# Education & Resources

The goal of the IRB Education Program is to facilitate research involving human subjects from initial submission to study completion through didactic and practical education. Whether it is for investigators, research study personnel, students or other institutional representatives, information is explained in a manner that fits the audience. By using a variety of delivery methods, such as lectures, webinars, live-streams, bulletins, one-on-one meetings and department in-service, from new student to seasoned investigator, our objective is to offer education of:

- The history and regulation of research ethics
- The local submission requirements and process
- The common pitfalls to improve the efficiency of the submission process.

The IRB is here to help!

All educational options will be tailored to meet the specific needs of the target audience, whether it be one-on-one about a specific research protocol or a lecture to a class regarding a general overview of research ethics and the IRB process.

If you would like to schedule a one-on-one meeting, department in-service, class lecture, Q&A session or any other type of IRB education, please contact IRB staff for assistance at irbora@unmc.edu

- HRPP Investigator Guidance Series
- Investigator Resources
- IRB Conference Content
- Mental health considerations
- Miscellaneous Resources

# HRPP Investigator Guidance Series

This page serves as a hub for all of the Investigator Guidance Series documents. Each document is an abbreviated version of one of our HRPP Policies and Procedures intended for investigators, coordinators, and other study team members. This page is a good starting point for any study team member with a question about a policy on a specific topic. A link to the full policy/procedure is included in each document.

| Document | Updated |
|---|---|
| Advertisements (3.5) | 12/13/2023 |
| Authority of the IRB | 12/13/2023 |
| Change Requests | 12/13/2023 |
| cIRB | 12/13/2023 |
| Closure of Research | 12/13/2023 |
| Compensation | 12/09/2024 |
| Confidentiality | 12/13/2023 |
| Continuing Review | 02/05/2024 |
| Contraception Requirements | 12/13/2023 |
| Data and Safety Monitoring | 12/13/2023 |
| Data Registries | 12/15/2023 |
| Emergency Research - Waiving Consent | 12/13/2023 |
| Emergency Use of a Test Article | 01/25/2024 |
| Employees as Subjects | 12/13/2023 |
| Ethical Access | 12/09/2024 |
| Exempt Research | 01/25/2024 |
| Expanded Access to Investigational Drugs and Devices | 12/14/2023 |
| Expedited Review | 12/13/2023 |
| Financial COIs | 01/25/2024 |

| Document | Updated |
| --- | --- |
| Full Board Review | 12/13/2023 |
| Humanitarian Use Device (HUD) | 12/13/2023 |
| Incidental Findings | 12/13/2023 |
| Increased monitoring, interim Continuing Review, and verification | 12/15/2023 |
| Informed Consent | 12/13/2024 |
| International Research | 12/13/2023 |
| Investigational and Marketed Devices | 01/26/2024 |
| Investigational and Marketed Drugs | 12/13/2023 |
| IRB Approval Criteria | 12/15/2023 |
| Obtaining Informed Consent for Non-English Speaking Persons | 12/13/2023 |
| Obtaining Informed Consent for Persons with Additional Needs | 12/13/2023 |
| PI Qualifications and Responsibilities (job description) | 12/13/2023 |
| Placebos | 12/13/2023 |
| Post-Approval Monitoring of Research | 12/09/2024 |
| Pregnancy Testing | 12/13/2023 |
| Privacy | 01/26/2024 |
| Recruitment | 12/13/2023 |
| Reimbursement | 12/13/2023 |
| Research Involving Children | 12/13/2023 |
| Research Involving Decisionally Impaired Persons | 12/13/2023 |
| Research Involving Neonates | 12/13/2023 |
| Research Involving Pregnant Women and Fetuses | 12/13/2023 |
| Research Involving Prisoners | 01/25/2024 |
| Research Personnel Qualifications & Responsibilities (study team job descriptions) | 12/13/2023 |
| Short Form Consent | 12/13/2023 |

| Document | Updated |
| --- | --- |
| sIRB | 12/13/2023 |
| Students as Subjects | 12/13/2023 |
| Study Hold | 12/13/2023 |
| Suspension | 12/13/2023 |
| Termination | 12/13/2023 |
| Using PHI in Research | 12/13/2023 |
| Vulnerable Populations - Additional Protections | 12/13/2023 |
| Waiving Consent Process | 12/13/2023 |
| Waiving Signed Consent | 12/13/2023 |
| Wash Out | 12/13/2023 |
| What requires IRB review and approval? | 01/10/2024 |

