



Vulnerable Populations in Clinical Research

Presented by: Addiction Medicine Research Team

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Agenda: Vulnerable Populations in Clinical Research

- **Vulnerable Populations in Clinical Research**
 - Brief definition and ethical framing
- **How Vulnerability Is Reviewed**
 - Regulatory and IRB context (high-level)
- **Historical Context: Why Protections Exist**
 - Lessons from past research abuses
- **Vulnerable Populations Reviewed Today**
 - Pregnant individuals
 - Incarcerated individuals
 - Children
 - Native American & Indigenous populations
 - Individuals with cognitive impairment
 - Racial & ethnic minorities
 - Unhoused individuals
 - LGBTQI+ individuals
 - Individuals with substance use disorders
- **Practical Tips for CRCs**

What is a “Vulnerable Population” in Clinical Research?

- **According to OHRP and HHS, vulnerable subjects are individuals who may:**
 - Be susceptible to coercion or undue influence
 - Have diminished decision-making autonomy
 - Require additional safeguards to protect their rights and welfare
- **Vulnerability may arise depending on the research, including:**
 - Characteristics of the subject population
 - The nature of the research and the research setting



Takeaway: Vulnerability does not require exclusion; it requires additional safeguards and documentation.

OHRP: Office for Human Research Protections
HHS: Department of Health and Human Services

Regulatory Framework: How Vulnerability Is Reviewed

- **Federal Regulations (45 CFR 46):**
 - **Subpart B:** Pregnant women & fetuses
 - **Subpart C:** Prisoners
 - **Subpart D:** Children
- **UA / IRB Additional Protections**
 - Individuals with Cognitive Impairments
 - Native and Indigenous Populations
- **What IRB looks for (in practice)**
 - Risk level and safeguards aligned to vulnerability
 - Consent approach (assent/LAR/capacity considerations)
 - Recruitment approach (coercion/undue influence; incentives)
 - Setting-specific protections (privacy, confidentiality, follow-up)

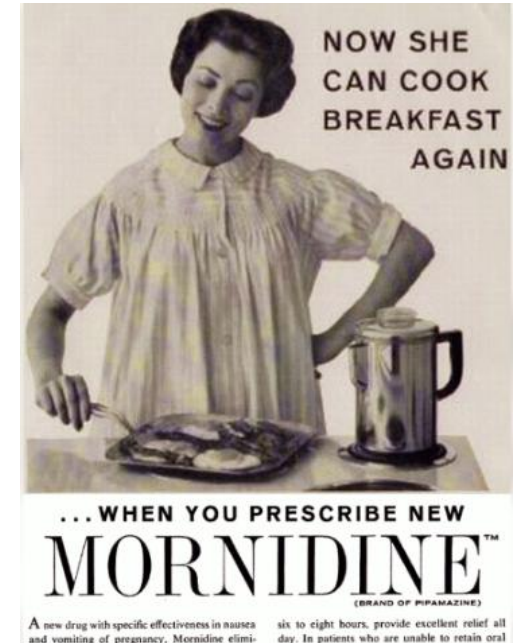




Research on Pregnant Individuals

Research History: Pregnant Individuals

- Pregnant individuals are historically **excluded or underrepresented** in research.
- ACOG notes that this has led to **preventable harms** due to limited evidence on medication safety and efficacy in pregnancy.
- **Thalidomide (1950-1960s)**
 - Approved based on studies in non-pregnant populations
 - Widely used during pregnancy (for morning sickness)
 - Resulted in severe congenital limb malformations
- **Key lesson:**
 - Lack of pregnancy-specific research can expose pregnant individuals and fetuses to unknown and avoidable risks



Research on Pregnant Individuals

- **Definitions (Federal)**
 - **Pregnancy:** the period from implantation to delivery (45 CFR §46.202)
- **When does Human Research involve Pregnant Individuals?**
 - Confirmation of pregnancy (by disclosure, missed menses, or pregnancy test).
 - The OHRP does not require investigators to determine pregnancy status.
- **Categories of Research Involving Pregnant Women**
 - Federally funded minimal risk research or has the prospect of direct benefit to the woman or the fetus (45 CFR §46.204).
 - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates (45 CFR §46.207).



