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Ethical research when abortion access is legally restricted:

Risks and benefits of some clinical research may be altered

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The legal landscape surrounding abortion in the United States has shifted dramatically since the Supreme Court's June 2022 decision in *Dobbs* v. *Jackson Women's Health Organization* eliminated a nationwide right to abortion (1) In the year since, roughly half of US states have expanded abortion restrictions. Some consequences of heightened restrictions —including increased maternal morbidity and mortality and deepening socioeconomic and racial inequities—have quickly come into view. However, little attention has focused on the

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ethical, legal, and practical implications that such restrictions have for research involving people who could become pregnant during research and research staff. Notably, limited access to abortion can pose risks to clinical research participants and potentially compromise the scientific and social value of some research. As a result, assessments of potential research risks and benefits may be altered. We outline points for various stakeholders [such as sponsors, investigators, research sites, and institutional review boards (IRBs)] to consider in addressing these issues.

To date, 13 US states have revived or adopted near-total bans on abortion, leaving approximately 22 million people who could become pregnant without access to abortion in their states. Other states have set early gestational limits on abortion access, and several penalize anyone who facilitates an abortion. Although most US states currently provide exceptions for the pregnant person's life (but not health), ambiguous laws and fear of criminal prosecution raise profound concerns among clinicians, those who might become pregnant, and others (2–4). Given the gender gap in evidence to inform clinical care that has resulted from a combination of traditional trial requirements for contraception and the active exclusion from research of those who might become pregnant, it is imperative that decision-makers pay careful attention to factors, such as limited access to abortion, that could reflexively restrict clinical research with that population.

IMPLICATIONS FOR CLINICAL RESEARCH

Abortion restrictions have special moral implications in the context of some clinical research with people who can become pregnant. First, research interventions, by definition, expose participants to unknown risks. When research participants become pregnant, those risks can include threats to the health or life of the pregnant person as well as potential harm to their fetus. A participant may decide that a timely and safe abortion is the best way to mitigate research-related harms.

Second, research studies can require participants to undergo pregnancy tests that they might not have taken outside the research context. These tests might detect and document early pregnancies that otherwise would have gone unnoticed given high rates of miscarriage in the first trimester, which in turn might raise concerns in some jurisdictions that the participant obtained an illegal abortion. That is, the simple fact that a research participant is not pregnant nor has given birth, but a test indicates that they were pregnant during research, could put them at risk of legal action.

Third, if risks to research participation that result from legal restrictions on abortion access are not sufficiently addressed, people who can become pregnant might be deterred from enrolling in clinical research. This could compromise the scientific and social value of research, reinforcing longstanding gender disparities, which are due in part to longstanding underrepresentation of people who can become pregnant in research (5, 6).

Fourth, fear of legal risks associated with facilitating an abortion, or uncertainty about the rapidly evolving legal status of abortion, might leave researchers reluctant to obtain rigorous data on pregnancy, possibly including adverse pregnancy-related outcomes. This

could further reduce the scientific and social value of clinical research because of incomplete data on clinical interventions for both pregnant people and their fetuses.

Fifth, clinical research staff may face legal risks in jurisdictions with laws that penalize those who facilitate abortion (for example, referring a participant to an abortion provider out of state). These risks, which are difficult to assess in a rapidly changing legal environment, might nevertheless have serious professional and personal implications.

POINTS TO CONSIDER

It is broadly recognized that research-related risks be minimized and reasonable in relation to the scientific and social value of research. Here, we outline points for stakeholders to consider in ensuring a reasonable risk-benefit profile for research that involves participants who may become pregnant when the research is conducted in locations with restrictive laws on abortion access (see the box). This includes considerations regarding research site selection and management as well as study design and implementation. There are additional considerations for research focused specifically on pregnant people and their fetuses or accruing data on the effects of particular interventions among them, but these are beyond our scope here.

Assess current laws

Laws that restrict abortion access are in flux and vary markedly across jurisdictions. Incomplete or outdated knowledge about local abortion laws and access to abortion services (such as mifepristone) can pose risks to research participants and staff. Therefore, an accurate and current understanding of relevant legal restrictions at each site is essential. Individuals with local legal expertise should be engaged to gather and interpret relevant local laws and policies not only as research is being planned but also over time to ensure understanding of the current landscape.

Evaluate site experience

The impact of laws often depends on the nature and extent of their enforcement. Thus, it is essential to have as clear an understanding as possible of the likelihood that laws will be enforced locally to more accurately assess the true risks. Investigators should explore local research and clinical staff experiences and knowledge related to legal restrictions on abortion at a site. For example, it would be important to ascertain whether any problems have previously arisen related to legal restrictions on abortion access, and if so, what was done to address them. Such information needs to be considered when making difficult decisions about whether and how the research might safely and appropriately be conducted at each proposed site.

