HUMAN SUBJECTS RESEARCH AND DISTRICT OF COLUMBIA (DC) LAWS

CONSENT CONSIDERATIONS

INFORMED CONSENT LAW LANGUAGE AND PROCESS REQUIREMENTS

Informed consent, in the District of Columbia (DC) is to give information, to make known, or to impart knowledge of a fact or circumstance of treatment or procedure. *See* D.C. Mun. Regs. Subt. 22-B, § 699.1. This requires mandatory disclosure of information to an individual on treatment of the individual's condition to the extent a reasonable person in the individual's position would consider material to his or her decision to receive the treatment. The information is material if a reasonable person would likely attach significance to risks in deciding to accept or forego a particular medical procedure or treatment. At a minimum, a physician must disclose the nature of the condition, the nature of the proposed treatment, any alternate treatment procedures, and the nature of the degree of risks and benefits inherent in undergoing and in abstaining from the proposed treatment. Not all risks need be disclosed, only material risks must be disclosed. Consent obtained without divulging material information is ineffective to grant physician permission to institute proposed treatment. These mandatory disclosures must be disclosed and accepted in writing or orally.

There is no DC statute or judicial ruling that incorporates the requirements of the Common Rule with regards to informed consent; the law of DC does not require that a physician make required disclosures concerning treatment risks and benefits in writing or in a form approved by an institutional review board (IRB). The only requirement is that a physician make all material disclosures; the form in which those disclosures must be made is not prescribed by DC law.⁶

MINORS

A. Legal Age of Consent.

The legal age of consent in DC is 18 years of age. See DC ST § 46-101. Otherwise, an individual is considered a minor unless they qualify as an emancipated minor under DC law. Any person who is 18 years of age or older may consent to the provision of health services for himself or herself, or for his or her child or spouse. See D.C. Mun. Regs. Subt. 22-B, §600.1. A minor parent may consent to the provisions of health services to his or her child. See D.C. Mun. Regs. Subt. 22-B, §600.3. Health services may be provided to a minor of any age without parental consent when, in the judgement of the treating physician, surgeon, or dentist, the delay that would result from attempting to obtain parental consent would substantially increase the risk to the minor's life,

¹ Miller-McGee v. Washington Hospital Center, 920 A.2d 430, 439-440 (D.C. 2007).

² Id. at 440.

³ *Id*.

⁴ Id.

⁵ Crain v. Allison, 443 A.2d 558, 562 (D.C. 1982).

⁶ *lacangelo v. Georgetown University*, 2010 WL 4807082, *6 (D.C. 2010).

health, mental health, or welfare, or would unduly prolong suffering. See D.C. Mun. Regs. Subt. 22-B, §600.4. A minor of any age may consent to health services which he or she requests for the prevention, diagnosis, or treatment of the following medical situations:

- 1. Pregnancy or its lawful termination;
- 2. Substance abuse, including drug and alcohol abuse; and
- 3. A mental or emotional condition and sexually transmitted disease.

See D.C. Mun. Regs. Subt. 22-B, §600.7.

Self-consent of minors shall not apply to sterilization, such as tubal ligation or vasectomy. *See* D.C. Mun. Regs. Subt. 22-B, §600.8.

While minors of any age can seek mental health treatment without parental consent, minors between the ages of 14 and 18 can only have mental health information disclosed if both the minor and his or her parent or guardian authorizes a disclosure; if a minor is under 14, only a parent or legal guardian can authorize a disclosure of mental health information. "Mental health information" means any written, recorded or oral information acquired by a mental health professional in attending a client in a professional capacity which: (a) indicates the identity of a client; and (b) relates to the diagnosis or treatment of a client's mental or emotional condition. *See* DC ST § 7-1201.01. This rule does not hold true if a minor did not obtain parental consent prior to seeking mental health treatment, in which case the consent of the minor is enough for disclosure.

B. Emancipated Minors.

The general definition of an emancipated minor in DC is a minor who is or has been married; who is serving or has served in the armed forces; who is employed and contributing more than half of his or her own support if residing with his or her parents; who is residing apart from his or her parents and managing his or her own affairs; or who is making the major decisions affecting his or her own life. *See* D.C. Mun. Regs. Subt. 22-B, § 699.1.

For purposes of mental health counseling, an emancipated minor is defined as any minor who is living separate and apart from his or her parent(s) or legal guardian, with or without the consent of the parent(s) or legal guardian and regardless of the duration of such separate residence, and who is managing his or her own personal and financial affairs, regardless of the source or extent of the minor's income. *See* DC ST § 7-1231.02.