Research on Pregnant Individuals: Practical Tips

- **Participant Interest**

- Most pregnant individuals are willing to participate in research
- High interest in observational, retrospective, and lifestyle studies
- Motivation is often related to maternal and fetal health



- **Recruitment Approach**

- Active recruitment is significantly more effective than passive methods (flyers, emails)
- In-person discussions during prenatal visits yield higher enrollment
- Assign follow-up responsibility to study staff, not participants

- **Provider Engagement**

- OB provider endorsement increases trust and participation
- Ongoing communication between CRCs and clinical teams improves recruitment flow





Research on Incarcerated Individuals

Research History: Incarcerated Individuals

- **Malaria Experiments (1942)**
 - 400+ prisoners were intentionally infected with Malaria to test WWII treatments
 - High risk, mosquito-borne infection under coercive conditions
- **The MK-ULTRA (1950s-60s)**
 - Secret CIA program testing mind control and behavioral manipulation
 - Unwitting subjects, including prisoners, exposed to hallucinogens (e.g., LSD) and other substances
- **Holmesburg Prison Experiments (1950s-70s)**
 - A major site of inmate experimentation, involving industry, military, and government sponsors
 - Exposure to harmful chemicals and infectious agents (e.g., dioxin, chemical warfare agents, viruses)
 - High cash payments and the captive prison environment create coercive conditions
- **Key Takeaway:**
 - Historical abuses in prisons highlight the need for protections to prevent coercion and ensure ethical research.



Incarcerated Individuals

- **Definition:** (45 CFR §46.303)
 - **Prisoner:** any individual involuntarily confined or detained in a penal institution.
- **When does Human Research involve incarcerated individuals?**
 - Prisoner participation via interaction, intervention, or collection of identifiable information
- **Requirements for inclusion of prisoners in Human research**
 - Protocol-specific justification for IRB review
 - May be Exempt if prisoners are incidentally included in a broader population
 - Expedited review may apply for record-based research without interaction
 - Prisoner representative not required unless designated by IRB Chair
- **Permitted Research Categories:** (45 CFR 46.306(a)(2))
 - Causes or effects of incarceration or criminal behavior (minimal risk)
 - Studies of prisons or prisoners as incarcerated persons
 - Research on conditions particularly affecting prisoners
 - Practices intended to improve prisoner health or well-being

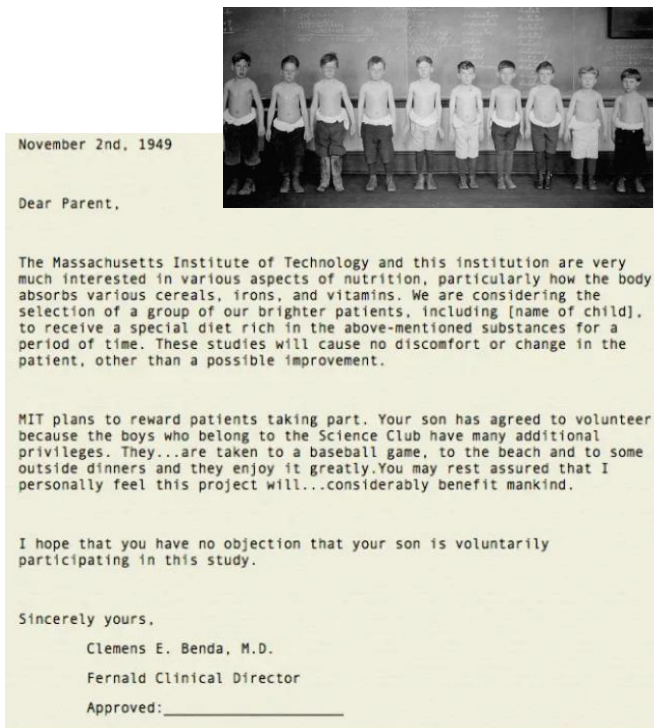




Research on Children

Research History: Children

- **MIT Human Radiation Experiments (1944-1974)**
 - Children exposed to radioactive iron and calcium in non-therapeutic research via food
 - Permission relied on misleading information (described as “Special Diet”) and incomplete risk disclosure.
 - Review found to be unacceptably risky, with no direct benefit and increased cancer risk.
- **Willowbrook State School Hepatitis Studies (1950-60s)**
 - Children with intellectual disabilities were deliberately infected with hepatitis
 - Participation was linked to expedited admission, raising concerns about coercive parental permission.
 - No direct therapeutic benefit to participating children.
- **Key lessons (National Commission, 1974–1978):**
 - Children should not be unfairly excluded from research
 - Pediatric research is essential to children’s health and well-being.
 - Adult data cannot always be safely extrapolated to children.
 - Research involving children can be ethical when risks are limited and protections are in place.



