Institutional Review Board DNA & Genetics

Introduction

Research proposals which include DNA or genetics as the focus of study are required to meet all expectations and guidelines related to research review, as well as Institutional Review Board (IRB) policy and procedure.

Rationale

The mandate of the Department of Children and Families is broad, reflecting families and children who require a complex array of services. Given this complexity, the DCF IRB must be particularly vigilant to human subject protections when considering any research endeavor involving clients, data or staff of DCF. DCF must balance access to clients, staff and data with respect for confidentiality and public accountability. The DCF IRB reviews all submitted proposals with specific attention to the human protection elements, consistent with the regulations of DCF of Health and Human Services, Office for Human Research Protections (OHRP). The standards set forth by the DCF IRB conform to OHRP Regulations, and often exceed the standards of these regulations.

The field of research which involves DNA or genetics is one which is evolving and promising. In 2008 Congress passed the Genetic Non-Discrimination Act which prohibits employers and insurance companies from discriminating against individuals based on the results of genetic testing. Nonetheless, the issues surrounding the security of genetic samples, information safeguarding, duty to warn, and confidentiality are examples of areas which ethicists, researchers and the courts continue to discuss and clarify. While there have been attempts to protect human subjects and genetic samples, there is no current certainty of protection through the federal government or the courts.

DCF is responsible to the children and families it serves, and to the people of the State of Connecticut. Any action taken by DCF or the DCF IRB must be such that vulnerable people are not made more vulnerable through their association with any research endeavor. Until such time as the government, on a federal level, has assured the protection of all human subjects involved with DNA or genetics research, and this protection has been assured through the judicial process, DCF will consider research proposals which include genetics as part of the research protocol only when the study is in the child's best interest to participate, the risks do not outweigh the benefits to the child, mechanisms are in place to address the issues outlined in this policy and all consents and assents can be secured.

Note: DCF encourages research which will enhance our understanding of children and their families. Research should contribute to the body of knowledge within a selected field and must reflect participation across all strata of society. The research subject cohort must therefore be comprised of DCF and non-DCF children and families unless the area of study is one which is unique to the children and families served by DCF. It is the responsibility of the primary investigator (researcher) to discuss and justify the selection of DCF children and families as part of the research protocol application.

Definitions

Direct Benefit is considered to be something of health-related, psychosocial or other value to an individual research subject. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

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Definitions (Continued)

Investigational Genetic Measure is any laboratory test, the meaning, validity or accuracy of which is being investigated in a research study, performed on human DNA, RNA, proteins, chromosomes or other biological molecules that is designed to identify in the individual the presence of a genetic variation linked to a predisposition to a trait or disease or to identify a variability in progression or severity of a diagnosed condition or a variability in response to treatment.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(h)(i)].

IRB Consideration

Upon receipt of a research proposal involving DNA or genetics, the IRB co-chairs will perform a preliminary review to determine:

- that the research proposal is complete, as required by DCF IRB policy;
- that the general regulatory requirements discussed in 45 CFR 46 are met;
- that the potential benefits, risks and discomforts of the research to children are clearly set forth;
- that the level of risk be not greater than minimal to the child and all those with a biological relationship to the subject;
- whether a direct benefit to the child will occur through participation and whether inclusion of the child is in the child's best interest;
- whether the justification for the inclusion of children involved with DCF as a specific focus in the research is clearly set forth;
- that the proposal outlines the circumstances of the children to be enrolled in the study, their health status, trauma history, age and ability to understand what is involved in the research;
- that adequate provisions have been made to obtain assent of the children and their counsel and that provisions have also been made for the informed consent of both parents and guardians;
- that the researcher has secured a federal Certificate of Confidentiality, which provides protection to all genetic samples and analysis from disclosure or subpoena;
- that investigators make explicit in the consent and assent form that participation is voluntary (the investigator must stress, verbally and in writing, that decisions surrounding participation or declining participation will not impact the child or parents' relationship with DCF or with any services provided).

Process

- All materials must be submitted as outlined in IRB policy.
- Consistent with the Office of Human Research Protection, approved research projects will be time-limited and not exceed a one-year approval period.
- Longitudinal research requires IRB application, review and approval prior to the expiration of the previous approval.

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Process (Continued)

- Children who have been freed for adoption through termination of parental rights will not be considered for inclusion in any study due to the issues related to "duty to warn" family members when there are issues of genetic significance and DCF's inability to locate families once discharged from DCF services.
- Where DCF is the custodian or guardian of a child, the child has been appointed an attorney through the Superior Court for Juvenile Matters. For the child to be considered in the research study, the child's attorney must agree to confer with the child regarding the assent process. If the attorney does not agree, or does not approve the child's participation, the child will not be included in the proposed research. The attorney may act as the child's advocate throughout the study process.
- Informed consent must be provided by both parents or guardians of the child, unless deceased or unknown. The consent will describe the potential risks, in clear and simple language, which must include the possible disclosure of familial genetic characteristics or may demonstrate a lack of genetic relationship where one has been assumed. The informed consent and assent are time limited; the IRB may require that re-consent be obtained by the primary investigator, for participants involved in longitudinal studies.
- In cases where DCF is the child's guardian and the parent(s) refuse consent, and it the position of the DCF Social Worker, the Medical Review Board, the child's treating physician and attorney that the child's lack of participation is not in the child's best interest, DCF may consent to the child's participation. The parent must be notified of this decision and be advised that he or she may seek a court order.
- In cases where DCF is guardian and pursuing termination of parent rights, with a potential adoptive family identified, the prospective adoptive family must be consulted and advised of the research and its potential risks and benefits. The adoptive family's opinions will be heavily weighted in the decision-making process, as will the opinions of the child's family of origin.
- The primary investigator will not identify any sample by using the child's name or any identifying information.
- The collection of any genetic material is to be utilized only for the research study that has been approved and when assent and consent have been appropriately secured. Materials will be safeguarded for confidentiality and include the immediate destruction of the materials, consistent with scientific standards and practice, following the analysis of the material. All analysis, and any related identifying information must be kept separate.
- Children under the age of ten, or children with cognitive, developmental or other impacts upon their functioning, will be excluded from research involving genetics unless their parent or guardian, Medical Review Board and IRB agree that the advantages of participation are particularly significant. The assent process must include, in addition to the child's attorney, someone who is sufficiently trained, experienced and skilled to explain the risks and benefits, answer questions and assess the child's ability to assent.