Emancipation is granted by the courts in DC, and may either be complete emancipation, or partial emancipation for only limited purposes. Once emancipated, any legal limitations that are generally attached to minors are extinguished, and the emancipated minor shall have the same rights to consent to healthcare and participation in research as adults; except that an emancipated minor cannot self-consent to an abortion without his or her parent's consent or a court order. When enrolling emancipated minors in research, a copy of the emancipation court order should be obtained and reviewed closely to ensure the court granted complete emancipation, or alternatively granted the minor the ability to consent to research.

C. Foster Children.

In DC, "foster care" means 24 hour substitute care for children placed away from their parents or guardians for whom the Child and Family Services Agency has placement care and responsibility. See DC ST § 4-342(2). "Foster child" and "foster children" mean a child, or children, who comes under the jurisdiction of the Superior Court of the District of Columbia pursuant to § 16-2320 or whose parents' rights have been relinquished pursuant to § 4-1406. See DC ST § 4-342(3). "Foster parent" means an individual with whom a foster child is legally placed. See DC ST § 4-342(4). Foster parents responsibilities include in part:

- 1. Assist the Child and Family Services Agency social worker to secure all necessary medical care, including dental and vision services on a preventive, routine, emergency, and follow-up basis.
- 2. Maintain current medical records, reports, authorization cards/forms, etc., in a safe and confidential file within the foster home.
- 3. Record in the foster parent case file, the administration of all medications to a child.
- 4. Notify the social worker or a hotline social worker immediately if the child(ren) has a serious illness or an injury requiring medical treatment.
- 5. Dispense medications prescribed by a child(ren) physician, in accordance with the directions provided, and notify the social worker of any new prescriptions or dosage change within two (2) working days.

Child and Family Services Agency social workers are responsible for overseeing foster children's health. Foster parents do not have the authority to consent to research for foster children in their care. Foster parents must provide notice to, and seek approval from, social workers prior to seeking any type of medical treatment for a foster child. Thus, any request to enroll a foster child in a research study must be coordinated with the DC Child and Family Services Agency.

D. Pregnancy Testing.

As noted above, a minor of any age may consent to pregnancy health services, including testing or its lawful termination, without the consent of her parents. Birth control information, services, and devices may be provided without regard to the age or marital status of a minor or the consent of the minor's parent or guardian. *See* D.C. Mun. Regs. Subt. 22-B, § 603.1. Except by specific legal requirements, no information about a minor's pregnancy can be given by a health professional to another professional, school, law enforcement official, court authority, government agent, spouse, future spouse, employer, or any other person without consent of the minor, unless giving the information is necessary to the health of the minor and the public, and only when the minor's identity is kept confidential. *See* D.C. Mun. Regs. Subt. 22-B, § 602.6.

TREATMEN TO INDIVIDUALS WITH DISABILITIES

Prior to any medical treatment, informed consent must be obtained from an individual with a disability, if competent. See DC ST § 7-1305.06a(a). As applied to individuals with disabilities, informed consent is defined as consent voluntarily given in writing with sufficient knowledge and comprehension of the subject matter involved to enable the person giving consent to make an understanding and enlightened decision, without any element of force, fraud, deceit, duress or other form of constraint or coercion. See DC ST § 7-1301.03(15). In seeking informed consent, the provider shall present the individual with available options and all material information necessary to make the decision, including:

- 1. Information about the proposed service.
- 2. Potential benefits and risks of the proposed service.
- 3. Potential benefits and risks of no service.
- 4. Side effects.
- 5. Information about feasible alternative services, if any.

See DC ST § 7-1305.06a(a).

If the provider reasonably believes that an individual with a disability lacks the capacity to provide informed consent for the proposed service, the provider shall seek a determination of the person's capacity in accordance with DC ST § 21-2204. If the person is certified as incapacitated for health-care decisions, the provider shall promptly seek the provision of substituted consent from the person's attorney-in-fact pursuant to DC ST § 21-2206 or, if no attorney-in-fact has been authorized pursuant to DC ST § 21-2205 or is reasonably available, mentally capable, and willing to act, from a person authorized to provide substituted consent pursuant to DC ST § 21-2210. *See* DC ST § 7-1305.06a(b).

If the person is certified as incapacitated and unable to consent to the proposed service, and no attorney-in-fact or person listed is reasonably available, mentally capable, and willing to act, then for any proposed services except psychotropic medications, the provider must work with the DC Department of Disability Services to petition the Superior Court of the District of Columbia for appointment of a guardian. The petition shall request the form of guardianship which is least restrictive to the incapacitated person in duration and scope, taking into account the incapacitated person's current mental and adaptive limitations or other conditions warranting the procedure. This does not preclude any other party from petitioning the Court for appointment of a guardian.

