Office of Regulatory Affairs and the IRB will increase the IRB review fees for the initial review of protocols where UNMC relies on a commercial IRB. This will apply only to protocols submitted on or after September 1, 2024.

- Central IRB initial review fee (UNMC relying on a commercial IRB) will increase from $1500 to $3000. This is a one-time fee.

All investigators involved in research projects relying on a commercial IRB should include the IRB review fee in their grant or contract budget. A funding account must be provided at the time of IRB submission.

If you have any questions, please contact the Office of Regulatory Affairs at irbora@unmc.edu.

Advarra Submissions

July 2nd, 2024

Effective immediately, UNMC site submissions to Advarra may begin as soon as a study has been assigned a UNMC IRB number in the RSS system. Previously, Advarra required an Acceptance letter from the Office of Regulatory Affairs in order for study teams to begin the submission process with Advarra. Study teams will be required to provide Advarra with a copy of the "New Protocol" email as documentation of having a UNMC IRB number.

Emergency Preparedness (EP/COOP)

May 16th, 2024

We would like to remind clinical researchers about our Emergency Preparedness & Continuity of Operations Plan (EP/COOP), which is designed to:

- Detail how decisions on altering or halting ongoing research might affect studies, investigators, and current/potential subjects.
- Establish a framework to restore essential functions to UNMCâ€™s Human Research Protection Program (HRPP), Institutional Review Board (IRB), and ORA during emergencies.
- Complement the broader UNMC/NM enterprise-wide COOP.

The plan is available here: https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/emergency-preparedness-continuity-of-operations-plan-%28epcoop%29

IRB Office Hours

January 19th, 2024

Intended for questions regarding research projects, filling in an application, policies, regulations, etc.

- 2nd Monday of every month 9-10 AM (Zoom link)
- 4th Thursday of every month 2-3 PM (Zoom link)

Please direct questions regarding office hours to the IRB Education Coordinator, Megan Berger: mberger@unmc.edu or 402-559-6044

We would like to remind everyone that IRB staff are available for assistance outside of office hours. If you ever need help outside of the designated office hours, please do not hesitate to reach out to an analyst or our main email, IRBORA@unmc.edu. We are happy to assist you via email, phone call, or video conference call during normal work hours.

Additional information can be found on our Education page [here](***insert link here***).

August 17th, 2023

The Office of the Vice Chancellor for Research and Office of Regulatory Affairs want to inform human subjects researchers about a temporary policy change.

Why it Matters: Over the next couple of months, temporary onboarding and training demands for new IRBORA staff may lead to a delay in timelines for IRB review and other ORA processes. The VCR and ORA recognize the potential impacts this could have on studies and have implemented a temporary policy change to lessen their effect and provide another option for studies.

What's New: This policy change is currently in effect and provides an option for certain study teams to use Advarra or WCG as a Central IRB (cIRB).

- This change applies to new investigator-initiated studies where the Principal Investigator is from UNMC, Nebraska Medicine, Children's Hospital & Medical Center, or the University of Nebraska—Omaha.
- This is a temporary change from the policy requiring local IRB review for UNMC investigator-initiated studies.
- This option will be in place until November 1, 2023 unless extended further by the VCR Office/ORA.
- Study teams are still encouraged to use the UNMC IRB, as this change only provides the option to use a Advarra or WCG as the IRB of record.

What to Do: Investigator teams seeking to use one of these commercial IRBs as the IRB of record are required to submit a CIRB application to the UNMC IRB in addition to the application required by the commercial IRB.

> Note: Studies should be aware of the following costs associated with using an external IRB: A one-time, $1,500 fee for UNMC review of CIRB studies to ensure compliance with local institutional guidelines. Any additional fees charged by external IRBs for review and use of their services

As a reminder: any human subjects research, whether reviewed by the UNMC IRB or by an external IRB, must adhere to all UNMC HRPP Policies, and must have the approval of all other relevant institutional committees.

For more information, visit the UNMC CIRB website or contact IRBORA@unmc.edu with any questions.

Bruce Gordon, MD Assistant Vice Chancellor for Regulatory Affairs Executive Chair, UNMC IRBs

Russell J. McCulloh, MD Associate Vice Chancellor for Clinical Research Institutional Official, UNMC IRBs

UNMC expanding support for ClinicalTrials.gov registrations

June 30th, 2023

The UNMC Office of the Vice Chancellor for Research and the Office of Regulatory Affairs are updating and expanding support for UNMC's investigator-initiated studies registered on ClinicalTrials.gov.

To assist UNMC investigators in meeting the complex registration and reporting requirements in ClinicalTrials.gov, the two offices are rolling out an enhanced record monitoring and communication plans that will take effect on July 1.

