IRB GUIDANCE: Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant

CONTENTS

INTRODUCTION

Investigators must follow the standards outlined in Policy IRB-01. This guidance provides information related to contraception, pregnancy testing, and unexpected pregnancy. To be inclusive, this guidance applies to "people of childbearing potential" in recognition that these individuals may include those who self-identify as women, adolescents, transgender, etc.

This guidance represents the IRB's current thinking on this topic; however, the use of the word "must" in this document means the concept is a Downstate policy or regulatory requirement. The use of the word "should" in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements. For more information, please contact the Downstate IRB Office at irb@downstate.edu

Additional guidance on informed consent, assent, pregnant partner consent is available in the following IRB guidance:

- The IRB Guidance documents for Obtaining Legally Effective Informed Consent and HIPAA Research Authorization and Local Context for Reviewing (External) IRB may be downloaded from the IRB Guidance for Investigators at Institutional Review Board Policies | SUNY Downstate Health Sciences University
- All-In-One Consent Template and Pregnant Partner Consent may be downloaded from Step 8 at SUNY Downstate ORA IRB - Electronic Submissions

FEDERAL DEFINITIONS

The definitions below are from Federal regulations, which apply to research in compliance with the Common Rule:

Assent means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Children means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

Fetus means the product of conception from implantation until delivery.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Neonate means a newborn.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation.

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Ward means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

Written, or ***in writing***, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

NEW YORK STATE DEFINITIONS

The definitions below are from NY State regulations:

Minor- anyone under the age 18.

DOWNSTATE IRB DEFINITIONS

The definitions below are from the Downstate IRB and should be viewed as general guidance:

Cis-gender individual means a person whose gender identity corresponds with the sex the person had or was identified at birth. Non-Trans.

Embryo means the product of conception from implantation to 9 actual weeks or 11 weeks from the last menstrual period.

Gender diverse individual. Gender diversity is about acknowledging and respecting that there are many ways to identify outside of the binary of male and female. Presenting as gender diverse is about one's authentic self.

Gender expression is how a person presents their gender on the outside, often through behavior, clothing, hairstyle, voice or body characteristics.

Gender identity is an individual's internal knowledge of gender – for example, the knowledge of being a man, a woman, or another gender.

Intersex is a general term used for a variety of conditions in which a person is born with a reproductive or sexual anatomy that doesn't seem to fit the typical definitions of female or male, or a person is born with mosaic genetics with some cells that have XX chromosomes and others with XY.

A ***Non-binary individual*** does not identify as male or female and may identify as non-binary, genderqueer, agender, or bigender, gender nonconforming, two-spirited, or other diverse gender presentations. These individuals may use non-binary or gender-neutral pronouns such as they/them or ze/hir.

Post menarche means an individual who has begun to menstruate.

Sex is an individual's biologic sex assigned at the time of birth.

Sex reassignment surgery or ***gender affirming surgery*** is a surgical procedure (or procedures) by which a transgender individual's physical appearance and function of their existing sexual characteristics are altered to resemble those socially associated with their identified gender.

Transgender individual is a broad term that can be used to describe people whose gender identity is different from the gender they were thought to be when they were born. "Trans" is often used as shorthand for transgender.

SUPPLEMENTAL IRB APPLICATION QUESTIONS

When submitting the Downstate IRB Application Form 11-A2 (Application for Full Board or Expedited Review), investigators will be prompted for information contained in this guidance and to submit supplemental IRB applications for the situations as indicated below:

- Prospective exclusion of pregnant people from research that involves an intervention upon the body (e.g., drug, biologic, medical device, physical intervention, etc.). Submit Form 11-8.
- Prospective enrollment of research participants of childbearing potential who require contraception to be included in the research. Submit Form 11-8.
- Prospective enrollment of pregnant people (and/or fetuses) that involves an intervention upon the body (e.g., drug, biologic, medical device, physical intervention, etc.). Submit Form 11-9.

- Prospective enrollment of research participants whose sexual partners may become pregnant AND the research may cause possible risk to the sexual partner, fetus, or neonate. Submit Form 11-8.
- Plans to study outcomes of unexpected pregnancies of research participants or the sexual partners of research participants. Submit Form 11-8.

CONSIDERATIONS WHEN EXCLUDING PREGNANT PEOPLE

Pregnant people may be excluded from research for any of the following reasons:

- To minimize the risk to study participants
- To mitigate unacceptable or high risk to a potential fetus conceived during the research
- To prevent potential harmful outcomes to the offspring
- To reduce exposure to teratogens or other toxic agents
- To prevent known or theoretical biological effects of pregnancy on study outcomes (such as physiological or pharmacological impacts of pregnancy).

