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## **Proposal of Ethical Guidelines for Research in Student-Run Clinics: A Three-Clinic Collaboration**

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### **Abstract**

Student-run clinics (SRCs) serve as vital healthcare access points for underserved populations while providing medical students with hands-on experience and reinforcing values of service and community care. As SRCs expand their services and reach, integrating clinical research into their operations has become increasingly common. However, research conducted in SRCs presents unique ethical challenges, particularly regarding informed consent, potential coercion, and maintaining the integrity of patient care. This paper examines some of the ethical concerns associated with conducting research in SRCs, including risks of coercion among vulnerable patients, challenges related to health literacy and language barriers, and the potential for lapses in oversight due to student-led administration. To address these concerns, a framework for ethical research in Student-Run Clinics (SRCs) has been developed through collaboration among three SRCs and discussions held during the 2024 Society of Student-Run Free Clinics 'Bridging the Gap' workshop. The framework emphasizes the establishment of research committees, the implementation of comprehensive needs assessments, prioritization of patient-centered research, and safeguards to ensure truly informed and voluntary participation. By implementing these ethical standards, SRCs can conduct meaningful research that enhances clinic operations and improves patient outcomes while proactively addressing the ethical challenges inherent in these settings. This approach ensures that research within SRCs remains a tool for advocacy and improvement rather than exploitation, allowing these clinics to continue their mission of providing equitable healthcare to vulnerable communities.

### **Introduction to the Reach of Student-Run Clinics**

Student-run clinics (SRCs) play a crucial role in bridging the gaps in healthcare access to underserved populations as well as offering health professional students service-focused, hands-on learning opportunities. These clinics serve low-income and uninsured patients, often from vulnerable groups such as individuals who are elderly, homeless, disabled, LGBTQIA+, migrant workers, or part of low-income families. In 2019, the Association of American Medical Colleges identified 106 student-run free clinics.<sup>1</sup> As of 2024, the SSRFC is associated with 213 clinics, with approximately 264 more awaiting confirmation.<sup>2</sup>

The function of these clinics varies depending on their available resources and community needs. Many SRCs provide primary care and medication assistance, others may provide full pharmacy services or specialty care, such as general surgery or dermatology consultations. As SRCs seek to improve patient care, secure funding, and address community needs, they may integrate research

into their operations to measure impact. A demonstrated positive impact can attract financial support from donors, grants, and affiliated institutions, as well as volunteers from local physicians and students.

Performing clinical research has the opportunity to improve patient care and clinic operations, but it introduces several ethical dilemmas. Conducting research involving vulnerable populations with limited healthcare options, language barriers, and low health literacy increases their risk of exploitation and coercion.<sup>3</sup> Additionally, clinics run by students without adequate faculty supervision risk lapses in oversight, execution, and prioritization of ethical standards during the administration of research projects.

This paper examines the ethical challenges of conducting research at SRCs and proposes a framework (Figure 1) to safeguard patient welfare and the integrity of the clinic, while also maximizing research quality. Developed through collaboration with three SRCs and informed by discussions at the 2024 Society of Student-Run Free Clinics (SSRFC) Bridging the Gap workshop, this framework emphasizes patient-centered care, research oversight, and strategies to mitigate coercion in the informed consent process. By implementing these guidelines, SRCs can continue to conduct research that contributes to their growth while ensuring patient safety and high-quality care.