Key enhancements include:

- Investigators and institutional leadership now will be kept apprised of records with update or reporting problems.
- For any studies experiencing issues with their ClinicalTrials.gov listing, UNMC's ORA will provide a timeline for correction and assistance as needed.
- A CITI training course is available to UNMC and University of Nebraska at Omaha learners, which provides video instructions for registering, uploading documents and submitting results in ClinicalTrials.gov
- IRB protocols linked to ClinicalTrials.gov records are easily identified via color-coded icons in RSS. Red icons indicate records with problems, and green icons indicate records that currently are compliant.

Over the next few months, additional support and resources will be provided through UNMC's ORA, including expanded ClinicalTrials.gov information on the UNMC IRB website, a new decision-making tool for determining registration requirements and timing and more robust processes for record management and closure.

The goal is to bring studies registered on ClinicalTrials.gov through UNMC into full compliance with federal regulations, while reducing the complexity and burden of this process on investigators.

The National Institutes of Health and U.S. Food and Drug Administration have increased their enforcement efforts against reports of registration and reporting failures. Penalties can include substantial monetary fines and the suspension of funding for an investigator or the institution.

However, by collaborating with UNMC's ORA and following the updated process, UNMC and its investigators can achieve full compliance and avoid these consequences.

ClinicalTrials.gov, launched in 2000, serves as a publicly accessible registry for clinical trials. The database provides the public with clinical trial information, while offering researchers access to valuable study data, promoting transparency and informed decision-making in clinical research.

Please email the Office of Regulatory Affairs for more information irbora@unmc.edu.

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cIRB webpage update

March 6th, 2023

The cIRB page of the IRB website has recently been reworked. Please feel free to visit the page for updated information as well as a list of helpful forms and links. Keep an eye out for upcoming changes to the sIRB information available on the website!

If you have any questions, please email sirb@unmc.edu or call 402-559-6463.

Reminder regarding Protocol Approval Expiration

January 17, 2023

Investigators and research teams are reminded that annual continuing review is required for research originally approved by the convened IRB (protocols designated FB) as well as most research approved before 2019. As always, reminders will be sent to the PI and the Lead Coordinator and/or Regulatory Contact 60 days and 45 days prior to approval expiration.

If Continuing Review is not submitted and re-approved by the IRB by the expiration date all human subject research activities must stop. This includes new subject accrual, as well as follow-up of existing subjects and data analysis.

If continuation of research activities is in the best MEDICAL interest of already enrolled subjects (that is, the research presents the potential for direct benefit to subjects) you may submit the “Request to Continue Treatment for Enrolled Subjects on Approval Expired Studies" form, available in RSS.

If a Continuing Review application is not submitted within 30 calendar days, the study will be closed, and re-activation of a closed protocol will require submission of a new IRB application.

If all study activities, including all follow-up and data analysis, are completed, and all ClinicalTrials.gov reporting requirements have been met, you must submit a Study Completion Report, available in RSS.

Research which qualifies for Expedited Review (protocols designated EP) and some FB research that is in data analysis or clinical follow-up may not require annual continuing review. The initial approval letter, or a subsequent communication from the Office of Regulatory Affairs, will notify you if CR is not required.

If your research does not require annual CR you must still complete an annual Demographics form. If this form is not submitted within 20 days the protocol will be closed as above.

If you require assistance, please contact us at IRBORA@unmc.edu, or at 402-559-6463

Consent regarding Human Biological Materials

August 26, 2022

Investigators are reminded that obtaining blood samples or other biological specimens for research, whether from a patient or from an employee or other normal volunteer, for use now or in the future, requires IRB approval and written informed consent. This includes drawing blood as “controls” for in vitro assays, unless those assays are performed solely for clinical purposes (and usually in a CLIA certified laboratory).

The IRB is happy to work with you to develop protocols to encompass a number of different activities involving collection of samples from human subjects, and to discuss further. Please contact us at IRBORA@unmc.edu, or at 402-559-6463.

Conducting human subject research without IRB approval and informed consent, including obtaining blood or other biospecimens for any research purpose, is serious non-compliance and may be reported to HHS, FDA, NIH, or other Federal authorities."