See DC ST § 7-1305.06a(c).

Individuals with disabilities may be enrolled in experimental research with their express and informed consent, or if the person cannot give consent, the consent of the person's parent or guardian. Such proposed research must first get approval from the DC Department on Disability Services before such consent shall be sought. Prior to such approval, the Department will determine whether such research complies with the principles of the statement on the use of human subjects for research of the American Association on Mental Deficiency and with the principles

for research involving human subjects required by the United States Department of Health and Human Services for projects supported by that agency. *See* DC ST § 7-1305.09.

DERTERMINING CAPACITY TO CONSENT TO HEALTH-CARE DECISIONS

DC law presumes, in the absence of an adjudicated determination of incapacitation, that an individual (adult) has appropriate capacity to consent to medical treatment for themselves. Incapacitation may not be inferred from the individual's voluntary or involuntary hospitalization for mental illness or from his or her disability. Mental incapacity to make a health-care decision shall be certified by 2 professionals who are licensed to practice in DC and qualified to make a determination of mental incapacity. One of the 2 certifying professionals shall be a physician and one shall be a qualified psychologist or psychiatrist. At least 1 of the 2 certifying professionals shall examine the individual in question within 1 day preceding certification. Both certifying professionals shall give an opinion regarding the cause and nature of the mental incapacity as well as its extent and probable duration.

The findings and opinions of the professionals shall be expressed in writing, included in the patient-care records of the individual, and provide clear evidence that the individual is incapable of understanding the health-care choice, making a decision concerning the particular treatment or services in question, or communicating a decision even if capable of making it. The findings and opinions of the professionals shall be limited in their effect to the capacity the individual to make health-care decisions and shall not be construed as a finding of incompetency for any other purpose.

See DC ST § 21-2204.

CONSENT FOR INDIVIDUALS DETERMINED/ADJUDICATED INCAPACITATED (SUBSTITUTED CONSENT)

In the absence of a durable power of attorney for health care and provided that the incapacity of a patient has been certified, the following individuals, **in the order of priority** set forth below, are authorized to grant, refuse or withdraw consent on behalf of an incapacitated individual with respect to the provision of any health-care service, treatment, or procedure:

- 1. A court-appointed guardian or conservator of the individual, if the consent is within the scope of the guardianship or conservatorship;
- 1A. A court-appointed intellectual disability advocate of the individual, if the ability to grant, refuse, or withdraw consent is within the scope of the advocate's appointment under DC ST § 7-1304.13.
- 2. The spouse or domestic partner of the individual;
- 3. An adult child of the individual;
- 4. A parent of the individual;
- 5. An adult sibling of the individual;
- 5A. A religious superior of the individual, if the individual is a member of a religious order or a diocesan priest;

- 5B. A close friend of the individual; or
- 6. The nearest living relative of the individual.

A decision to grant, refuse or withdraw substitute consent must be based on the known wishes of the individual or, if the wishes of the individual are unknown and cannot be ascertained, on a good faith belief as to the best interests of the individual. Researchers should attempt to ascertain from the person providing substituted consent the bases of the individual's known wishes, whether their wishes were in writing or verbally communicated.

There must be at least one witness present or, during a period of time for which a public health emergency pursuant to DC ST § 7-2304.01 has been declared, electronically present whenever an authorized person grants, refuses or withdraws substitute consent on behalf of an individual.

A person listed above authorized to provide substitute consent is not authorized to grant, refuse, or withdraw consent on behalf of an individual with respect to a decision regarding a health-care service, treatment, or procedure if the individual is:

- 1. A health-care provider who is treating or providing services to the incapacitated individual at the time of the health-care decision; or
- 2. An owner, operator, administrator, or employee of, or a person with decision-making authority for, a health-care provider treating or providing services to an incapacitated individual at the time of the health-care decision.

If no person listed above is reasonably available, mentally capable, and willing to act, the health-care provider, the District of Columbia, or any interested person may petition the Superior Court of the District of Columbia for appointment of a guardian pursuant to § 21-2044 or § 21-2046.

The health-care provider who is treating or providing services to the incapacitated individual at the time of the health-care decision shall accept the decision of the person authorized to grant, refuse, or withdraw consent on behalf of an individual as the decision of the individual.

See DC ST § 21-2210.

PRIVACY AND CONFIDENTIALITY

DISTRICT OF COLUMBIA DATA BREACH NOTIFICATION ACT

The DC Data Breach Notification Act ("DBNA") applies to "Personal Information" in electronic form and must be considered in addition to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") with respect to any Personal Information in the medical treatment or research context.