Research on Children

- **Definitions (Federal):** (45 CFR §46.402)
 - **Children:** individuals who have not reached the legal age for consent for research.
 - **Assent:** a child's affirmative agreement to participate
 - **Parental Permission:** agreement of parent(s) or guardian
- **When does Human Research Involve Children?**
 - Child participation via interaction, intervention, or collection of identifiable information
- **Categories of Research Involving Children?**
 - No greater than minimal risk
 - Greater than minimal risk with prospect of direct benefit
 - Greater than minimal risk, no direct benefit, but may yield generalizable knowledge about a serious problem affecting children
- **Requirements for Research Involving Children:**
 - **IRB justification** to include children
 - **Parental permission** unless IRB waived
 - **Minor assent** when developmentally appropriate
 - **Re-consent** if participant reaches adulthood during research
 - **Additional protections** for wards of the state



Research on Children: Practical Tips (Assent & Communication)

- **Use plain, simple language**
 - Choose familiar words (e.g., “choose” instead of “decide”)
 - Use short, direct sentences with one idea at a time
- **Keep structure consistent and predictable**
 - Maintain the same subject and message within sections.
 - Break information into small segments, not long paragraphs.
- **Reduce cognitive load**
 - Avoid sentences that require remembering multiple ideas to understand the message.
 - Present information step-by-step.
- **Use visual supports**

Include images or visuals in assent forms when appropriate to support understanding.
- **Check understanding actively**
 - Ask open-ended questions (e.g., “How could this study hurt you?”).
 - Encourage teach-back using the child’s own words.
- **Match feedback to demonstrated understanding**
 - Simplify or add detail based on responses





Research on Native/Indigenous Populations

Research History: Native American /Indigenous Populations

- **Havasupai Tribe v. Arizona Board of Regents (Early 1990s)**
 - ASU researchers collected blood samples from ~200 Havasupai Tribe members, who believed the research was limited to diabetes
 - **Broad consent language** allowed additional studies, but this conflicted with the tribe's understanding and cultural expectations of narrowly defined consent
 - **Samples were later used without re-consent for unrelated research**
 - Including schizophrenia, inbreeding, and migration theories
 - Discovered by the tribe in 2003, a 2010 settlement returned the samples and provided financial compensation.
 - Highlighted the need for clear, **culturally grounded** informed consent and community engagement
- **Key Takeaway:**
 - Research with Indigenous communities requires informed consent that must be specific, culturally grounded, and ongoing consent to prevent harm and loss of trust.



Havasupai people visited Tempe to say prayers over disputed blood

Native American / Indigenous Populations

- **Definitions:**
 - **Indian:** a person who is a member of a sovereign Indian Tribe as defined below. Indian is synonymous with American Indian, Alaska Native, and Native American.
 - **Indian Tribe:** any state-recognized tribe and any Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe
- **When Special Considerations Apply (Per UA):**
 - Research conducted in Indian Country or on tribal land
 - Studies in Indian Health Service (IHS) facilities or using IHS resources
 - Targeted recruitment of Native American or Indigenous populations
 - Genetic testing or collection of identifiable biospecimens
 - Research leading to tribal or community-level conclusions
 - Data collection or dissemination with implications for a tribe or Indigenous community
- **Key regulatory protections:**
 - Submit documentation of Indigenous community consultation and approval
 - Submit Site Authorization permission to receive IRB review
 - A special secondary reviewer for projects involving Native or Indigenous populations
 - Appendix for Native Americans and Indigenous Populations



Native American / Indigenous Populations: Practical Tips

- **Build trust through long-term relationships:** Partner with community organizations, seek Tribal/ community approval, and involve local AI/AN staff or researchers *throughout the study lifecycle*.
- **Reduce participation barriers:** Offer flexible scheduling, transportation support, and ensure consent and study materials are clear and accessible.
- **Show cultural respect and reciprocity:** Use culturally relevant, strengths-based messaging and *share study findings* back with the community.
- **Be transparent about data and biospecimen use:** Clearly explain how data will be used, stored, shared, and protected, especially in genomic research.





