Working with Vulnerable Populations

Karen Christianson
Senior Vice President

Overview

Purpose of this Session:

- Discuss “vulnerability” in the research context
- Explore types and examples of participant vulnerabilities
- Identify strategies to minimize risk and enhance respect

hrp CONSULTING GROUP

Who is vulnerable? – The Regs

- Pregnant Women, Fetuses, & Neonates (Subpart B)
- Prisoners (Subpart C)
- Children (Subpart D)
- "When some or all of the subjects are likely to be **vulnerable to coercion or undue influence**, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." (45 CFR 46.111(b))

hrp CONSULTING GROUP

Regulations are the Floor

- **Regulatory focus is narrow**
  - But many real-world vulnerabilities fall outside of those boundaries
- **Ethical responsibility goes further**
  - Even if risks aren't explicitly covered, we still have an obligation to recognize and minimize *reasonably foreseeable risks*
- **Assess vulnerabilities contextually**
  - Who is vulnerable – and in what way?
  - What are the risks associated with the vulnerability?
  - What is the *probability, nature, and magnitude* of potential harms?
  - Under what conditions might the likelihood or severity of risks increase?
  - Does vulnerability/risk vary by *setting, culture, or geography*?

hrp CONSULTING GROUP

Identifying and Understanding Vulnerabilities

Vulnerabilities are not always obvious – they depend on *who* is involved, *what* is being studied, and *how* the research is conducted.

Key Questions to Ask

- ✓ Who are the participants?
  - Start with *people* – are there demographic, social, or situational characteristics that may make someone more vulnerable?
- ✓ What is the research topic?
  - Next focus on the *subject matter* – is it sensitive, stigmatizing, or emotionally charged?
- ✓ What data is collected?
  - Then consider the *information* itself – could it result in personal, reputational, or legal risks?

Identifying and Understanding Vulnerabilities

Key Questions (Continued)

- ✓ How is recruitment and consent managed (and by whom)?
  - Consider whether the recruitment plan and consent process support *voluntary decision-making free* from undue influence or coercion
- ✓ What are the research procedures?
  - Move to methods – are there interventions, focus groups, sensitive or triggering questions, observations, or other procedures that could increase vulnerability?
- ✓ Where is the research conducted?
  - Are there laws, cultural factors, norms that might impact vulnerability? Does the setting limit privacy or introduce power imbalances?
- ✓ Are there any contextual factors that could amplify vulnerability?
  - Think culturally, historically, and socially.

Institutional or Power-Based Vulnerabilities

Arise from power imbalances that may result in a sense of obligation to participate, belief that it will curry favor, or fear of repercussions

Examples:

- Students or employees participating in research conducted by their instructors or supervisors
- Athletes whose coaches, trainers, or other athletic staff are conducting the research or facilitating recruitment
- Patients who are recruited for research by their treating clinicians

hrp CONSULTING GROUP

Situational or Contextual Vulnerabilities

Arise from life circumstances or environmental or other factors that may impact a person's ability to protect their own interests.

Examples:

- Individuals experiencing homelessness who may participate for access to compensation or basic needs.
- People in emergency situations or disaster settings, where stress and confusion may impair consent.
- Families engaged with child protective services who may fear repercussions if they decline participation
- Prisoners, detainees, or individuals in correctional facilities who may feel obligated due to institutional authority structures.

hrp CONSULTING GROUP

Health-Related Vulnerabilities

Arise when health conditions may limit the ability to make fully informed choices or impact the acceptance of risks.

Examples:

- Terminally ill patients seeking experimental treatments with limited understanding of the true potential for benefit or the risks involved
- Individuals with impaired or fluctuating decision-making capacity
- Individuals with mental illness during periods of acute instability

hrp CONSULTING GROUP

Economic Vulnerabilities

Arise when participation in research provides access to compensation or other benefits that might otherwise not be accessible

Examples:

- Research that provides access to medical assessments or care
- Research that provides access to behavioral health support
- Research that provides access to technologies that would otherwise be unaffordable
- Research that provides a high level of compensation

hrp CONSULTING GROUP

Legal Vulnerabilities

Arise when participation in research—or the disclosure of data—could expose participants to criminal liability, civil penalties, or loss of legal status

Examples:

- Research that gathers information about illegal actions or behaviors
- Research that recruits at-risk populations (e.g., undocumented immigrants, individuals who have sought reproductive care, clinicians who provide gender-affirming care)
- Research on socio-political “hot topics” or polarizing subject matter

Reputational and Social Vulnerabilities

Arise when participation in research—or the disclosure of data—could damage a person's social reputation or integration, professional or community standing, or relationships.