Personal Information includes an individual's first name, first initial and last name, or any other personal identifier, which, in combination with any of the following data elements, can be used to identify an individual or the individual's information:

- 1. Social security number, individual taxpayer identification number, passport number, driver's license number, District of Columbia identification card number, military identification number, or other unique identification number issued on a government document commonly used to verify the identity of a specific individual;
- 2. Account number, credit card number or debit card number, or any other number or code or combination of numbers or codes, such as an identification number, security code, access code, or password, that allows access to or use of an individual's financial or credit account;
- 3. Medical information;
- 4. Genetic information and deoxyribonucleic acid profile;
- 5. Health insurance information, including a policy number, subscriber information number, or any unique identifier used by a health insurer to identify the person that permits access to an individual's health and billing information;
- 6. Biometric data of an individual generated by automatic measurements of an individual's biological characteristics, such as a fingerprint, voice print, genetic print, retina or iris image, or other unique biological characteristic, that is used to uniquely authenticate the individual's identity when the individual accesses a system or account; or
- 7. Any combination of data elements included above that would enable a person to commit identity theft without reference to an individual's first name or first initial and last name or other independent personal identifier;

Personal Information also includes a user name or e-mail address in combination with a password, security question and answer, or other means of authentication, or any combination of data elements listed above that permits access to an individual's e-mail account.

Under the DBNA, Genetic Information has the meaning ascribed to it under HIPAA, and Medical Information means any information about an individual's dental, medical, or mental health treatment or diagnosis by a health-care professional.

See DC ST § 28-3851.

The DBNA requires a person or entity that owns, licenses, maintains, handles, or otherwise possesses Personal Information of an individual living in DC, or a nonaffiliated third party hired by the person or entity to perform services, to implement and maintain reasonable security safeguards, including procedures and practices that are appropriate to the nature of the Personal Information and the nature and size of the entity or operation, to protect the Personal Information from unauthorized access, use, modification, disclosure, or a reasonably anticipated hazard or threat.

A person or entity who is subject to and in compliance with requirements for security procedures and practices contained in the Gramm-Leach-Bliley Act, HIPAA, or the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and any rules, regulations, guidance and guidelines thereto, shall be deemed to be in compliance with the DBNA security requirements and procedures.

See DC ST § 28-3852a.

The DBNA requires any person or entity who owns or licenses computerized or other electronic data system that includes Personal Information, and who discovers a breach of the security of the system, to promptly notify any DC resident whose Personal Information was included in the breach. The notification shall be made in the most expedient time possible and with any measures necessary to determine the scope of the breach and restore the reasonable integrity of the data system. The notification shall include: to the extent possible, a description of the categories of information that were, or are reasonably believed to have been, acquired by an unauthorized person, including the elements of personal information that were, or are reasonably believed to have been, acquired; contact information for the person or entity making the notification, including the business address, telephone number, and toll-free telephone number if one is maintained; the toll-free telephone numbers and addresses for the major consumer reporting agencies, including a statement notifying the resident of the right to obtain a security freeze free of charge pursuant to 15 U.S.C. § 1681c-1 and information how a resident may request a security freeze; and the tollfree telephone numbers, addresses, and website addresses for the following entities, including a statement that an individual can obtain information from these sources about steps to take to avoid identity theft-The Federal Trade Commission and The Office of the Attorney General for the District of Columbia.

Notice shall also be given to the Office of the Attorney General for the District of Columbia if the breach affects 50 or more DC residents. This notice shall be made in the most expedient manner possible, without unreasonable delay. The written notice must include:

- 1. The name and contact information of the person or entity reporting the breach;
- 2. The name and contact information of the person or entity that experienced the breach:
- 3. The nature of the breach of the security of the system, including the name of the person or entity that experienced the breach;
- 4. The types of personal information compromised by the breach;
- 5. The number of DC residents affected by the breach;

- 6. The cause of the breach, including the relationship between the person or entity that experienced the breach and the person responsible for the breach, if known;
- 7. The remedial action taken by the person or entity to include steps taken to assist DC residents affected by the breach;
- 8. The date and time frame of the breach, if known;
- 9. The address and location of corporate headquarters, if outside of DC;
- 10. Any knowledge of foreign country involvement; and
- 11. A sample of the notice to be provided to DC residents.

Notice shall also be given to all consumer reporting agencies that compile and maintain files on consumers on a nationwide basis, as defined by the Fair Credit Reporting Act, of the timing, distribution and content of the notices if notice is given to more than 1,000 persons of a breach of a security system. There is no requirement to provide to the consumer reporting agency the names or other personal identifying information of breach notice recipients.

