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## Guidelines for Student-Run Clinic Research Involving Undocumented Immigrants

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### Abstract

The intensifying immigration policy landscape in the United States poses serious challenges for those serving immigrant populations, particularly in student-run clinic (SRC) settings. Undocumented immigrants represent a significant portion of patients served by SRCs, yet there is no formally recognized framework to help SRCs navigate the ethical, legal, and social complexities of research involving this population. This article proposes a structured set of tailored guidelines designed to support SRCs in conducting meaningful research involving undocumented immigrants that prioritizes participant confidentiality, autonomy, and trust, while ensuring community benefit, minimizing legal and ethical risk, and promoting accountable research practices. Although well-intentioned, student-led studies may inadvertently expose participants to risk, especially when academic motivations take precedence over ethical oversight and meaningful community benefit. Our framework responds to the pressing need for standardized ethical oversight and quality assurance mechanisms in SRC research. Recommendations include ensuring the research provides actionable answers which directly benefit the patient population, excluding questions about immigration status, submitting thorough protocols to institutional review boards to assure protections for human research participation in special populations are followed, and focusing on data security through immediate de-identification and robust storage practices. This article also calls attention to culturally sensitive recruitment approaches, the importance of interpreters and detailed information during the consenting process, and ensuring participants receive clear information about how their personal data will be used and understand that their refusal to participate will not impact the medical care they receive. These recommendations draw from interdisciplinary literature, community partnerships, and the real-world experiences of SRC administrators working with immigrant populations. By adapting to shifting immigration enforcement policies and encouraging transparency about legal limits of data protection, this proposed framework aims to help clinicians and researchers conduct ethical studies while protecting the vulnerable undocumented patients who rely on student-run clinics for care.

### Introduction

#### *Evolving Enforcement Landscape*

Healthcare and quality improvement research play a critical role in addressing healthcare disparities among vulnerable populations. However, recent shifts in United States immigration policy are creating new barriers to both healthcare access and research participation for undocumented individuals. Immigration policy debates in the United States have intensified, and the current federal administration aims to expand physical barriers at the southern border, expedite deportation

proceedings, and reevaluate the future of Deferred Action for Childhood Arrivals.<sup>1</sup> Additionally, plans to reinstate Title 42 public health restrictions to limit asylum claims could restrict access to vital healthcare services for migrants seeking refuge. Stricter eligibility requirements for social services are expected to further deter undocumented immigrants from accessing much-needed health programs, exacerbating disparities in care for this vulnerable population.<sup>2</sup> Policies aimed at curbing humanitarian protections and deporting millions of undocumented immigrants could also disrupt continuity of care for individuals with chronic conditions, increasing the risk of preventable complications and poor health outcomes.<sup>3</sup>

Heightened public rhetoric around illegal entry, combined with stricter requirements for social service eligibility, has increased anxiety among undocumented immigrants, who fear detention and deportation.<sup>4,5</sup> This pervasive climate of mistrust discourages undocumented individuals from participating in research studies, seeking medical care, or disclosing personal information, especially about legal status, which can carry grave consequences if records fall into the hands of immigration authorities.<sup>6,7</sup>

### *Protective Measures and Shifting Norms*

Researchers who study undocumented populations in student-run clinic settings grapple with the challenge of collecting meaningful data while preventing harm to participants.<sup>8,9</sup> The stakes are high because legal documents, even when anonymized, may be subpoenaed in immigration enforcement cases, and some institutions have historically complied without notifying investigators.<sup>7,10</sup> In the coming years, caution becomes all the more critical. Although some projects require basic demographic details to analyze health disparities, immigration status itself should not be collected or reported in most cases due to the possible legal implications and the increasingly fraught political climate.<sup>11,5</sup>

### *The Role of Student-Run Clinics (SRCs)*

As many undocumented individuals have difficulty obtaining public health insurance, they often default to relying on employer-based insurance or seeking out emergency departments, community health clinics, and free clinics for healthcare.<sup>12</sup> Student-run free clinics thus serve as vital access points for this patient population, offering lower-cost or free services with fewer bureaucratic barriers than mainstream facilities. These clinics' educational missions also foster a supportive environment where future health professionals can gain practical experience under physician volunteers while delivering care to communities that may otherwise remain underserved. In pursuit of improved clinical outcomes and broader advocacy for the patients they care for, these emerging clinicians often engage in research to better recognize and address the unique needs of their communities.