Research on Individuals with Cognitive Impairment

Research History: Individuals with Cognitive Impairment

- **UCLA Schizophrenia Medication Withdrawal Study (1983–94)**
 - Antipsychotics withdrawn from stabilized adults with schizophrenia, assessing relapse risk and psychosis predictors
 - Serious harms occurred (suicide & severe deterioration)
 - Federal review found inadequate informed consent and unclear criteria for restarting treatment
 - Note: Schizophrenia can involve impaired decision-making capacity
- **Psychosurgery and Behavioral Control Studies in State Hospitals (1940s–1960s)**
 - Institutionalized patients (including dementia) subjected to psychosurgery
 - Procedures (e.g., lobotomy) used for behavioral control, not patient benefit
 - Patients lacked decisional capacity, and consent was often absent, invalid, or institution-provided rather than LARs
- **Key Takeaway**
 - Research involving individuals with serious mental illness or cognitive impairment requires capacity-sensitive consent, strict risk limits, and ongoing safeguards to prevent harm and exploitation.



Cognitive Impairment

- **Definitions:**

- **Cognitively Impaired:** A condition that significantly limits judgment, reasoning, or decision-making capacity due to impaired cognitive or emotional functioning.

- **Common causes include:**

- Psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders),
- Organic impairment (e.g., dementia)
- Developmental disorder (e.g., intellectual or developmental disability)

- **Key regulatory protections:**

- If capacity is lacking, informed consent must be obtained from a Legally Authorized Representative (LAR)
 - Court-ordered legal guardian: should obtain a copy of the court order appointing guardianship
 - A healthcare power of attorney (HCPOA) may consent: should obtain a copy of HCPOA
- Assent from the participant may be required when feasible, as determined by the IRB



Cognitive Impairment: Practical Tips

- **Older people with Cognitive Impairments**
 - **Use capacity-sensitive consent** using plain language, memory/organizational aids, and informal discussion to improve understanding and avoid unnecessary exclusion
 - **Engage caregivers/proxies** early and treat recruitment as a dyadic process
 - **Recruit in non-clinical familiar settings** (community programs, assisted living) to reduce stigma, gatekeeping, and cognitive burden
- **Cognitive Impairment (Schizophrenia)**
 - Dedicated, interpersonally skilled recruiters trained in:
 - Clear, paced communication to explain study procedures,
 - Assessing comprehension
 - Recognizing when to pause or escalate concerns related to understanding or safety.
 - **Patient-Friendly Study Materials:** Provide concise, visually clear, 1-page study summaries with simplified explanations of procedures, risks, and compensation to support comprehension
 - **Ongoing Rapport and Flexible Follow-Up:** Maintain regular, familiar contact through recruiters to compensate for cognitive difficulties such as forgetfulness or disorganization



Citations:

- [Challenges and Strategies for the Recruitment of Patients With Schizophrenia in a Research Setting](#)
- [Strategies to Improve Research Participation By Older People With Cognitive Impairment: A Systematic Review](#)



Research on Racial & Ethnic Minorities

Research History: Racial & Ethnic Minorities

- **The Tuskegee Syphilis Study (1932–1972)**
 - 400 African American men were deliberately denied treatment for syphilis for 40 years
 - Participants were misled about their diagnosis and that the placebo was therapeutic
 - Informed consent was not obtained
 - Withheld penicillin even after it became standard treatment
- **The US Sexually Transmitted Disease Experiments Study (1946-1948)**
 - Over 1,300 Guatemalans were intentionally infected with STIs (syphilis, gonorrhea, and chancroid) without informed consent
 - Participants included children, prisoners, soldiers, and psychiatric patients
- **Key Takeaways:**
 - Racial and ethnic minorities have a documented history of mistreatment and lack of informed consent, giving rise to mistrust in the healthcare system (including in clinical research)



Some of the subjects in the Guatemalan experiments

Racial & Ethnic Minorities

- **Definitions:**
 - Racial and ethnic minorities: individuals identifying as Black, Hispanic/Latinx, Asian, American Indian, Alaska Native, and Pacific Islander.
- **Why Inclusion Matters**
 - Racial and ethnic minorities remain underrepresented in clinical research.
 - Underrepresentation contributes to persistent health disparities.
 - Diverse enrollment improves generalizability and helps identify differences in treatment response.
- **Key Considerations**
 - **Race is a social, not biological, construct;** however, it may correlate with ancestry-related genetic variations that are relevant to certain treatments.
 - Race and ethnicity **reflect lived social experiences** that influence health outcomes.
 - E.g., structural racism, socioeconomic factors
 - **Non-genetic and epigenetic factors** may affect populations differently and contribute to outcome variability.