A person or entity that maintains procedures for a breach notification system under the Gramm-Leach-Bliley Act, the breach notification rules pursuant to HIPAA, or under HITECH, and provides notice in accordance with such Acts, and any rules, regulations, guidance and guidelines thereto, to each affected resident in the event of a breach, shall be deemed to be in compliance with the notification requirements of the DBNA with respect to the notification of DC residents whose Personal Information is included in the breach. However, written notice of the breach of the security of the system must still be made to the Office of the Attorney General for the District of Columbia in accordance with the requirements stated above.

See DC ST § 28-3852.

HIV TESTING

DC law requires all Human Immunodeficiency Virus (HIV) infection cases and pregnancies in HIV-infected women (including Acquired Immune Deficiency Syndrome (AIDS)) be reported to the Director of the DC Department of Health or his or her designee. Physicians and others licensed to practice in DC in charge of an AIDS diagnosis, must report the AIDS diagnosis to the Director within forty-eight (48) hours of diagnosis and furnish information the Director deems necessary to complete a confidential case report. Additionally, a report of a HIV positive test result must be given to the Director or his or her designee. The physician or provider, laboratory, blood bank, or other entity or facility that provides HIV testing shall report all cases of HIV infection to the Director or his or her designee. A physician, physician's assistant, nurse-midwife, and other person licensed to practice in DC who attends to, treats, examines, or provides perinatal treatment to a pregnant woman infected with HIV shall report the pregnancy to the Director within forty-eight (48) hours of diagnosis of the pregnancy and furnish information the Director deems necessary to complete a confidential case report. At a minimum, the reports must include the patient's name, address of residence, including city, state, and zip code, gender, race or ethnicity, mode of exposure, place or country of birth, date of birth, date of diagnosis of HIV or AIDS and opportunistic infections, the name and telephone number of the person making the report, and the name of the entity providing health or medical services.

See D.C. Mun. Regs. Subt. 22-B, § 206.

Informed consent is not required for HIV testing,⁷ and there is no requirement to notify third-parties of a positive test result under DC law.

SUBSTANCE ABUSE TREATMENT

The confidentiality protections for participation in substance abuse treatment programs in DC generally defer to the federal law and DC regulations. All research involving substance abuse and related activities that involve human subjects must comply with "Protection of Human Subjects" 45 CFR, Part 46 and "Confidentiality of Alcohol and Drug Abuse Patient Records" 42 CFR, Part 2. See D.C. Mun. Regs. Tit. 29, § 2317.1.9 All substance abuse and treatment records must be kept confidential and must be handled in compliance with the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and DC laws and regulations regarding the confidentiality of patient records. With respect to minor's confidentiality, no information in regards to substance abuse can be given by a health professional to another professional, school, law enforcement official, court authority, government agent, spouse, future spouse, employer, or any other person without the consent of the minor, unless giving the information is necessary to the health of the minor and the public, and only when the minor's identity is kept confidential. See D.C. Mun. Regs. Subt. 22-B, § 602.8.

SEXUALLY TRANSMITTED DISEASES

Information and records related to treatment for sexually transmitted diseases are confidential and are treated with the same confidentiality protections as medical records. As previously stated, no information regarding a minor's treatment for sexual assault or abuse can be disclosed by a health professional to another professional, school, law enforcement official, court authority, government agent, spouse, future spouse, employer, or any other person without the consent of the minor, unless giving the information is necessary to the health of the minor and the public, and only when the minor's identity is kept confidential. Healthcare providers are permitted to provide information and treatment to partners of individuals treated for sexually transmitted diseases, but may not disclose the name of the individual treated.

⁷ See Centers for Disease Controls and Prevention, Policy, Planning and Strategic Communication, HIV Legal Landscape at: https://www.cdc.gov/hiv/policies/law/states/index.html).

⁸ DC regulations on Substance Abuse Treatment are currently reserved at 29 DCMR Chapter 23.

⁹ Note that this DC regulation is currently in "reserved" status.