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cIRB Application Update

June 24, 2022

1 - The CIRB application has been updated to include a contact information sheet which can be automatically generated in RSS. This contact sheet includes the Rights of Research Subjects and Research Questions

- a. Check the box next to personnel you would like to list on the Contact Information sheet. (6/24/22 IRB update 1)
- b. When all personnel have been selected, click “Save.” The page will refresh.
- c. Select “Contact Information Sheet” from the left side menu to generate a pdf that includes a list of authorized personnel and the last 2 pages appended to any consent form. (6/24/22 IRB update 2)

2 - Additional questions have been added to the CIRB application:

- a. “Does this study involve an investigational drug or device?” If yes, prompted for IND/IDE#.
- b. “Will subjects age 18 years of age or younger be included in this research?” If yes, prompted to enter age range.
- c. “Method of Subject Identification and Recruitment” section added for consistency with other IRB applications and to ensure UNMC investigators are following UNMC policies.
- d. “Process of Informed Consent” section added for consistency with other IRB application and to ensure UNMC investigators are following UNMC policies.

Financial Interest Disclosure

June 21, 2022

As of June 21, 2022, PIs and Faculty Advisors must personally complete the Financial Interest Disclosure questions at the time they are signing section I of the application. Though other research personnel may collaborate on completing other sections of the IRB application, no one other than the individuals signing the application will have the ability to answer the financial disclosure questions. This change applies not only to new applications but also to approved applications when a change request is initiated.

Revised Paper Continuing Review Forms

June 17, 2022

The continuing review applications for existing paper applications have been revised. These forms have been revised to remove personnel changes from the continuing review so that the continuing review and personnel changes on paper applications are handled like the electronic applications in RSS. These forms can be found on the IRB website:

https://www.unmc.edu/irb/procedures/forms/paper-protocols.html

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RSS New Application Update

June 8, 2022

All IRB applications begun after today will no longer require certification and signature by a Resource Reviewer.

Investigators are reminded that they are still responsible for assuring that there are adequate resources available to conduct the research, and to protect the rights and welfare of human subjects.

COVID-19 Update

February 9, 2022

The request to voluntarily defer the start of new protocols and pause face-to-face research activities is now lifted. Investigators should continue to use remote visits, when and where feasible, and review all subjects for potential exposures or risk before any scheduled face-to-face visit. Location or timing of visits may still be impacted by changes in Nebraska Medicine or other clinical facility changes and/or staff shortages.

Reinforcing COVID-19 Guidelines

January 11, 2022

With increasing cases of COVID and COVID breakthrough, we want to clarify/reinforce the new UNMC/Nebraska medicine policies as they are relevant to research spaces. We will make one change in our current policy regarding volunteers in research labs.

For all research programs:

- Masks should be worn everywhere indoors, unless by yourself behind a closed door.
- Cloth masks should not be used anywhere, as per recent Nebraska Medicine and UNMC guidance, unless on top of a surgical/procedural mask
- Conduct any and all research activities remotely, if they can be done remotely, including one on one meetings and seminars
- Visitors should be limited, masked, and escorted with rigorous questions about recent exposures beforehand
- Take turns eating in designated spaces, by yourself or behind a closed door, or socially distanced if in a larger space
- Minimize time unmasked while eating, whether eating alone or in a room where others are sitting

For all lab building and lab-based programs:

- Return to scheduling time on shared equipment and other measures to enhance social distancing in the lab
- Starting Monday Jan 17, research volunteers will no longer be allowed to work in laboratories (such as high school, undergraduate, visiting students) except the following:

- International Scholars who have been already approved through the Office of Global Engagement
- UNMC health professions students or students enrolled in a University of Nebraska course
- High school alliance students in their currently assigned laboratories.

All volunteers must be vaccinated, no exceptions or exemptions, and show evidence of vaccination, per our policy. They should be strongly encouraged to obtain a booster, as soon as they are eligible.

For all face to face clinical research programs:

- Study monitors can come to campus if they are required to, if masked and escorted, and vetted for recent exposures
- Continue to ask research subjects before face to face contact as to recent exposures or symptoms,

Continue to follow your approved biosafety protocol, and all policies of the institution where the research is to be conducted regarding masking, which may now require providing surgical/procedural masks for subjects or accompanying persons.

Demographic Data Requirement Update

January 10, 2022

The Vice Chancellor of Research and the IRB now require that all human research studies provide demographic data (gender, race, and ethnicity) of all enrolled subjects, at time of annual review. This information will be submitted as part of the Continuing Review form, for studies requiring continuing review. For studies not requiring Continuing Review, PIs and Lead Coordinators will receive an email directing him/her to a new Demographics form which has been generated in the FORMS section of your application in RSS.

DocuSign Availability for Electronic Signature

December 6, 2021

DocuSign may now be available for use to document research informed consent in the limited cases where sponsors require its use. This is limited to research NOT subject to the FDA regulations. There may be a charge associated with use of DocuSign; contact Courtney Kennedy in IT for approval or for more information. In addition to DocuSign, investigators may continue to use the RSS e-signature system as previously noted.