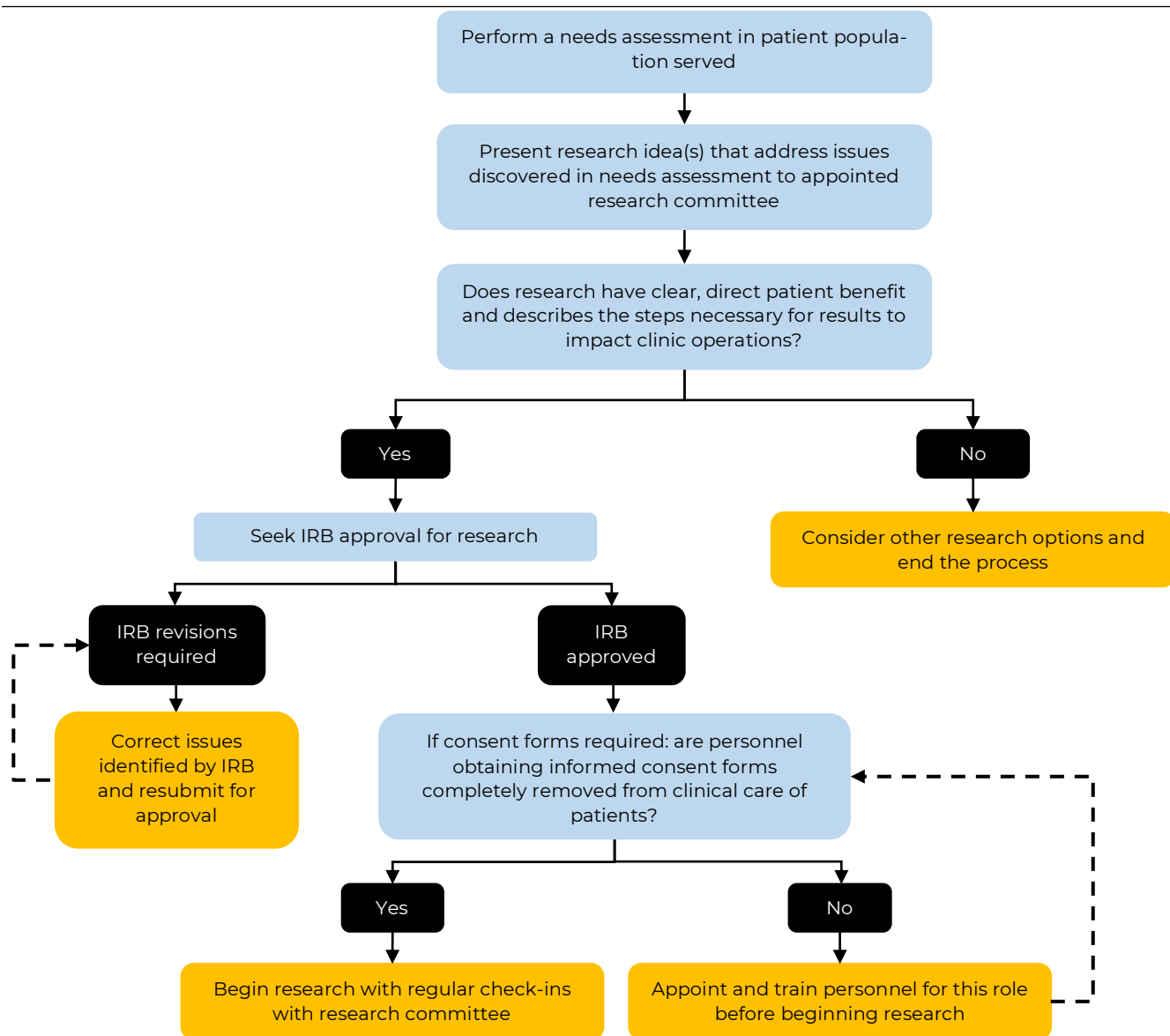
### **Ethical Challenges in Research at Student-Run Clinics**

In the United States per the Emergency Medical Treatment and Labor Act, emergency departments must examine and offer to treat any emergency medical condition, thereby providing a safety net for all individuals, regardless of ability to pay or insurance status.<sup>4</sup> Despite the availability of this safety net, the unpredictable and possibly exorbitant costs of emergency department visits frequently deter the most vulnerable patients from seeking this help when needed.<sup>5</sup> Therefore, SRCs represent one of the few free or low-cost options for many patients seeking healthcare. Patients who need to manage chronic conditions or would typically seek primary care in an emergency department rely heavily on the availability and accessibility of clinics like SRCs.<sup>6-8</sup> Due to this dependence, patients are at increased risk of being coerced into complying with even completely optional requests by clinic staff for fear that they may receive substandard care or be discharged from the clinic.<sup>9</sup> This risk of coercion is not dependent on the reality of whether these consequences feared by the patient would happen, therefore completely sincere attempts by clinic staff to recruit patients for optional research participation may be misinterpreted as a demand to comply.<sup>10</sup> On the other hand, for patients at free or low-cost clinics in particular, financial compensation for participation may exploit their financial vulnerability to induce participation in or decline to withdraw from a study, regardless of their concerns otherwise.<sup>11</sup>

In addition to financial and healthcare barriers, patients seeking care at SRCs are more likely to have lower health literacy or present with language or cultural barriers, leading to misunderstandings about the purpose of clinical research or the benefit or harm it may provide them.<sup>12-14</sup> For instance, individuals may become concerned that they will become test subjects and receive substandard care and may become distrustful of the clinic and reluctant to continue seeking care at healthcare institutions.<sup>15</sup>

While many SRCs are tied to institutions with research protections for participants, research conducted at SRCs runs the risk of inadequately protecting participants. Even once ethical approval is obtained from institutional review boards (IRB), ultimately students, as opposed to professionals, are often the ones primarily overseeing and carrying out research protocols. For students, time and effort devoted to research is unpaid and usually secondary to the requirements and demands of classwork, which can lead to substandard execution of research protocols. This substandard execution can result in compromised data collection, as well as harm to participants if expectations or promises are not robustly kept.