Whenever pregnancy is an exclusion criterion for participation for biomedical research, the Principal Investigator MUST provide the following as applicable to the specific research:

- Pregnancy screen testing, and repeat testing when applicable
- Strong counseling on the inadvisability of pregnancy during the course of the research and during any washout period in which study agents could have effects on pregnant people, the fetus, or the offspring
- Counseling regarding risks to sexual partners
- Counseling to include a process to obtain commitment of the participant to use one or more contraceptive method
- Assessment plans for birth control practices of research participants
- Information and resources for contraceptives
- Discussion of risks including risks of pregnancy
- Plans for reminding study participants of risk related to pregnancy throughout the duration of the study
- Opportunities to withdraw from a study.

The above requirements do not typically apply for social behavioral research (e.g., educational tests, survey, focus groups, observations, benign behavioral interventions, etc.) or retrospective research involving data or specimens that have already been collected.

CONTRACEPTION

The investigator and IRB should consider when contraception is required for research participants of childbearing potential, most broadly understood to be those who are post menarche and premenopausal, whether transgender, gender diverse, or female, and when contraception is required for the research participants' partners of childbearing potential. This does not include those reproductive-aged people who do not have a uterus (e.g., post-hysterectomy, having been born without a uterus), have been surgically sterilized, or those who abstain from sex that could result in pregnancy during the length of the study.

Contraception requirements extend to research participants who may impregnate others, most broadly understood to be cis-gender males or transgender females who have not undergone gender affirming surgery, if there is a theoretical risk of study agents affecting the biological male reproductive system or adversely affecting the conceived fetus or offspring.

The protocol and informed consent document must outline when contraception is required and the methods of contraception which are acceptable, the duration for which contraception is required, including any washout period, whether a double method of birth control is required, the use of contraception in the context of the research participant's and any current sexual partner's preferences. Contraceptive options may include barrier methods (male/female condoms, diaphragms, cervical caps), or surgical methods (vasectomy, tubal ligation), abstinence, hormonal methods (oral, injectable, implant, skin patch, vaginal ring) intrauterine devices, or other reliable contraception.

Contraception is not required for people who have had a bilateral salpingectomy, bilateral oophorectomy, or hysterectomy.

Investigators may be required by the IRB to provide contraception to study participants.

PREGNANCY TESTING

Pregnancy testing must be scientifically and ethically grounded.

A negative screening pregnancy test must be required for study participants who are of childbearing potential when pregnancy is an exclusion criterion. This requirement is predicated on the notion that the risk to pregnant people, their fetus, or the offspring justifies the exclusion, such as when studying investigational drugs, known teratogens, or other toxic agents.

The screening pregnancy test protects people of childbearing potential, the fetus, and/or offspring and may protect the institution, the IRB, and investigators from liability for adverse pregnancy outcomes related to the research.

Pregnancy testing is required during the recruitment and enrollment phase for studies in which pregnancy may affect study outcomes and thus pregnant people are excluded, even when there

is no anticipated risk to pregnant people, their fetus or offspring (e.g., one-time intervention with an Endopap device).

The investigator should include the following information in the research proposal or IRB application materials:

- Type of pregnancy testing required for screening purposes
    - Obtaining a serum pregnancy blood test rather than urine test is not justified unless blood is being drawn for other reasons.
    - Pregnancy testing may be done either using a Point of Care testing method or within a CLIA or CAP certified lab, according to applicable hospital or institutional policy
- Timeframe for testing (generally within 7 days of enrollment)
- Frequency of ongoing testing, which should be commensurate with the magnitude of potential harm and intervals consistent with clinical practice (generally not more than monthly)
- Process for informing the participant of pregnancy test results in private
- Research budget to cover the cost of pregnancy screening when the test is done exclusively for research purposes
- Include language within the consent and assent concerning the confidentiality for pregnancy testing. Templates are available in Step 8 on the Electronic IRB submissions website: https://www.downstate.edu/research/administration/institutional-review-board/electronic-application-process.html
- Include a process for providing or referring people for appropriate care or options counseling related to a positive pregnancy test.

ENABLING CERTAIN PERSONS TO CONSENT TO MEDICAL, DENTAL, HEALTH, AND HOSPITAL SERVICES.

As it relates to this guidance, in New York, under Public Health Law Section 2504, the following apply to clinical consent:

1. Any person who is eighteen years of age or older, or is the parent of a child or has married, may give effective consent for medical, dental, health and hospital services for themselves, and the consent of no other person shall be necessary.
2. Any person who has been married or who has borne a child may give effective consent for medical, dental, health and hospital services for their child.
3. Any person who is pregnant may give effective consent for medical, dental, health and hospital services relating to prenatal care.
4. Medical, dental, health and hospital services may be rendered to persons of any age without the consent of a parent, legal guardian or person possessing a lawful order of custody when, in the physician's judgment an emergency exists and the person is in

immediate need of medical attention and an attempt to secure consent would result in delay of treatment which would increase the risk to the person's life or health.