# Investigator Resources

## Regulations:

- Common Rule (45 CFR 46)
- eCFR: 21 CFR Part 50-Protection of Human Subjects
- eCFR: 21 CFR Part 56-Institutional Review Boards

## National Institutes of Health:

- NIH Home Page
- Office of Recombinant DNA Activities (ORDA)
- Office of Grants and Contracts
- National Human Genome Research Institute
  - Ethical, Legal and Social Implications (ELSI)

## UNMC Links:

- General Counsel's Memo on Mandatory Reporting of Child Abuse and Related Statute of Limitations
- Institutional Biosafety Committee (IBC)
- Animal Care and Use Program (IACUC)
- Sponsored Programs Administration (SPA)

## Food and Drug Administration:

- FDA Web Site
- FDA - Center for Drug Evaluation and Research (CDER)
- FDA - Center for Devices and Radiological Health

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## International Standards:

- International Compilation of Human Research Standards

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## Other Federal Agencies:

- National Archive and Records Administration
  - Federal Register Online
- Office for Civil Rights
  - Medical Privacy - National Standards to Protect the Privacy of Personal Health Information
- Department of Health and Human Services
  - Child Abuse Reporting Memo

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## Organizations and Other Items of Interest:

- Public Responsibility in Medicine & Research (PRIM&R)
- National Bioethics Advisory Commission (NBAC)
- American Society for Bioethics and Humanities

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## IRB History and Principles:

- “What Makes Clinical Research Ethical?” Emanuel, et al; JAMA 283(20):2701, 2000
- THE BELMONT REPORT: Ethical Principles and Guidelines for the Protection of Human Subjects of Research(UNMC)
- The Belmont Report(HHS)

# IRB Conference Content

## 2024

- 2024 IRB Conference Introduction (Bruce Gordon)
- 2024 IRB Conference Conclusion (Bruce Gordon)
- Big Data and Ethics (Scott Campbell)
- Considerations for Patient Safety in Studies of Psychedelics and other Non-Ordinary States of Consciousness. (Lou Lukas)
- De-Centralized Trials (Megan Singleton)
- Let's Review Some Research (Nancy Olson/Nichelle Cobb)
- Research on the Edge (Bruce Gordon)

## 2023

- 2023 IRB Conference Introduction (Bruce Gordon/Russell McCulloh)
- Participant Compensation (Joe Brown/Dustin Krutsinger)
- Personal Narrative and Research Ethics (Gigi McMillan)
- Re-examining the IRB's Role in Protecting Research Subjects (David Strauss)
- Uncovering Bias in Artificial Intelligence (John Windle)
- Understanding CBPR (Keyonna King/Russell McCulloh)

# 2022

- 2022 IRB Conference Introduction (Bruce Gordon)
- Genetics, Research, and Diversity (Omar Rehman/Kristi DeHaai)
- Informed Consent & Teach Back Workshop (Elizabeth Bankert)
- Intro to the IRB (Bruce Gordon)
- Readability is Fundamental (Nichelle Cobb)
- Review of Research Involving Products with EUA (Kindra Cooper)
- Risk of Harm to Non-Subjects (David Borasky)

# Mental health considerations

## MENTAL HEALTH CONSIDERATIONS FOR RESEARCHERS

DECEMBER 2023

### EXPLANATION OF RISKS:

- Be clear in application and ICD about risks associated with mental health assessments (cognitive status assessments, IQ screens, mental health assessments, exploitation/abuse/violence assessments, and drug testing).
- Describe how and by who mental health assessments and outcomes are reviewed and reported.
- Remember to report psychiatric adverse events, including serious adverse events, appropriately.

### SELF-REPORT MEASURES:

- Protocols using **subject self-reports** that ask about depression, worthlessness/guilt, and quality of life, should include a process of review by personnel with plan to notify investigator of pertinent positives.
- Protocols using **subject self-report** reports with items specifically addressing **self-harm or suicidal ideation, or related items indicating a subject may be at risk**, should have a mechanism for responses to be reviewed in **REAL TIME** so action can be taken as appropriate.
- Protocols using remote self-reports (Ipad, EMA device, web-based, etc.) should include a mechanism for notification of the investigator or designated member of the study team when threshold responses are received so that **REAL TIME** management can occur.