**Figure 1.** Proposed flowchart for the step-by-step approval process of ethical research initiatives in student-run clinics



Solid lines indicate essential flow of process. Dashed lines indicate optional flow of process as needed. IRB: institutional review board.

### Proposed Ethical Standards Framework for Student-Run Clinics

The following framework for ethical research standards for SRCs was developed through collaboration between three distinct medical SRCs to ensure its applicability across diverse clinical operations. These three clinics will be described as Clinic A, Clinic B, and Clinic C. Clinic A provides free weekly clinic hours for uninsured patients, featuring an on-site no-cost pharmacy and social worker support. Additionally, they offer specialty care days tailored to patient needs, including dermatology, ophthalmology, mental health, and physical therapy. Clinic A has an established ethical standard that all research proposals must include guidelines on how results will be used to impact clinic operations, which will be included as a key pillar of this proposed framework. Clinic B is an urban SRC affiliated with a large academic hospital that conducts free weekly clinics for uninsured patients with

departments for primary care, gynecology, behavioral health, medical debt, lab draws, vaccines, social services, patient education, medical-legal partnership, and more. Clinic B is established in its research endeavors and provides numerous first-hand experiences into ethical dilemmas faced in SRC research that were utilized in the creation of the framework. Clinic C is a rural, medical student-run free clinic that offers bimonthly primary care services to patients in need through a mobile clinic. Clinic C is in its first year of research initiatives, bringing a perspective that is unshaped by prior research expectations to the ethical framework outlined in this paper.

Topics included in this framework were discussed among medical students and medical professionals at the 2024 SSRFC Bridging the Gap workshop. Examples of concerns from these discussions and student experiences at the three clinics are included as examples of ethical research practices in SRCs.

### *Step 1: Appoint a Research Committee*

Before engaging in patient-focused research, an SRC should establish a dedicated research committee as an essential first step. The primary responsibilities of this committee would include evaluating research applications for ethical soundness and ensuring that ongoing research activities do not compromise the quality of care provided. At the 2024 SSRFC Bridging the Gap workshop, discussions highlighted that this committee should comprise relevant faculty and staff overseeing the SRC, the medical director(s), designated student research representatives, and, if possible, community members or patients.

According to this framework, students interested in conducting research at an SRC must first present their research proposal to the research committee and qualified faculty adviser. The proposal should include clearly defined actions aimed at improving clinic operations based on the study's findings. The research committee will ensure the proposal is ethical, suitable, and won't affect care quality. Once approved by the committee, the proposal may proceed to IRB submission for further review under oversight from the qualified faculty adviser. Following IRB approval, the research committee should establish a schedule to regularly monitor clinic operations and ensure that the ongoing research is not compromising the quality of care their patients receive.

To further address the unique ethical challenges faced by SRCs, it is recommended that the partnering institution's IRB team conduct annual workshops for clinic leadership. These workshops should focus on common ethical issues in SRC settings, IRB requirements for conducting research involving vulnerable patient populations, and any other topics deemed pertinent by the SRC. This opportunity would enable proactive engagement before projects begin and allow leadership to serve as a source of guidance and support, helping to uphold clinical standards for ongoing research conducted by students.

By establishing a robust research committee, implementing a structured approval process, and addressing ethical challenges through regular IRB collaboration and education, SRCs can ensure that their research initiatives enhance clinical operations while upholding the highest standards of care and ethical responsibility.

### *Step 2: Perform a Needs Assessment for In-House Use*

To develop research initiatives that effectively address the needs of patients of an SRC, conducting a comprehensive needs assessment is essential, whether or not it will be published. A needs assessment should be conducted annually or biannually to ensure that patient needs remain the primary focus over research initiatives. A needs assessment facilitates strategic planning for the clinic, ensuring that research initiatives are designed to achieve the best outcomes and drive meaningful improvements for the populations served. Conducting research without first performing a needs assessment risks wasting time and resources on initiatives that fail to benefit patients, undermining the ethical and patient-centered foundation that is integral to research in SRCs. To

ensure a high-quality needs assessment is created, clinics can partner with qualified faculty affiliated with the clinic, or lacking such, public health programs or local public health professionals.