Engage local stakeholders

Potential or enrolled participants may be particularly well situated to provide relevant information regarding the risks related to restrictive abortion laws and how best to manage them. Consequently, they should be explicitly engaged around these issues. Community-based reproductive health providers and advocates are also potential resources in this regard.

Consistent with good participatory research practices, investigators should work with local site staff to elicit such information and explore options for navigating optimal care (7).

Evaluate site suitability

Information about current abortion laws, site experience, and stakeholder engagement should be used as part of any evaluation of whether existing legal restrictions could reasonably be expected to negatively affect research at the site. For example, as discussed above, legal restrictions might pose risks to research staff or participants and their fetuses, impede recruitment of a sufficient number of participants, or compromise the research study's scientific and social value. In such circumstances, the feasibility of modifying the research and its implementation should be assessed. However, if it cannot be ensured that the risks are reasonable in relation to the potential scientific and social value, researchers and sponsors should consider not pursuing research at that particular site. Of course, such decisions should not be taken lightly because such a choice obviates the opportunity for people who can become pregnant to participate in research and generate locally relevant data.

Make provisions for legal abortion access

Before study commencement, stakeholders should develop mechanisms to ensure timely abortion access mechanisms for participants who may become pregnant during the study that minimize physical, social, legal, and economic risks. In settings where those who facilitate abortion access face legal risk, investigators should prepare research staff who may be interacting directly with participants who become pregnant and desire abortion services regarding appropriate ways to manage such requests. The need for these sorts of provisions should be revisited in the event that the legal landscape changes.

Ensure confidentiality

The current legal environment underscores the criticality of maintaining confidentiality of all information about pregnancy and use of abortion services because such information may pose direct risks to participants and research staff. As in other research settings that necessitate strict confidentiality protections, it is essential to consider this issue during the design and implementation of data collection procedures and data management. For example, simple measures may include the use of participant identifiers with links to actual participants maintained elsewhere and using appropriate encryption and password protection of data. Obtaining a Certificate of Confidentiality, issued by the National Institutes of Health to prevent compelled disclosure of protected information, may provide additional protection in the case of civil or criminal prosecution, although such certificates have yet to be tested in this context in court (8). Furthermore, even if the research record is protected by the Health Insurance Portability and Accountability Act Privacy Rule, entities covered by this rule are currently permitted to disclose this information in the event of legal action. However, a revision has been proposed to prohibit such disclosures, so this should be monitored closely (9).

Mitigate risks to participants

Researchers and sites should develop and implement locally informed approaches to managing the physical, social, legal, and economic risks associated with laws restricting abortion. This may involve modifying study designs or standard operating procedures. Of note, this may involve the need to reconsider some aspects of research implementation that may typically seem mundane. For example, although it is commonplace to regularly assess pregnancy during the course of some clinical research, researchers should consider risks to participants when planning both the frequency, if any, of pregnancy testing as well as the inclusion of these test results in research records. Frequent testing may result in documenting pregnancies that otherwise would have gone undetected because of spontaneous early abortion. When it is necessary to have longitudinal information about the possibility of pregnancy over the course of a research study, stakeholders should consider whether pregnancy self-testing might be an appropriate substitute for testing done at research sites. Study staff should be appropriately educated and regularly reminded about the importance of gathering accurate data about pregnancy-related outcomes in a manner that minimizes potential risks to participants. On the basis of experience in other research settings that pose heightened legal and social risks to participants, consideration should be given to developing and implementing participant safety plans to minimize potential social and legal harms to participants (10, 11). The obligation to mitigate risk also underscores the need to ensure that participants have access to effective contraception.

Obtain informed consent

Although researchers and study teams may feel confident in their ability to navigate restrictions on abortions, ultimately participants will be those most affected. Therefore, potential participants should be informed about possible clinical risks to themselves, or their fetuses, should they become pregnant during research, along with possible options for continuing with study interventions while pregnant as well as for accessing effective contraception if they wish to avoid pregnancy while in the study. Critically, potential participants may be unaware of the status of abortion restrictions and how these may relate to the research (12). This information, along with associated risks (social, legal, and economic) and measures taken to minimize them, should be explicitly included in the consent process. Given the potentially rapid evolution of legal restrictions, research teams and IRBs should monitor for relevant legal changes, determine whether any changes affect the ethical acceptability of continuing research, and obtain IRB-approved reconsent if risk profiles and the potential for social harms to participants dramatically change (13).