However, controversy exists regarding the ethics of research completed in SRCs. Yearly changes in leadership limit continuity of management, and increasing pressures on medical students to submit research projects and publications may result in low-quality research initiatives motivated by career advancement rather than actual benefit to SRC patient populations.<sup>13</sup> Undocumented immigrants are among those most in need of free clinic services and meaningful clinical research, as they face socioeconomic insecurity, stigma, marginalization, and the constant threat of deportation—factors that severely jeopardize their health and well-being.<sup>14–16</sup> To address these concerns and ensure SRC research is both ethical and impactful, new guidelines must be established.

### *Objectives*

The following guidelines (Figure 1) provide much-needed ethical standards for conducting research with undocumented participants, especially in an era of expanding government immigration enforcement and plans for deeper collaboration between federal agents and local entities to increase deportation.<sup>17</sup> These guidelines aim to help SRCs conduct high-quality research that respects participant autonomy while mitigating the risk of legal repercussions. By emphasizing confidentiality,

Figure 1. Flowchart of guidelines for student-run clinic research involving undocumented immigrants



This flowchart presents guidelines for student-run clinic research with undocumented immigrants. These guidelines include direct benefits for undocumented patients, ethical oversight, secure data management, culturally informed approaches, and responsiveness to shifting immigration policies. The framework also includes therapeutic misconceptions, minimizing the collection of identifying information, and transparent communication regarding potential legal implications. IRB: institutional review board

reducing unnecessary data collection, and ensuring cultural sensitivity, this framework seeks to protect these vulnerable individuals in our clinics, who already live under constant threat of deportation and financial insecurity.<sup>6,18</sup> Furthermore, these guidelines contribute to addressing the broader need of an institutional culture shift in student-led SRC research toward higher ethical accountability with stronger oversight and quality assurance mechanisms in place.

## The Guidelines

### I. *Will the Research Question Produce Actionable Answers That Will Directly Benefit the Patient Population?*

The goal of conducting research on vulnerable populations is first and foremost to better their health outcomes. Asking this question ahead of time ensures that the research is both purposeful and ethical and does not merely serve academic or personal career-building purposes. Thus, research proposals must be evaluated not only for their methodological rigor but also for their potential to create actionable insights that directly benefit the undocumented population of study. Research that is driven primarily by academic self-interest, lacks meaningful or generalizable findings, or fails to improve care for underserved populations should be strongly discouraged. This ethical dilemma of whether students truly have patient welfare in mind as their primary research goal, or if instead they are creating rushed and substandard quality work due to high academic pressure to publish, is an important question that has been discussed in the literature.<sup>19–22</sup> In addition to examining this existing literature, we recommend utilizing structured evaluation tools when deciding if a project justifies risk to undocumented participants, such as the rubric proposed by Peoples et al. which assesses the alignment of research goals with community-centered outcomes.<sup>19</sup>

### II. *Have You Assessed the Necessity of Immigration Status Data?*

Determining whether legal status is genuinely essential for your research is a critical second step.<sup>11,23</sup> Collecting immigration information can place participants at extreme legal risk and reduce their willingness to enroll, ultimately undermining both the ethical standards and the validity of your study.<sup>5</sup>

Omit questions on immigration status unless they are indispensable for answering a research question that could directly benefit undocumented communities.<sup>6</sup> Replace specific documentation queries with broader demographic items whenever possible.<sup>18</sup>

### III. *Have You Implemented Appropriate Institutional Review Boards (IRB) Safeguards?*

Institutional Review Boards expect researchers to account for increased vulnerabilities, even though undocumented immigrants are not formally categorized as a protected group under federal regulations.<sup>6,18</sup> Submitting a thorough IRB application that addresses potential legal harms can encourage earlier discussions of alternate consent processes and specialized data protection measures.<sup>18,24</sup>

If possible, proactively involve your IRB in crafting protocols that reduce identifying data and clarify subpoena risks. Seek official approval for storing critical information offline or in encrypted systems.<sup>6</sup> However, many student-led projects do not undergo rigorous scrutiny beyond IRB review. A formalized ethics review process within SRCs—composed of faculty and community advisors who have expertise on the challenges undocumented patients face and the ethical issues implicated—should evaluate whether proposed studies are methodologically sound, community-driven, and warranted enough to justify the risk posed to participants.