MANDATORY REPORTING OBLIGATIONS

CHILD ABUSE

- A. Persons required to make report.
 - 1. Child and Family Services Agency employees, agents, and contractors, and every physician, psychologist, medical examiner, dentist, chiropractor, registered nurse, licensed practical nurse, person involved in the care and treatment of patients, lawenforcement officer, humane officer of any agency charged with the enforcement of animal cruelty laws, school official, teacher, athletic coach, Department of Parks and Recreation employee, public housing resident manager, social service worker, day care worker, human trafficking counselor, domestic violence counselor, and mental health professional, who knows or has reasonable cause to suspect that a child known to him or her in his or her professional or official capacity has been or is in immediate danger of being a mentally or physically abused or neglected child, as defined in DC ST § 4-1301.02(15A), must immediately report or have a report made of such knowledge or suspicion to either the Metropolitan Police Department of the District of Columbia or the Child and Family Services Agency.
 - 2. Any person required to make a report must report to the Child and Family Services Agency any child who is age 5 through 13 years and who has 10 or more days of unexcused absences within a school year.
 - 3. Whenever a person is required to report in his or her capacity as a member of the staff of a hospital, school, social agency or similar institution, he or she must immediately notify the person in charge of the institution or his or her designated agent who must then be required to make the report. The fact that such a notification has been made does not relieve the person who was originally required to report from his or her duty of having a report made promptly to the Metropolitan Police Department of the District of Columbia or the Child and Family Services Agency.
 - 4. Any health professional, or a law enforcement officer, humane officer of any agency charged with the enforcement of animal cruelty laws, except an undercover officer whose identity or investigation might be jeopardized, must report immediately, in writing, to the Child and Family Services Agency, that the law enforcement officer or health professional has reasonable cause to believe that a child is abused as a result of inadequate care, control, or subsistence in the home environment due to exposure to drug-related activity.
 - 5. Any person required to make a report who knows or has reasonable cause to suspect that a child known to him or her in his or her professional or official capacity has been, or is in immediate danger of being, the victim of "sexual abuse" or "attempted sexual abuse"; or that the child was assisted, supported, caused, encouraged, commanded, enabled, induced, facilitated, or permitted to become a prostitute; or that the child has an injury caused by a bullet; or that the child has an injury caused by a knife or other sharp object which has been caused by other than accidental means, must immediately report or have a report made of such knowledge, information, or suspicion to the Metropolitan Police Department or the Child and Family Services Agency.

- 6. A health professional, who in his or her own professional or official capacity knows that a child under 12 months of age is diagnosed as having a Fetal Alcohol Spectrum Disorder, must immediately report or have a report made to the Child and Family Services Agency.
- B. Other persons who may make a report.

Any other person, who knows or has reasonable cause to suspect that a child known to him or her in his or her professional or official capacity has been or is in immediate danger of being a mentally or physically abused or neglected child, as defined in DC ST § 4-1301.02(15A), may make a report to the Metropolitan Police Department of the District of Columbia or the Child and Family Services Agency.

See DC ST § 4-1321.02.

- C. Nature and contents of reports.
 - 1. Each person required to make a report of a known or suspected neglected child must:
 - (i) Immediately make an oral report of the case to the Child and Family Services Agency or the Metropolitan Police Department of the District of Columbia; and
 - (ii) Make a written report of the case if requested by said Division or Police or if the abuse involves drug-related activity.
 - 2. The report must include, but need not be limited to, the following information if it is known to the person making the report:
 - (i) The name, age, sex, and address of the following individuals:
 - (A) The child who is the subject of the report;
 - (B) Each of the child's siblings and other children in the household; and
 - (C) Each of the child's parents or other persons responsible for the child's care;
 - (ii) The nature and extent of the abuse or neglect of the child and any previous abuse or neglect, if known;
 - (iii) All other information which the person making the report believes may be helpful in establishing the cause of the abuse or neglect and the identity of the person responsible for the abuse or neglect; and
 - (iv) The identity and occupation of the source of the report, how to contact the source and a statement of the actions taken by the source concerning the child.

See DC ST § 4-1321.03.

D. Definitions.

- 1. "Abused", when used in reference to a child, means:
 - (i) infliction of physical or mental injury upon a child; sexual abuse (including sex trafficking) or exploitation of a child; or negligent treatment or maltreatment of a child.

The term "abused", when used with reference to a child, does not include discipline administered by a parent, guardian or custodian to his or her child; provided, that the discipline is reasonable in manner and moderate in degree and otherwise does not constitute cruelty. "Discipline" does not include: burning, biting, or cutting a child; striking a child with a closed fist; inflicting injury to a child by shaking, kicking, or throwing the child; non-accidental injury to a child under the age of 18 months; interfering with a child's breathing; and threatening a child with a dangerous weapon or using such a weapon on a child; or

2. "Neglected child" means a child:

- (i) who has been abandoned or abused by his or her parent, guardian, or custodian, or whose parent, guardian, or custodian has failed to make reasonable efforts to prevent the infliction of abuse upon the child;
- (ii) who is without proper parental care or control, subsistence, education as required by law, or other care or control necessary for his or her physical, mental, or emotional health, and the deprivation is not due to the lack of financial means of his or her parent, guardian, or custodian;
- (iii) whose parent, guardian, or custodian is unable to discharge his or her responsibilities to and for the child because of incarceration, hospitalization, or other physical or mental incapacity;
- (iv) whose parent, guardian, or custodian refuses or is unable to assume the responsibility for the child's care, control, or subsistence and the person or institution which is providing for the child states an intention to discontinue such care;
- (v) who is in imminent danger of being abused and another child living in the same household or under the care of the same parent, guardian, or custodian has been abused;
- (vi) who has received negligent treatment or maltreatment from his or her parent, guardian, or custodian;
- (vii) who has resided in a hospital located in the District of Columbia for at least 10 calendar days following the birth of the child, despite a medical determination that the child is ready for discharge from the hospital, and the parent, guardian, or custodian of the child has not taken any action or made any effort to maintain a parental, guardianship, or custodial relationship or contact with the child:
- (viii) who is born addicted or dependent on a controlled substance or has a significant presence of a controlled substance in his or her system at birth;

- (ix) in whose body there is a controlled substance as a direct and foreseeable consequence of the acts or omissions of the child's parent, guardian, or custodian; or
- (x) who is regularly exposed to illegal drug-related activity in the home; or
- (xi) who is the victim of sex trafficking or a commercial sex act.

See DC ST § 4-1301.02.

VULNERABLE ADULTS

A. Persons required to make a report.

A conservator, court-appointed mental retardation advocate, guardian, health-care administrator, licensed health professional, police officer, humane officer of any agency charged with the enforcement of animal cruelty laws, bank manager, financial manager, or social worker has as a result of his or her appointment, employment, or practice substantial cause to believe that an adult is in need of protective services because of abuse, neglect, or exploitation by another, he or she must immediately report this belief to District of Columbia Department of Aging and Community Living.

B. Other persons who may make a report.

Any person may voluntarily report an alleged case of abuse, neglect, self-neglect, or exploitation when he or she has reason to believe that an adult is in need of protective services.

C. Exceptions.

The duty to report does not apply to a social worker or licensed health professional who has as a client or patient, or is employed by a lawyer representing, a third person who is allegedly responsible for the abuse or neglect.

D. Nature and contents of reports.

A report made may be either oral or written and must be transmitted to the District of Columbia Department of Aging and Community Living. Each report must include, if known:

- 1. the name, age, physical description, and location of the adult alleged to be in need of protective services;
- 2. the name and location of the person(s) allegedly responsible for the abuse, neglect, or exploitation;
- 3. the nature and extent of the abuse, neglect, self-neglect, or exploitation;
- 4. the basis of the reporter's knowledge; and
- 5. any other information the reporter believes might be helpful to an investigation.
- 6. Required reporters are required to identify himself or herself.

See DC ST § 7-1903.

E. Definitions.

- 1. "Abuse" means:
 - (i) The intentional or reckless infliction of serious physical pain or injury;
 - (ii) The use or threatened use of violence to force participation in "sexual conduct;
 - (iii) The repeated, intentional imposition of unreasonable confinement or threats to impose unreasonable confinement, resulting in severe mental distress;
 - (iv) The repeated use of threats or violence, resulting in shock or an intense, expressed fear for one's life or of serious physical injury; or
 - (v) The intentional or deliberately indifferent deprivation of essential food, shelter, or health care in violation of a caregiver's responsibilities, when that deprivation constitutes a serious threat to one's life or physical health.
- 2. "Adult in need of protective services" means an individual 18 years of age or older who:
 - (i) Is highly vulnerable to abuse, neglect, self-neglect, or exploitation because of a physical or mental impairment, self-neglect, or incapacity;
 - (ii) Has recently been or is being abused, neglected, or exploited by another or meets the criteria for self-neglect; and
 - (iii) Has no one willing and able to provide adequate protection.
- 3. "Neglect" means:
 - (i) The repeated, careless infliction of serious physical pain or injury;
 - (ii) The repeated failure of a caregiver to take reasonable steps, within the purview of his or her responsibilities, to protect against acts of abuse;
 - (iii) The repeated, careless imposition of unreasonable confinement, resulting in severe mental distress; or
 - (iv) The careless deprivation of essential food, shelter, or health care in violation of a caregiver's responsibilities, when that deprivation constitutes a serious threat to one's life or physical health.
- 4. "Self-neglect" means the failure of an adult, due to physical or mental impairments or incapacity, to perform essential self-care tasks, including:
 - (i) Providing essential food, clothing, shelter, or medical care;
 - (ii) Obtaining goods or services necessary to maintain physical health, mental health, emotional well-being, and general safety; or
 - (iii) Managing his or her financial affairs.

See DC ST § 7-1901.