Monitor for social harms

Despite best and well-intended efforts to ensure safety in research that at the outset seems to pose particular risks related to undesired pregnancies (such as testing contraceptive modalities) or other research that simply includes people who can become pregnant, some participants may experience physical, social, legal, and economic harms related not only to research but also to restrictive abortion laws. Consequently, researchers should use explicit mechanisms to detect and help manage both expected or unexpected harms (14). For example, this could include a safe mechanism for participants and study staff to seek

urgent assistance as well as explicitly inquiring about these issues at regular study visits. Research participants' partners may also face harms that warrant monitoring and attention. Although issues that arise in relation to restrictions on abortion access may be outside the narrow scope of some research studies, researchers and sites arguably have ancillary care obligations that extend to this issue and therefore should anticipate this possibility.

Conduct independent oversight

In meeting their oversight responsibilities, IRBs should explicitly assess risks related to restrictions on abortion access to participants who may become pregnant along with proposed approaches to minimizing these risks. This can be complicated given variability in laws both across states or countries and within any one state or country over time. Additional concerns arise for research overseen by single IRBs when research is conducted in multiple states or countries. Single IRBs must be especially vigilant to ensure that they have adequate and updated information when conducting local context reviews (15). Where necessary, IRBs should consult with those with appropriate expertise to help guide their deliberations. IRBs should also require information about changing laws and local context as these arise as well as during the process of continuing review. In addition, data safety and monitoring boards should include considerations of participant safety related to restrictions on abortion access during their initial and interval review. In especially restrictive environments, stopping rules regarding these issues may be indicated.

CLOSING COMMENTS

Stakeholders involved in research with participants who could become pregnant should explicitly consider the points outlined here, both to minimize the risks to participants and staff and to help safeguard the scientific and social value of research. If on careful examination it seems implausible to safely conduct the proposed research at a particular site, consideration should be given to conducting the research elsewhere. Nevertheless, lessons learned about efficient processes for the safe design and implementation of research with people who can become pregnant in the face of restricted abortion access should be described and disseminated widely as a means of helping generate best practices. Doing so would be facilitated by collecting and analyzing systematic data regarding how often challenges due to abortion restrictions are encountered in research as well as how they are managed. In the meantime, education of researchers, IRBs, institutional officials and state and local policy-makers is crucial. Last, those contemplating the development and implementation of policies pertaining to abortion should also consider the potential negative impact on the ability of researchers to advance science that can improve the health and well-being of those who are or may become pregnant and their fetuses.

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Points to consider

RESEARCH SITE SELECTION AND MANAGEMENT

Current laws.

What are the current state laws regarding access to abortion services at the research site? Include information concerning provisions for legal abortions, any allowance for citizen enforcement, penalties for referral, and resulting risks to participants and staff.

Site experience.

Have any problems arisen related to legal restrictions on abortion access in current studies? If so, what was done to address these problems?

Stakeholder engagement.

Have research staff, potential participants, or enrolled participants expressed concern about legal restrictions on abortion access at the site? Has there been community engagement regarding legal restrictions on abortion access at the site in relation to this study and/or research in general? Who was included in that engagement?

Site suitability.

What, if any, legal restrictions on abortion access may affect the study at the site (for example, do they affect recruitment or the ability to carry out the study)?

Provisions for abortion access.

What plans are in place at the site to ensure that participants who may become pregnant can access timely abortion services without risks (physical, social, legal, or economic) to themselves or to study staff?

STUDY DESIGN AND IMPLEMENTATION

Confidentiality.

Are there any special provisions being made for data privacy regarding pregnancy test results or access to abortion services? Has a Certificate of Confidentiality been obtained?

Mitigating risk.

Has the site, local research institution, or protocol team implemented or considered any standard operating procedures or provisions to manage the risks (physical, social, legal, and economic) associated with legal restrictions on abortion access?

Informed consent.

Are the risks (physical, social, legal, and economic) associated with legal restrictions on abortion access at the site clearly stated in the study's consent form? Is there a need for reconsent to address legal restrictions on abortion access given a change in the law after enrollment?

Social harm monitoring.

Are participants explicitly asked about risks (physical, social, legal, and economic) associated with legal restrictions on abortion access at regular study visits? Is there a mechanism for participants and study staff to seek urgent assistance?

Independent oversight.

Has the responsible institutional review board (IRB) made any determinations related to risks or issues associated with legal restrictions on abortion access for this study? For sites using a single IRB, was information about the local context requested by, or provided to, the single IRB?