### IV. *Are You Minimizing the Identifiers Collected?*

Names, exact birthdates, and addresses can easily be used by authorities to locate participants,

making such information especially dangerous to store.<sup>11</sup> Undocumented participants may feel too exposed to continue or even to seek medical care from the clinic in the future if the study requests more personal details than needed.<sup>5,23</sup>

Choose age categories or zip codes over precise dates of birth or street addresses, and refrain from asking about legal status except when absolutely necessary.<sup>9</sup> Be able to justify every potentially identifying data point in your protocol and explain why it cannot be assessed through alternative means.<sup>17</sup>

V. *Is Your Data Security and Confidentiality Framework Robust?*

Proper storage and encryption are key to protecting participants from potential law enforcement inquiries or unauthorized access. Even with a National Institutes of Health Certificate of Confidentiality, institutions can turn over data if they perceive a legal obligation.<sup>10,25</sup>

Use password-protected, non-networked databases when possible and consider physically securing transcripts or signed documents in locked locations.<sup>6</sup> Maintain limited data backups to reduce the risk of multiple access points.<sup>5</sup>

VI. *Have You Prepared for Possible Subpoenas or Seizures?*

Court orders and subpoenas can force researchers or institutions to disclose sensitive records, no matter the promised level of confidentiality.<sup>5,7</sup> Transparent communication with participants about these legal limits helps them decide whether to proceed with your study if it involves any identifying data.<sup>6,10</sup>

Immediately de-identify transcripts and, if absolutely necessary, maintain master participant lists separately and securely.<sup>26</sup> Be transparent and notify participants during consent that absolute anonymity cannot be guaranteed if you are collecting any identifying data.<sup>5</sup>

VII. *Are You Using Culturally Sensitive Recruitment Methods?*

Immigrant communities face language barriers, mistrust of institutions, and fear of deportation, all of which reduce the likelihood of participation.<sup>27,18,16</sup> Limited English proficiency most notably places immigrants at a higher risk of medical mismanagement, creating concerns for patient safety due to lower health literacy and treatment compliance.<sup>12</sup> The same premise can apply to conducting research with this population, especially when recruiting participants and obtaining informed consent. Ensure full comprehension of the research and its implications to limit any misunderstanding or potential harm. Develop recruitment materials in participants' primary languages and involve cultural liaisons and interpreters who can advocate for their interests.<sup>9</sup> Cultural liaisons have been shown to improve research participation among undocumented immigrants by addressing mistrust, language barriers, and fear of deportation. Acting as advocates and interpreters, they foster understanding, reduce misunderstandings, and create a more inclusive environment, ultimately enhancing trust and accessibility.<sup>10</sup>

Working closely with local community leaders, providers, and advocates can help alleviate some of these anxieties and ensure that research goals align with patient needs.<sup>10,6</sup> Cultural competency training for providers and volunteers has been shown to improve communication with immigrant populations, reduce implicit biases, and enhance the delivery of culturally sensitive care. Research highlights that such training nurtures trust and increases participation among underserved communities, leading to improved health outcomes and better engagement with healthcare systems.<sup>27,18</sup> Establishing partnerships with community-based organizations, such as immigrant advocacy groups or cultural associations, that already have trusted relationships within undocumented communities has proven to be an effective strategy for building trust and fostering engagement.<sup>27,18</sup> Schedule data collection at times and in locations that feel safe and accessible.<sup>11</sup> Conducting outreach in trusted and familiar locations, such as community centers, places of worship, and cultural events, helps create a welcoming environment that minimizes fear and

mistrust among undocumented patients. Recruitment efforts can be more effective when ethnically matched staff are involved, as they help build trust and improve engagement with marginalized populations like undocumented immigrants.<sup>28</sup>