Racial & Ethnic Minorities: Practical Tips

- **Build trust intentionally**
 - Use culturally sensitive, participant-centered recruitment approaches
 - Hire and train diverse research staff; ensure all staff are sensitive to beliefs affecting participation
- **Partner with trusted healthcare providers**
 - Engage clinicians serving diverse populations to encourage referrals
 - Minimize clinician burden and address concerns to support sustained referrals
- **Engage and involve the community**
 - Build relationships with community leaders and advisory groups
 - Share study results with participants and communities after study completion





Research on Unhoused Individuals

Research History: Unhoused Individuals

- **New York City TB Control and Research Programs (1980s–90s)**
 - Shelter-based TB screening, adherence, and Directly Observed Therapy (DOT) research
 - Disproportionate enrollment of unhoused individuals
 - Concerns: limited consent capacity, inducement, poor follow-up
- **CDC HIV Seroprevalence and Behavioral Risk Factor Studies in Homeless Shelters (1980s–1990s)**
 - Multi-city surveillance studies in shelters and meal programs
 - Often received testing without guaranteed linkage to care
 - Confidentiality and stigma risks were poorly addressed
- **Post-Deinstitutionalization Psychiatric Outcome Studies (1970s–1980s)**
 - Longitudinal observational studies of unhoused individuals with serious mental illness
 - Documented psychosis, deterioration, and survival without intervention
 - Major ethical concerns: consent capacity and duty to rescue



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Key Takeaway

doi: 10.1016/s0277-9536(96)00143-8

doi: 10.21107/ps.97.2.225

doi: 10.1563/ama.1040088

doi: 10.1056/NEJM199105233242111

doi: 10.2105/aoph.94.7.1039

doi: 10.1176/appi.ps.52.8.1039

Without strong consent protections, follow-up care, and rescue obligations, research involving unhoused individuals risks

Unhoused Individuals

- **Definition** (U.S. Department of Housing and Urban Development)
 - **Unhoused People:** individuals who lack a fixed, regular, and adequate nighttime residence, including those in sheltered (e.g., emergency or transitional housing) and unsheltered (e.g., streets, encampments, vehicles) situations.
- **Importance of including unhoused individuals in clinical research**
 - Promotes equity and justice by ensuring populations with high disease burden are not systematically excluded
 - Improves scientific validity by making findings more generalizable to real-world clinical settings
 - Informs effective care models that reflect the realities of housing instability
 - Addresses structural vulnerability by generating evidence relevant to social determinants of health
 - Builds trust and inclusion when research is conducted ethically and in partnership with communities



Citation

- <https://www.hudexchange.info/programs/hdx/guides/hdx-homeless-definition/>
- Gelberg, L., Andersen, R. M., & Leake, B. D. (2000). The Behavioral Model for Vulnerable Populations: application to medical care use and outcomes for homeless people. *Health services research*, 34(6), 1273–1302.

Unhoused Individuals: Practical Tips

- **Build Trust Through Transparency**
 - Be explicit about
 - What the study will and will not provide
 - How data will be used and who will see it
 - Clearly explain confidentiality limits (e.g., mandatory reporting)
 - Avoid jargon or language that resembles surveillance or eligibility screening
- **Trauma-Informed Engagement**
 - Assume high prevalence of trauma (violence, loss, institutional harm)
 - Do not require detailed trauma narratives unless absolutely necessary
- **Flexible scheduling and locations**
 - Use low-barrier follow-up methods
 - Avoid punitive responses to nonattendance
- **Clarify Research vs. Services**
 - Explicitly distinguish research participation from:
 - Case management
 - Clinical care
 - Housing services



Citation

- doi: 10.2174/1874924001003020096
- Gelberg, L., Andersen, R. M., & Leake, B. D. (2000). The Behavioral Model for Vulnerable Populations: application to medical care use and outcomes for homeless people. *Health services research*, 34(6), 1273–1302.
- <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
- <https://store.samhsa.gov/product/TIP-57-Trauma-Informed-Care-in-Behavioral-Health-Services/SMA14-4816>