5. Anyone* who acts in good faith based on the representation by a person that he is eligible to consent pursuant to the terms of this section shall be deemed to have received effective consent. *[*Note that "anyone" refers to the individual obtaining consent.]*

MINOR RIGHTS TO CONSENT

In New York, a minor is anyone under the age of 18. Under NY laws, minors have rights to make their own medical decisions in specific areas of healthcare, which may include participation in medical research. A minor has the legal right to provide their consent either because they are part of a group to whom the law gives this right (i.e. pregnant teens, married minors, minors who are parents, minors in the military, emancipated minors, incarcerated minors) or because the minor is seeking a type of healthcare for which the law allows minors to give independent consent (e.g. reproductive healthcare, certain mental health services, certain alcohol and drug abuse services, sexual assault services). When treating minors who do not fit into the categories above, healthcare providers must ordinarily obtain consent from a parent or lawful guardian. A minor must have the capacity to provide consent, meaning they must have the maturity and intelligence to assess the risks and benefits and alternatives to treatment, and the healthcare provider should document in the medical record how the minor's capacity to consent was determined. In order to authorize treatment independently, a minor must have both the legal right to consent and the capacity to give informed consent. For more information and guidance, please see: Teenagers, Healthcare and the Law: A Guide to Minors' Rights in New York State.

A pregnant minor may consent to medical, dental, health, and hospital services related to prenatal care, labor, and delivery services. If a healthcare provider concludes, based on sound medical judgement, that a service is related to prenatal care, the provider may offer the services based on the minor's consent.

After a child is born, the minor parent can consent to all medical care for themselves and for their child.

CONFIDENTIALITY IN HEALTH CARE

In New York, a minor must give authorization to disclose information about their healthcare when a minor provides consent to their healthcare. When disclosing HIV-related information, written consent must specify that HIV-related information is to be disclosed.

Without parental involvement, a minor is entitled to confidential family planning services, birth control, emergency contraception (commonly called the morning after pill), abortion, treatment for sexually transmitted disease, testing and treatment of HIV/AIDS, sexual assault care, certain

types of mental health counseling and services, inpatient treatment (for minors 16 and over), certain alcohol and substance abuse services, emergency care when an attempt to secure consent from a parent or guardian would delay treatment.

Note: Sterilization may not be performed on anyone under the age of 21.

No New York law specifically allows teens to consent on their own to trans-related health services. To the extent that a minor seeks mental health care related to gender identify, however, the general rules granting minors independent access to such care apply. Trans children and teens are entitled to be treated like any patient with a health care need when they seek services of any kind, including services related to their gender identity.

If a minor obtains a positive pregnancy test, disclosure of these results to their parent or legal guardian can only occur if the minor consents. The IRB has language in the informed consent and assent templates that disclose this process.

WAIVER OF PARENTAL PERMISSION FOR RESEARCH CONSENT

When enrolling people who are pregnant and under the age of 18 in research related to prenatal care or pregnancy, it is not necessary to obtain parental or legal guardian permission for the research; however, a waiver would be required for research not related to prenatal care or pregnancy.

The IRB may waive parental or legal guardian permission to comply with federal regulations to be in harmony with minor rights of NY State requirements. All of the criteria to waive consent must be met in order for the IRB to approve the waiver. The specific criteria are outlined in the IRB waiver request forms posted in Step 8 of the IRB Electronic Submission Process webpage at https://www.downstate.edu/research/administration/institutional-review-board/electronic-application-process.html

REFERENCES

DeMartino Emily. Introduction to the Healthcare of Transgender and Gender Diverse Individuals. Nurse Practitioners in Women's Health. Presented by. Click here for Vimeo Video.

Gross, Marielle S., and Schonfeld, Toby. Chapter 9-3, Contraception, Pregnancy, and Pregnant Partners. Pages 485-489. Institutional Review Board: Management and Function: Management and Function 3rd Edition, by Public Responsibility in Medicine & Research (PRIM&R) (Author), Elizabeth A. Bankert (Author), Bruce G. Gordon (Author), Elisa A. Hurley (Author)

Intersex Society of North America. What is intersex?

Kapitan, Alex. Update to Transgender Style Guide: Avoiding Invalidating language Traps. Posted 7/13/2018. Click here for PDF version.

National Center for Transgender Equality. Understanding Transgender People: The Basics July 9, 2016

New York Civil Liberties Union. Teenagers, Healthcare and the Law: A Guide to Minors' Rights in New York State. 3rd Edition, 2018.

New York State Public health Law § 2504. Enabling certain persons to consent for certain medical, dental, health and hospital services.

AUTHORS

Jeffrey Birnbaum
Stanley Friedman
Laura Henderson
Ronnie Lichtman
Shoshana Milstein
Kevin Nellis
Kathleen Powderly
Tonya Taylor
William Versfelt

REVIEW AND APPROVAL HISTORY

Original Issue Date: 02/02/2022

Supersedes: N/A

Revision Date: N/A

Date Reviewed & Approved	**Revision Required**		**Responsible Staff Name and Title**	
	Yes	No		
02/02/2022		X	Downstate IRB	