VIII. *Have You Revised Consent Procedures to Address Potential Concerns?*

Standard signed consent forms can potentially frighten undocumented participants who worry about leaving a paper trail of their identity.<sup>6,10</sup> Even minimal documentation can be traced back to the individual if seized or subpoenaed, placing these individuals at risk of legal action.<sup>5</sup> Safeguards must be established to minimize any breach of confidentiality that can result in harm to prospective participants.<sup>29</sup>

Seek IRB approval for oral consent or brief unsigned forms that do not link names to immigration details.<sup>30</sup> Translate these materials accurately and explain them thoroughly using an interpreter to reduce confusion.<sup>28</sup>

IX. *Are You Preventing Therapeutic Misconception and Emphasizing Continued Care?*

Undocumented participants might assume that participating in research guarantees health services or legal aid, leading to misunderstandings and possible disappointment.<sup>26,11</sup> This confusion undermines voluntary participation and legitimate consent if individuals feel obligated to comply in hopes of immigration relief.<sup>10</sup>

Have an interpreter present whenever obtaining consent if the potential participant is not fluent in English. Emphasize that the study is independent from any potential healthcare or legal resources.<sup>6</sup> Clarify and reiterate that non-participation does not jeopardize access to clinic services and will have no impact on the care they receive.

X. *Will You Continue Adapting to Changing Immigration Policies?*

Immigration enforcement policies can shift quickly, especially if new executive orders prioritize deportations or limit undocumented immigrants' rights to public benefits.<sup>11</sup> Researchers must remain vigilant about changing laws and be ready to adjust protocols to preserve participant safety.<sup>6</sup>

Regularly review relevant policy changes, communicate with your IRB, and solicit feedback from community partners.<sup>17</sup> Consider updating consent forms or data security measures if new legislation raises risks.

## Discussion

Research studies involving undocumented participants in student-run clinic settings can yield insights that inform public health interventions and policy improvements.<sup>8,31</sup> Nevertheless, the federal agenda of intensified immigration enforcement, combined with new proposals targeting border security and broader avenues of deportation, has escalated perceived threats to immigrant communities.<sup>11</sup> Many individuals may simply refuse to engage with any study that records immigration status, fearing it could surface in legal proceedings if the institution is compelled to divulge records. Moving forward, even more vigilance and empathy is warranted. In most cases, requesting explicit immigration documentation details is neither ethically justified nor pragmatically wise, especially because the current political administration's actions will expand enforcement mechanisms.

Cultivating trust through collaborative partnerships, sensitive consent approaches, and careful data minimization can support more equitable and informative research outcomes.<sup>10</sup> Obtaining demographic data without pinpointing immigration status often suffices to investigate health inequities while preserving safety for participants who already live in constant fear of detection and deportation.<sup>11</sup> Even with these safeguards in place, a thorough risk-benefit analysis should be done for every research study involving undocumented immigrants to ensure that the benefits of the study significantly outweigh the potential risks that may be imposed on this vulnerable population. Careful

adherence to these guidelines ensures that student-run clinics uphold the principles of respect, beneficence, and justice—especially under shifting political terrains where the cost of missteps can be dire.

While research conducted in student-run clinics can yield valuable insights into the health needs of underserved populations, it is essential to acknowledge the limitations often inherent in such studies. Small sample sizes, methodological weaknesses, and the short-term nature of student-led projects may undermine the generalizability and applicability of findings. As such, SRC research should prioritize high-quality, methodologically sound studies that produce actionable outcomes, rather than those driven by academic motivations alone.

The need for further standardization of ethical oversight, quality assurance, and faculty involvement in student-run clinics is crucial. While this paper offers guidelines specifically for conducting research involving undocumented populations, the larger framework for SRC operation remains an area for future development.

### Disclosures

The authors have no conflicts of interest to disclose.

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