Examples:

- Research about institutional leadership, culture, and equity
- Research that enrolls marginalized populations or communities
- Research on sensitive or stigmatizing health conditions or behaviors
- Research on socio-political "hot topics" or polarizing subject matter

hrp CONSULTING GROUP

Dignity or Identity Vulnerabilities

Arise when research interactions or findings may impact participants' sense of respect, self-worth, or identity – even when no tangible harm occurs

Examples:

- Research involving deception in which participants are exposed to triggering content
- Research that challenges a community's beliefs about their origin
- Research findings that portray communities in a way that feels stereotyped, disrespected, or misunderstood
- Cross-cultural research that fails to account for local values, norms, or traditions

hrp CONSULTING GROUP

Case Study: The Hopeful Oncology Patient

Scenario:

A team of oncologists is conducting a Phase II trial of a new immunotherapy drug for advanced cancer. Participants must have already completed first-line chemotherapy with limited success. The study offers frequent monitoring and travel reimbursement, but no guaranteed therapeutic benefit.

Maria, a 52-year-old woman with recurrent cancer, enrolls after her oncologist—who is also the site investigator—mentions it during her clinic visit. She expresses hope that 'this new treatment might finally be the cure.'

Potential Vulnerabilities:

- Health-Related – Serious illness, emotional distress, limited alternatives
- Power-Based – Treating physician is also the researcher
- Economic – Study covers care and scans otherwise unaffordable
- Dignity/Identity – Feelings of desperation may affect sense of agency

Case Study: Adolescent Gender Identity and Well-Being

Scenario:

A university psychology department is conducting a **mixed-methods study** exploring the mental health and school experiences of **adolescents (ages 14–17) with gender dysphoria**.

The study involves:

- An anonymous online survey about school climate, family support, and identity affirmation
- Optional in-depth interviews via video conference about coping and resilience

Parental permission is generally required, but the IRB is asked to consider a **waiver of parental consent** because some participants may not be "out" to their families or may face rejection if their gender identity is disclosed.

Potential Vulnerabilities:

- Age-Related (Decisional) – Adolescents may have limited understanding of research implications and confidentiality limits
- Identity-Based (Dignity & Social Risk) – Disclosure of gender identity could lead to stigma, family conflict, or peer harassment
- Legal/Climate – State laws related to discussing gender dysphoria with minors and for parental permission for research vary
- Contextual – Online participation raises confidentiality and data-security concerns (e.g., shared personal devices, school devices, monitoring)
- Psychological – Discussions about identity, rejection, or discrimination could trigger emotional distress

Case Study: Immigrant Access to Social Benefit Programs

Scenario:

A public policy research team is studying **barriers to accessing social benefit programs**—such as food assistance, Medicaid, and childcare support—among **recent immigrants and mixed-status families**.

The study involves:

- Recruitment through local community organizations and English as a Second Language (ESL) programs
- Focus groups and interviews with qualifying adults who have applied for or avoided applying for public benefits
- Questions about immigration status, income, and interactions with government offices

Participants are told that their responses will remain confidential, but they express fear that sharing information could affect their immigration status or eligibility for services.

Potential Vulnerabilities:

- Legal - Fear that disclosure of undocumented status could lead to deportation, loss of benefits, or government scrutiny.
- Economic - Participation may be motivated by incentives (e.g., gift cards, food stipends), creating risk of undue influence.
- Social/Reputational - Fear of stigma or mistrust within their community for discussing sensitive issues.
- Cultural/Contextual Vulnerability - Language barriers, differing expectations about confidentiality, and power dynamics with researchers.
- Dignity/Identity Vulnerability - Participants may feel stereotyped, “studied,” or misrepresented in findings

Minimizing Risks Related to Vulnerability

Protecting vulnerable populations begins with thoughtful study design, transparency, and respect for participants' autonomy, context, and wellbeing.