This assessment can be carried out through various methods, such as collecting patient feedback via post-appointment surveys, organizing patient focus groups to identify areas for clinic improvement, or gathering input from volunteers regarding common patient requests. Once the results of the needs assessment are analyzed, the research committee can use this data to evaluate research proposals more effectively, approving only those that align with the identified needs and priorities of the clinic. An example of this approach is demonstrated by Clinic C, which is developing a patient satisfaction survey with space for patients to indicate any services they wished to utilize during their appointment but were not offered by the clinic. This feedback will enable the clinic to identify gaps in care so they may develop strategies to offer the requested services or establish community partnerships for appropriate referrals.

By approving research that aligns with the identified needs of the patient population, SRCs can maximize the impact of their initiatives and implement informed, patient-centered improvements in clinic operations.

### *Step 3: Confirm Research is Patient-Centered*

The primary focus of the workshop discussion was the importance of ensuring that research endeavors in SRCs prioritize patient benefit. Patient-centered research should focus on enhancing clinic operations, improving patient satisfaction, and maintaining high-quality care, rather than serving the interests of student volunteers in search of research experiences. One solution to address this concern is to ensure that the research committee only approves projects that provide direct or indirect benefits to patients. This could include requesting a detailed plan outlining how research outcomes will be used to improve clinic operations in every research application. An example of patient-centered research is seen in Clinic A, which conducted research on transportation barriers to access, and the results were used to advocate for free bus tickets for patients through the local city government.

Another element of establishing patient-centered research is to ensure that the research does not place an undue burden on patients. An example of undue burden would be requiring excessive follow-up appointments beyond their healthcare needs. Requiring additional visits could impose time and financial hardships on patients who already face difficulties accessing care or must take time off work to attend appointments. A possible solution to this problem is scheduling research meetings during patients' existing medical appointments to minimize the number of clinic visits required.

If the research committee determines that the quality of care for patients is compromised due to a project, that project should be halted until an appropriate solution is discussed and implemented. Ultimately, patient-centered care must be the top priority in SRCs opposed to research initiatives, as their core mission is to provide high-quality care to vulnerable populations.

### *Step 4: Obtain Informed Consent and Mitigate Coercion*

Another key topic addressed in the workshop was the complexity of ensuring informed consent in student-run clinics for research projects that specifically require consent forms. These organizations primarily serve populations with a significant proportion of underinsured and uninsured patients, who may feel compelled to consent to research participation out of concern for losing access to free or low-cost healthcare. This perceived obligation can undermine the principle of voluntary participation, which is fundamental to ethical research practices. Transparency about what it means to consent to clinic research ensures that patients fully understand their options and can make an informed decision about whether to participate or decline.

To mitigate this pressure, clinics can adopt strategies to ensure patients fully understand their rights and that their decision to participate, or not participate, will not impact the care they receive. The researcher tasked with recruitment and obtaining patient consent should be completely separate

from the patient's clinical team. This discussion should include notice that the medical care team will not be made aware of a patient's decision to accept or deny being involved in clinic research endeavors, emphasizing that the quality and availability of care will remain unchanged by this decision. Being transparent about the research goals and potential impact is crucial for fostering trust and ensuring the patient feels comfortable with their decision. By clearly separating the roles of clinical care and research consent, clinics can promote trust and respect for patients' autonomy.

Additionally, since SRCs serve a diverse population, it may be necessary to enlist the help of medical translators or volunteers who speak multiple languages to ensure that the informed consent forms are accurately translated and understood. In addition to having someone who speaks the patient's language to explain the informed consent process and answer questions, all written documents the patient needs to read and sign should also be provided in their native language. This ensures that non-native speakers receive the same information as patients who speak the clinic's primary language and can make an informed decision to be involved or not involved in clinic research.

In the setting of SRCs, suitable candidates for discussing informed consent forms should be individuals who are knowledgeable about research ethics and procedures but will remain independent of patient clinical care. Such candidates may include SRC faculty advisors or mentors, those in dedicated research coordinator roles, students who operate on the clinic executive committee and will not be involved in patient care, residents not involved in patient care, or community members who will act solely in this role. These individuals should be thoroughly trained to explain the informed consent process clearly, answer any patient questions, and emphasize that the patient's decision will not affect their access to medical care. By carefully selecting and training these candidates, SRCs can uphold ethical standards and promote patient autonomy.