Research on LGBTQI Individuals

Research History: LGBTQI+ Individuals

- **Aversion Therapy Studies (1950s-1970s)**
 - Electric shock, nausea-inducing drugs, and negative imagery to “treat” homosexuality
 - Participants were often coerced via courts, military, or psychiatric commitment
 - Sexual orientation framed as pathology, causing psychological harm
- **Tearoom Sex Study (1966-1970)**
 - Covert observation of consensual encounters in public restrooms
 - Deception used to identify and interview participants
 - No informed consent; serious legal, employment, and social risks
- **Early HIV/AIDS Natural Cohort Studies**
 - San Francisco Men’s Health Study (began 1983)
 - Multicenter AIDS Cohort Study (launched 1984)
 - Gay and bisexual men enrolled during a public health emergency
 - Limited treatments and confidentiality protections
 - Participants faced stigma, discrimination, and social risk without guaranteed linkage to care
- **Key Takeaway**
 - Historical LGBTQI+ research frequently involved coercion, deception, and inadequate protections, shaping today’s emphasis on informed consent, confidentiality, and community-engaged research.



Citations

- Humphreys, L. (1968). Tearoom trade: A study of homosexual encounters in public places. *Trans-Action*, 5(5), 4–17.
- doi: 10.1192/bjp.115.523.1417
- doi: 10.1093/aje/126.2.310
- doi: 10.2105/AJPH.77.6.685

LGBTQI+ Individuals

- **Definition**

- Individuals whose sexual orientation, gender identity or expression, or sex characteristics differ from heterosexual and/or cisgender norms.
- Includes lesbian, gay, bisexual, transgender, queer or questioning, and intersex people, with the "+" recognizing additional diverse identities (e.g., asexual, nonbinary).

- **Importance of including LGBTQI+ individuals in clinical research**

- Addresses historical exclusion and health disparities
- Improves scientific validity and generalizability
- Identifies population-specific risks and protective factors (e.g., mental health, substance use, HIV/STIs, cancer screening)
- Supports inclusive care models that build trust and improve engagement
- Shifts research from pathologization toward ethical, community-engaged practice



LGBTQI+ Participants: Practical Tips

- **Use inclusive, participant-centered language**
 - Ask about sexual orientation, gender identity, and pronouns using validated, optional questions
 - Avoid assumptions based on appearance, name, or anatomy
 - Use person-first and affirming terminology consistently across consent forms, surveys, and staff interactions
- **Avoid pathologizing frameworks**
 - Frame research questions around health equity and resilience, not deficits or “risk behavior” alone
 - Avoid language or measures that imply LGBTQI+ identities are disordered
 - Ensure outcome interpretation does not reinforce stigma





Research on People with SUD

Research History: People with SUD

- **Lexington Narcotic Farm (U.S. Public Health Service Hospital, KY)**
 - From the 1930s–1970s, individuals with opioid and alcohol use disorders were recruited into research at the U.S. Public Health Service Hospital
 - Participants were often actively using or in withdrawal, promised early release, treatment access, or payment
 - Studies deliberately administered addictive drugs (heroin, morphine, synthetic opioids), induced relapse or withdrawal to observe craving and behavior
- **Addiction “Challenge” Studies (1940s–1960s)**
 - Researchers intentionally re-exposed people with known use/misuse histories to opioids and alcohol to study reinforcement, tolerance, and dependence trajectories
 - Participants were rarely informed that relapse risk was high
 - Long-term consequences were poorly understood
 - Many subjects relapsed after studies without continuity of care
- **Key Takeaway**
 - Research that exploits illness, dependence, or constrained choice, especially by inducing relapse or withdrawal without full disclosure or follow-up, violates autonomy and beneficence, even when framed as scientific advancement.

- Campbell, N. D., Olsen, J. P., & Walden, L. (2014). The narcotic farm: The rise and fall of America's first prison for drug addicts. Abrams Press.
- Musto, D. F. (1987). The American disease: Origins of narcotic control. Oxford University Press.
- Beecher, H. K. (1966). Ethics and clinical research. New England Journal of Medicine, 274(24), 1354–1360.