### INVESTIGATOR-ADMINISTERED MEASURES:

- Investigator-administered measures of psychiatric symptoms should be completed by those with appropriate training.
- If the study team does not have the specific expertise, consider consultation with psychiatry or psychology colleagues.

## PHQ-9:

- PHQ-9: Suggestion to align with Suicide Risk BPA's used by NM PCMH clinics rooming staff starting 8/8/2022:
  - if >14 and + response to question 9 = refer for emergency eval
  - if >14 and – response to question 9 = refer for mental health consult
  - if <14 and + response to question 9 = further assessment needed; refer as appropriate
  - if <14 and – response to question 9 = no further specific intervention

## The Columbia Suicide Severity Rating Scale-Revised (CSSRS-R):

- Baseline ("lifetime") and "since last visit" versions available on-line.
- Validated and available in Spanish.
- Use of this scale should include training for non-mental health providers as it explores suicidality in a very thorough manner:
  - To complete the C-SSRS Training for Clinical Practice, visit http://c-ssrs.trainingcampus.net/
  - General information, go to http://cssrs.columbia.edu/

## RESOURCES:

- CURRENT – include **988** for the suicide hotline, don't give numbers to agencies now closed (**911 is still ok to use**).
- ACCURATE—know the policy for referral to the Department of Psychiatry, procedures for accessing ER, the Psychiatric Emergency Service (PES). Consider age- and/or diagnosis-appropriate services (e.g. Nebraska Family Help Line [1-888-866-8660]; Professional Partners-Region specific).
- LOCAL—while resources are limited in some areas of the state, please make sure you list the ones close to the subject's home.

## UNMC/NE MEDICINE PSYCHIATRY SERVICES:

- Psychiatry (ADULT) accepts referrals from PCP's within the system.
- C/A psychiatry not limited to UNMC/NE Med providers.
- Behavioral Health Connections team (402-552-6007) facilitates referrals to community agencies.
- When referring to the "PES" (Psychiatric Emergency Service), understand that patients still must go through the regular NE Med ER or Bellevue Medical Center ER first.

## PSYCHIATRY SERVICES FOR CHILDREN

- Immanuel (CHI) ER is primary location for inpatient triage for children/teens; other ER's may transfer there if hospitalization is needed.
- Bryan LGH (Lincoln) has inpatient care for children/teens as well as emergency shelter placement.
- Boys Town (Grand Island) has emergency shelter placement.
- Mercy (Council Bluffs) will accept NE youth (even Medicaid if no NE beds available).
- Boys Town has an inpatient unit—triage through Methodist ER's.

## PSYCHIATRY SERVICES FOR STUDENTS:

- **For UNMC students**: call UNO Health Center, 402-554-2374 (select option 2 to leave message for the nurse for scheduling).
- For **UNO students**: Call CAPS 402-559-7276 (initial appointments are covered by student fees).
- **Gender and Sexuality Resource Center (GSRC)**: Confidential and free, Student Life Center 2031. Call 402-559-7276.

## KEARNEY COMMUNITY RESOURCES

- S.A.F.E. Center: 24/7 hotline 1-877-237-2513

## LINCOLN COMMUNITY RESOURCES

- Voices of Hope: Crisis hotline 402-475-7273 (non-emergencies, 402-476-2110)

## NORFOLK COMMUNITY RESOURCES

- Bright Horizons: call 877-379-3798 or text 402-370-8817

## SCOTTSBLUFF COMMUNITY RESOURCES

- Doves Program: call 308-436-4357 or 866-953-6837; text 515-599-6620

## NATIONAL RESOURCES

- National Domestic Violence Hotline: 1-800-799-7233, TTY 1-800-787-3224
- National Suicide Prevention Lifeline: Text or Call 988
- Trans Lifeline: 1-877-565-8860

# Miscellaneous Resources

Below investigators will find a variety of resources that may assist with research goals:

- Allowable Costs Related to Participant Inclusion Activities
- Emergency Preparedness / Continuity of Operations Plan (EP/COOP)