## Conclusion

The establishment of ethical guidelines for research in SRCs is essential to uphold the trust and integrity fundamental to these unique healthcare institutions. By addressing the specific ethical dilemmas faced by SRCs who serve vulnerable populations and are led by students who act as both caregivers and researchers, this proposal outlines actionable strategies to ensure ethical research practices. Through collaboration between three SRCs, this framework emphasizes patient-centered care, informed consent, and strong oversight, setting a precedent for ethical leadership in healthcare research. As SRCs continue to grow and impact underserved communities, the adoption of such guidelines will be pivotal in maintaining the balance between advancing medical knowledge and protecting the dignity and autonomy of their patients. This proposal invites continued dialogue and refinement, ensuring these ethical standards evolve alongside the expanding scope and influence of SRCs.

## Disclosures

The authors have no conflicts of interest to disclose.

## References

1. Smith S, Thomas R, Cruz M, Griggs R, Moscato B, Ferrara A. Presence and characteristics of student-run free clinics in medical schools. *JAMA*. 2014;312(24):2407-2410. doi:10.1001/jama.2014.16066 [LINK](#)
2. Home page. Society of Student-Run Free Clinics. Accessed May 21, 2025. <https://www.studentrunfreeclinics.org/> [LINK](#)
3. Gehlert S, Mozersky J. Seeing beyond the margins: challenges to informed inclusion of vulnerable populations in research. *J Law Med Ethics*. 2018;46(1):30-43. doi:10.1177/1073110518760844 [LINK](#)
4. Centers for Medicare & Medicaid Services. Emergency Medical Treatment & Labor Act (EMTALA). September 6, 2023. Accessed May 21, 2025. <https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act> [LINK](#)
5. Zhou RA, Baicker K, Taubman S, Finkelstein AN. The uninsured do not use the emergency department more—they use other care less. *Health Aff (Millwood)*. 2017;36(12):2115-2122. doi:10.1377/hlthaff.2017.0218 [LINK](#)

6. Alhallak I, Williams DK, Eudy R, Puryear E, Clark M. Impact of student-run free clinics in urgent care. *J Community Health*. 2020. doi:10.1007/s10900-020-00890-0 [LINK](#)
7. Kramer N, Harris J, Zoorob R. The impact of a student-run free clinic on reducing excess emergency department visits. *J Stud Run Clin*. 2015;1(1). doi:10.59586/jsrc.v1i1.3 [LINK](#)
8. Trumbo SP, Schuering KM, Kallos JA, et al. The effect of a student-run free clinic on hospital utilization. *J Health Care Poor Underserved*. 2018;29(2):701-710. doi:10.1353/hpu.2018.0053 [LINK](#)
9. Wilson S, Draper H, Ives J. Ethical issues regarding recruitment to research studies within the primary care consultation. *Fam Pract*. 2008 Dec;25(6):456-461. doi:10.1093/fampra/cmn076 [LINK](#)
10. Hempeler C, Braun E, Potthoff S, Gather J, Scholten M. When treatment pressures become coercive: A context-sensitive model of informal coercion in mental healthcare. *Am J Bioeth*. 2024;24(12):74-86. doi:10.1080/15265161.2023.2232754 [LINK](#)
11. Millum J, Garnett M. How payment for research participation can be coercive. *Am J Bioeth*. 2019;19(9):21-31. doi:10.1080/15265161.2019.1630497 [LINK](#)
12. Butala NM, Chang H, Horwitz LI, Bartlett M, Ellis P. Improving quality of preventive care at a student-run free clinic. *PLoS One*. 2013;8(11):e81441. doi:10.1371/journal.pone.0081441 [LINK](#)
13. Jiang JJ, Link K, Mellgard G, et al. Evaluation of patient health outcomes of a student-run free clinic in East Harlem. *BMC Med Educ*. 2024;24(1):323. doi:10.1186/s12909-024-05070-5 [LINK](#)
14. Kamimura A, Christensen N, Tabler J, Ashby J, Olson LM. Patients utilizing a free clinic: Physical and mental health, health literacy, and social support. *J Community Health*. 2013;38(4):716-723. doi:10.1007/s10900-013-9669-x [LINK](#)
15. Grady C, Hampson LA, Wallen GR, Rivera-Goba MV, Carrington KL, Mittleman BB. Exploring the ethics of clinical research in an urban community. *Am J Public Health*. 2006;96(11):1996-2001. doi:10.2105/AJPH.2005.071233 [LINK](#)