People with SUD: Practical Tips

- **Assess capacity at the time of consent (not just eligibility)**
 - Ensure withdrawal management and medical stabilization before research procedure
- **Trauma-Informed & Stigma-Free Engagement**
 - Use person-first, nonjudgmental language (e.g., “person with SUD,” not “addict”)
 - Assume high prevalence of trauma; avoid shaming or surveillance-style monitoring
 - Train staff in motivational interviewing and de-escalation techniques
- **Flexibility & Accessibility**
 - Offer flexible scheduling, reminder calls/texts, and transportation support when feasible
 - Expect variable engagement, design protocols that accommodate relapse and re-engagement
 - Avoid punitive responses to missed visits or substance use
- **Minimize Coercion & Undue Influence**
 - Keep incentives modest and proportional to time/effort, not contingent on abstinence or outcomes



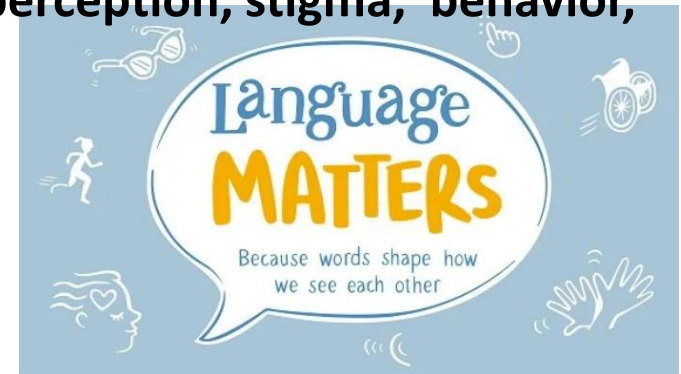


Why Language Matters in SUD Research

The Impact of Language on Bias and Stigma

- **Language shapes both implicit and explicit bias**
 - Explicit bias: conscious beliefs or attitudes that influence judgement
 - Implicit bias: unconscious beliefs or attitudes that shape automatic reactions without intentional awareness
- **Bias impacts:**
 - Patients' willingness to seek and engage in care
 - The relationship patients have with the healthcare systems and within research
 - Quality of care we can provide to ALL patients
- **Certain terms trigger automatic negative associations, leading to perpetual stigma**
- **Language is not *neutral* – it influences public perception, stigma, behavior, and outcomes**
Stigma = a label + a stereotype

"A label (i.e., addict) links a person to a set of undesirable characteristics that work to form the stereotype (i.e., beliefs held about a group of people with a substance use disorder)."



What the Evidence Supports

- **Stigmatizing terms show stronger negative implicit bias**

– “addict”
“substance abuser”

“alcoholic”

“relapse”

What Not to Say	Appropriate Alternatives	Explanation
"addict," "substance abuser," "junkie," "pothead" (Goodyear et al., 2018; Hulsey et al., 2023; Weber et al., 2021; Wilson, 2020)	"person with a substance use disorder," "person with an addiction," "person who uses drugs and/or alcohol" (Green, 2024; Lipsett et al., 2023; Weber et al., 2021; Wilson, 2020)	Stigmatizing terms like "addict" can lead to negative perceptions, increased blame, and reduced access to treatment (Goodyear et al., 2018). Person-first language emphasizes that the disorder is only one aspect of a person's life, not their defining characteristic (Lipsett et al., 2023; Volkow et al., 2021).
"addicted baby" (Weber et al., 2021)	"baby experiencing substance withdrawal" (Weber et al., 2021)	This avoids labeling an infant and focuses on the medical condition, which is temporary and treatable (Weber et al., 2021).
"dirty urine," "getting clean" (Wilson, 2020)	"positive/negative urine," "abstinent," "in recovery" (Wilson, 2020)	These phrases imply moral judgment and can be pejorative (Wilson, 2020). Neutral, clinical terms or recovery-focused language is preferred (Wilson, 2020).



Your Words Have Power

- **Be mindful of the language you use in different situations**
 - When documenting in patient charts
 - Remember that patients also have access to their records, so we want to ensure the language used promotes advocacy and best clinical practices
 - **During interactions with patients**
 - Language in clinical conversations about SUDs impacts research validity and accurate representation → informs SUD educational awareness and growth
 - Lead with the language patients use, and educate them on why the language they use to describe themselves can impact their growth and mindset

Citation: <https://doi.org/10.1016/j.drugalcdep.2018.05.005>

