



Pennsylvania laws do not directly address human research (except for research involving fetuses). IRB carefully reviews the facts and circumstances of each case to determine if state laws are relevant in the research context. The IRB and IRB administrative may also rely on the Office of General Counsel in applying state laws to research involving human subjects. The OGC may extrapolate from common law in setting university policies.

### **SURROGATE CONSENT**

Pennsylvania law does not set up a surrogate hierarchy in the clinical care or research setting. 8 Pa. Code § 103.22 states that a patient or, in the event the patient is unable to give informed consent, a "legally responsible party", has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program, and the patient, or legally responsible party, must give informed consent prior to actual participation in such a program. Pennsylvania law does not define "legally responsible party". Accordingly, the lawyers at Penn used case law to write the IRB Standard Operating Policy IC 705, Surrogate Consent/Authorization. Pennsylvania case law recognizes substituted judgment where a patient cannot express his/her own wishes. Pursuant, re Fiori, the substituted judgment aims solely at determining what the patient would have chosen for himself/herself based on prior expressions of view concerning medical issues by the patient, if any, and on the entire personality, philosophy and value system of the patient.

While Pennsylvania statutory law does not explicitly authorize substituted consent in the absence of a power of attorney or court-appointed guardian, case law strongly supports substituted consent by close family members when patients lack capacity to make medical decisions. When the subject is unable to give informed consent, the subject's close family member or significant partner is in the best position to determine the wishes of the subject regarding participation in therapeutic research.

The following individuals may be considered legally authorized representatives of the subject and capable of providing surrogate consent (or surrogate HIPAA Authorization):

- A court-appointed guardian authorized to consent to the subject's participation in the protocol in a current court order issued within the subject's jurisdiction.
- A health care agent appointed by the subject in a power of attorney.
- A "health care representative" when the subject cannot speak for themselves and where there has been no guardian appointed by the court or health care power of attorney designated by the patient. (PA Act 169). Any member of the following classes, in descending order of priority, who is reasonably available may act as the subject's health care representative.
  - The spouse (unless an action for divorce is pending) and adult child or children of another relationship.
  - Adult children (18 years of age or older).
  - A parent.
  - An adult sibling.
  - An adult grandchild



- An adult who has knowledge of the patient's preferences and values, including but not limited to religious and moral beliefs, who assess how the patient would make decisions.

**MANDATORY REPORTING OF DISEASES, INFECTIONS, AND CONDITIONS**

28 Pa. Code § 27 requires health care professionals and health care facilities to report to the Department of Health (Department) of all diseases, infections and conditions listed in the table below.

WITHIN 24 HOURS	WITHIN 5 DAYS
Anthrax Arboviruses Botulism Cholera Diphtheria Enterohemorrhagic E. coli Food poisoning outbreak Haemophilus influenzae invasive disease Hantavirus pulmonary syndrome Hemorrhagic fever Lead poisoning Legionellosis Measles (rubeola) Meningococcal invasive disease Plague Poliomyelitis Rabies Smallpox	AIDS (Only physicians and hospitals are required to report cases of AIDS) Amebiasis Brucellosis CD4 T-lymphocyte test result with a count of less than 200 cells/ $\mu$ L or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes (effective) Campylobacteriosis Cancer Chancroid Chickenpox (varicella) Chlamydia trachomatis infections. Congenital adrenal hyperplasia (CAH) in children under 5 years of age Creutzfeldt-Jakob Disease Cryptosporidiosis Encephalitis Galactosemia in children under 5 years of age Giardiasis Gonococcal infections Granuloma inguinale Guillain-Barre syndrome HIV (Human Immunodeficiency Virus) Hepatitis, viral, acute and chronic cases Histoplasmosis Influenza Leprosy (Hansen's disease) Leptospirosis Listeriosis Lyme disease Lymphogranuloma venereum Malaria Maple syrup urine disease (MSUD) in children under 5 years of age Meningitis



	<p>Mumps          Perinatal exposure of a newborn to HIV          Pertussis (whooping cough)          Phenylketonuria (PKU) in children under 5 years of age          Primary congenital hypothyroidism in children under 5 years of age          Pitacosis (ornithosis)</p> <p>Rickettsial diseases.          Rubella (German measles) and congenital rubellasyndrome          Salmonellosis          Shigellosis          Sickle cell disease in children under 5 years of age</p> <p>Staph infections          Streptococcal invasive disease (group A).          Streptococcus pneumoniae, drug-resistant invasive disease          Syphilis (all stages)          Tetanus          Toxic shock syndrome          Toxoplasmosis</p> <p>Trichinosis          Tuberculosis, suspected or confirmed active disease          Tularemia</p>
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**OTHER REPORTING REQUIREMENTS**

Healthcare providers in Pennsylvania are required to report:

- child neglect or abuse
- child sexual abuse

Child abuse or suspected child abuse reporting requirements extend to abuse committed by a parent, a person responsible for the welfare of the child (i.e., anyone who provides care or supervises the child), an individual living in the same house, or a paramour of the child's parent.

**EMANCIPATION**

Pennsylvania law does not have an emancipation statute. Instead, each county has its own procedures for emancipation. The laws are not very clear on what it means to be emancipated and what rights this status gives to an individual who is under eighteen. The legal status of emancipation generally gives to minors rights that are similar to adults and makes a difference in the acquisition of health care.



Each county in Pennsylvania has its own procedures for emancipation when it is done through the court system. Some counties do not recognize any formal procedure for emancipation, but in such counties it can be ordered by a judge at his or her own discretion. In these situations a minor, through an attorney or on her own, must petition the court for emancipation. Generally the court will be looking for the following characteristics to be demonstrated: (1) evidence of economic self-support, and (2) that a separate self-sufficient household has been created by the minor apart from parents or guardians.

Becoming a parent does not emancipate a minor for all purposes. If a minor is not able to support herself and does not live independently of her parents, she is not considered emancipated, whether or not she has a child.

Minors do acquire some of the rights of adults when they have a child. For example, teenage parents have the right to custody of their child and to make decisions regarding the child's upbringing, such as consenting to medical treatment. Teenage parents maintain these rights regardless of whether they live with their own parents or not, as long as they adequately care for their child. Mothers who are minors also have the right to consent to their own health care, except for abortions.

### **CONSENT TO HEALTH SERVICES**

Pennsylvania law generally requires consent of a parent or guardian for medical treatment of a minor (a person under 18 years of age). The law permits a minor to consent to medical, dental or other health care services, except abortion, if the minor has (1) graduated from high school, (2) been married, or (3) been pregnant. Under these conditions, consent of no other person is necessary.

### **NONTHERAPEUTIC RESEARCH ON "UNBORN CHILDREN"**

Pennsylvania's law prohibits "knowingly perform[ing] any type of nontherapeutic experimentation or nontherapeutic medical procedure... upon any unborn child..." Pa. Statute, Title 18 § 3216 (a). Performing such experimentation is a felony.

"Unborn child" means "an individual organism of the species *homo sapiens* from fertilization until live birth." §3203.

### **REFERENCES**

Pennsylvania Code may be accessed on the internet:  
<http://www.pacode.com/secure/browse.asp>