OTHER CONSIDERATIONS

GENETIC TESTING

Under DC Law, "genetic information" means, with respect to any individual, information about an individual's genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual. Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. Any reference to genetic information concerning an individual or family member of an individual who is a pregnant woman, includes genetic information of any fetus carried by such pregnant woman, or with respect to an individual or family member utilizing reproductive technology, includes genetic information of any embryo legally held by an individual or family member. The term "genetic information" does not include information about the sex or age of any individual.

"Genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detect genotypes, mutations, or chromosomal changes. The term "genetic test" does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

See D.C. Mun. Regs. Subt. 26-A, § 2228.

Genetic testing may performed only with the consent of the person being tested, unless ordered by the DC court. An individual may request, in writing, access to or copies of the results of the individual's own genetic laboratory tests, otherwise all requests for clinical laboratory services, the results of all clinical laboratory tests, and the contents of an individual's specimens shall be confidential. Persons other than the individual tested or the individual's physician may have access to the results of the tested individual's laboratory tests if:

- 1. The individual has given written consent to the person seeking access for the release of the records for a specific use; or
- 2. The court has issued a subpoena for the results of the tested individual's laboratory tests, and except in a law enforcement investigation, the person seeking access has given the tested individual notice and an opportunity to contest the subpoena.

All clinical laboratory results shall be reported to the requesting physician. When there is no requesting physician, the clinical laboratory shall report the test results to the individual being tested and shall recommend that she or he forward the laboratory results to her or his personal physician as soon as possible.

See DC ST § 44-211.

CONDUCTING RESEARCH WITH THE DC DEPARTMENT OF HEALTH

The DC Institutional Review Board for Public Health (IRBPH) is responsible for protecting the rights and welfare of human research subjects recruited to participate in research activities or data collected on human subjects conducted under the auspices of the DC Department of Health with which it is affiliated. The IRBPH has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction, as specified by federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by DC Department of Health officials. However, DC Health officials may not approve research if it has been disapproved by the IRB.

The IRBPH functions independently of but in coordination with other communities. For example, an institution (e.g., university, hospital, government body, research institute) may have a research committee that reviews protocols to determine whether the institution should support the proposed research. The IRBPH, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.

The following institutions, organizations, and people must apply for IRBPH review:

- 1. Researchers partnering with DC Health Agencies/Programs conducting public health research involving human subjects or DC Health program data collected on human subjects who are residents of the District of Columbia;
- 2. Institutions/Government Agencies receiving Federal dollars for research or grants must submit protocol to IRBPH for review and approval; and
- 3. Researchers, administrators, etc., requesting data with identifiers from the DC Health's Vital Records Office.

All proposals must be received by the DC Health's IRB office ten (10) business days prior to the IRB meeting date. Investigators/researchers must submit one (1) original copy and an electronic copy of completed application packet.

See https://dchealth.dc.gov/service/institutional-review-board-public-health.

CONDUCTING RESEARCH WITH DC VITAL RECORDS

Research with copies or data from the system of DC vital records may be conducted if approved by the JHM IRB and the DC IRBPH. Researchers and investigators may request copies or data from the Registrar of Vital Records in the Vital Records Division of the DC Department of Health. Researchers/investigators must submit to the Registrar a completed application that is on a prescribed form and meets the following conditions:

- 1. Has the signed approval of an Institutional Review Board constituted according to federal guidelines for the protection of human subjects, as set forth in 42 U.S.C. § 289 (Health Research Extension Act of 1985 § 2); and
- 2. Has a signed statement of assurances in which the applicant agrees to the terms and conditions of the application, which shall include the following statements:

- (i) That the information will be used solely for research or administrative purposes;
- (ii) That the information will be used only for the project described in the application;
- (iii) That the information will not be used as a basis for legal, administrative, or other actions that directly affect any person or institution identifiable from the data; and
- (iv) That the statements made in the application form are correct to the applicant's best knowledge and belief.

See 29 DCMR Chapter 2822.

REPORTING COMMUNICABLE DISEASES

| See 22-B DCMR § 201.1: | Communicable diseases that must be reported by telephone immediately to the Director of the DC Department of Health upon provisional diagnosis or the appearance of suspicious symptoms, and confirmed in writing within 24 hours. |
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| See 22-B DCMR § 201.2: | Communicable diseases that must be reported to the Director of DC |
| | Department of Health in writing within 24 hours after diagnosis or |
| | the appearance of suspicious symptoms. |
| See 22-B DCMR § 201.3: | Communicable diseases that must be reported to the Director of DC |
| | Department of Health in writing within 48 hours after diagnosis or |
| | the appearance of suspicious symptoms. |
| See 22-B DCMR § 201.11: | Nature and contents of written report on communicable diseases. |
| See 22-B DCMR § 215: | Monitoring and reporting the occurrence of cancer. |
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