Electronic Signature through RSS Expanded Availability

November 11, 2021

Previously only available for studies that were not Federally funded, the RSS e-signature function may now be used for Federally funded research studies also. To request use of this function, please send a message to the IRB via the RSS message portal. Please note, the RSS e-signature function is NOT available for any study that is FDA regulated regardless of funding source.

Remote Consent and Electronic Signatures FAQs

1 - What is remote consent?

- Remote consent refers to the use of techniques like telephone, videoconferencing, or desktop, mobile, or web-based applications (for example, Zoom) as an alternative to face to face discussions in the process of obtaining informed consent.
- HRPP policy 5.3 (Use of a Remote Consent Process)
- To the extent that remote consent facilitates the process of consent, the IRB endorses and encourages its use. However, the Board must approve the specifics of the process.

2 - What is e-Signature?

- e-signature refers to the use of various platforms (like DocuSign, or Adobe Sign) to obtain signatures on a consent form electronically.
- The use of e-signature is independent of the use of a remote consent process. A face-to-face consent process may include an electronic signature, and remote consent may include a “wet” (physical) signature.
- The UNMC IRB must approve the platform used to obtain e-signatures. The specific electronic platforms allowable are dictated by FDA regulations and by Nebraska law.

3 - What is the difference between remote consent and e-signature?

- Remote consent is the process of consent, when consent is not conducted face-to-face.
  - E-signature is signing the consent form electronically.

4 - What platforms are allowed for e-signature?

- RSS e-signature is now available for use for Federally funded research. RSS e-signature cannot be used for research which is FDA regulated. In addition, RSS e-signature does not at present support consent forms that require a second signature for optional studies.
- DocuSign, GMO GlobalSign and Solutions Notarius platforms may also be used for Federally funded research, since those platforms are recognized by Nebraska law as equivalent to a “wet” signature. Other platforms may become available in the future, as allowed under Nebraska Law.

- 21 CFR Part 11 (“FDA Part 11”) compliant systems, such as Part 11 compliant DocuSign may be used for FDA regulated research (research involving a drug or device). Note that the standard version of DocuSign, which is not part 11 compliant, is not acceptable.
- REDCap e-signature can only be used for research which is neither Federally funded nor FDA regulated.

5 - How do I access these systems?

- DocuSign, GMO GlobalSign and Solution Notarius: must be licensed by the investigator.
- RSS: the IRB must turn on the e-signature function
  - Active Studies: no change request is required. Send a message through the message portal requesting the use of e-signature. Note: If you are adding a remote consent process, a change request will be required.
  - For new studies, if you are planning to use a remote consent process, or an e-signature platform (like RSS or DocuSign), the plan must be described in the Consent section in the IRB application.

Changes in the IRB Application

June 10, 2021

Which applications are affected?

Biomedical and Soc/Beh, Human Biologic Material, Medical Records research, Tissue Bank, Data Registry and Humanitarian Use Device protocols.

What are the changes?

- You will be asked to provide an estimate of the time it will take to accrue the target number of subjects for this research.
- You will be asked to describe the timing of consent related to when screening tests are performed.
- The subject identification section has been simplified.
- The process of consent section has been revised.

When do these changes take place?

- These changes went into effect June 9, 2021.

I just started a new application last week and have not yet submitted it, do I need to start another new application?

- No. Much older applications which have not been submitted, however, may need to be updated. If so, an IRB administrator will contact you.

If you have any concerns please contact us by phone 402-559-6463 or email irbora@unmc.edu

IRB Commercial/Industry Fee Changes

March 17, 2021

In line with most other academic medical centers and universities, effective July 1, 2021, the Office of Regulatory Affairs and the IRB will begin charging an annual fee for continuing review of commercial/industry sponsored protocols. This will apply only to protocols submitted after July 1, 2021. In addition, fees for expedited review, and for protocols where UNMC relies on a commercial IRB (like Advarra or WIRB) will increase.

- Full board review of commercial/industry sponsored protocols will remain unchanged at $3000 at time of initial submission. Annual continuing review will now be billed at $1250.
- Expedited review of commercial/industry sponsored protocols will increase from $1000 to $2000 at time of initial submission, and annual continuing review will be billed at $1000.
- Central IRB review (UNMC depending on a commercial IRB) will increase from $1000 to $1500. There is no charge for continuing review for studies using a commercial IRB.

A WBS number must be provided at the time of IRB submission, and billing will occur at the time of IRB review. The protocol will not be released until review fees are paid. Therefore, all investigators involved in commercially sponsored research projects should include the IRB review costs in their grant or contract budget.

If you have any questions regarding this policy, please contact Bruce Gordon, MD

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