Strategies

- **Informed Consent Process**
  - Use plain language and culturally appropriate materials
  - Address reasonably foreseeable risks and the steps being taken to mitigate these risks
  - Allow time for questions and discussion
  - Confirm understanding through teach-back or other checks
  - Consider use of participant advocates or consent monitors when appropriate (e.g., high-complexity studies, power dynamics, trust)

hrp CONSULTING GROUP

Strategies

➢ Reduce Power Imbalances

- Ensure that recruitment and consent occur in neutral settings with adequate privacy
- Where there are power relationships, consider use of intermediaries to manage recruitment and consent
- Emphasize voluntariness – services, grades, relationship will not be impacted (positively or negatively)
- When conducting research in group settings such as classrooms, consider strategies to protect the identities of who decided to (and to not) participate until the power relationship has less of an impact (e.g., after final grades)

hrp CONSULTING GROUP

Strategies

- **Engage with Communities**
  - Don’t exclude because of vulnerability, plan for managing the risks
  - Nobody understands the risks of being a member of a vulnerable or marginalized community more than the members of the community themselves
  - Design research will benefit the community or that the community will support as important
  - Continue consultation with the community during the research, in understanding and contextualizing the findings, and in dissemination

hrp CONSULTING GROUP

Strategies

- **Protect Confidentiality**
  - Collect only the data (including demographics) necessary to meet study aims
  - It takes very little information for re-identification to become possible
  - Avoid the collection of direct identifiers when possible
  - When allowable, destroy identifiers as soon as they are no longer needed.
  - Use coding or pseudonyms when appropriate
  - When audio or video recording – consider the use of pseudonyms during recording and minimizing the intervals between recording, transcribing, member checking, scrubbing data, and deleting recordings
  - Avoid transmission of sensitive data when possible – use shared folders behind secure firewalls for collaboration instead
  - Avoid the use of platforms or technologies that may use or disclose data for other purposes
  - Use quotes in publications and presentations only with permission

Strategies

➢Certificates of Confidentiality (CoC)

- When in place, understand and communicate the limitations of CoCs
- When deciding whether to apply for a discretionary CoC, keep the following in mind (retrieved from NIH webpage):

Certain Participant Populations

As previously noted, issuance of a CoC for research that is not funded by NIH is at the discretion of NIH. NIH will not issue a discretionary CoC for non-NIH funded research when the research includes certain participant populations: sex offenders, child abusers, elder abusers, minor attracted persons, domestic/intimate partner abusers, and perpetrators of homicide. NIH limits issuance of CoCs for research involving these participant populations to NIH-funded studies, all of which must follow the terms and conditions of the award. NIH funded studies with these populations are deemed issued a CoC under the NIH Policy for Issuing Certificates of Confidentiality. The list above may be updated in the future at NIH discretion.

NIH will consider CoC requests for non-NIH funded research involving victims or family members of these populations that otherwise meet requirements.

Certain Research Topics

Issuance of CoCs to non-NIH funded studies is at NIH's discretion. NIH generally limits issuance of discretionary CoCs to research topics that are consistent with agency priorities.

Strategies

- **Monitor for harms related to vulnerability**
  - Think more broadly than Adverse Events when developing your Data & Safety Monitoring Plan
  - Modify the research if serious issues or patterns emerge
  - Have a communication plan for informing participants of new information that may be relevant to their well-being or willingness to continue
  - Offer referrals or resources for participants experiencing distress

hrp CONSULTING GROUP

Key Takeaways

Protecting vulnerable participants isn't just about the rules – it's about respect, relationships, and responsibility

- **Recognize:** Vulnerability is contextual
- **Reflect:** Ask who might be at risk, in what way, and why
- **Respond:** Design research that minimizes harm and maximizes respect and trust

Regulations are the floor, thoughtfully designed and responsive research protects participants

hrp CONSULTING GROUP

References

- **45 CFR 46.111 –** Criteria for IRB approval of research
- **OHRP:** Federal Policy (“Common Rule”) & Subparts B-D
- **Belmont Report** (Respect, Beneficence, Justice)
- **CIOMS** (Vulnerability, Community, Justice)
- **NIH:** Certificates of Confidentiality

hrp CONSULTING GROUP


hrp
CONSULTING GROUP