New York City Children's Services
Division of Policy and Planning
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Administration for Children's Services

John B. Mattingly
Commissioner

Belinda M. Conway
Executive Deputy Commissioner for Operations

To: Provider Agency Staff

From: John B. Mattingly

Date: March 21, 2011

Re: Clinical Trial Policy

Please find attached the finalized version of Children's Services' new policy regarding the participation of children in foster care in clinical trials. This policy describes processes for reviewing clinical studies, requirements for consent and enrollment, and the procedures for subsequent tracking and monitoring. It incorporates comments and suggestions we received from subject matter experts, as well as internal and external stakeholders. Additionally, this policy clarifies the responsibilities of foster care agencies and provides guidance to case planning and medical staff, so that every child in care who participates in a clinical trial does so safely and appropriately.

Under this policy, it is the foster care agency's responsibility to immediately bring any proposed clinical trial enrollments to the attention of the Clinical Programs and Services Unit of the Office of Child and Family Health (OCFH). Likewise, OCFH should also be made aware of any child participating in a clinical trial at the time when s/he enters foster care. OCFH will provide the agency with technical assistance in order to gather all the needed information and meet all the process requirements so that an informed decision in the best interests of the child can be reached.

For additional information on this policy please contact Beatrice Aladin at Beatrice.aladin@dfa.state.ny.us or (212) 676-6481. The case practice expectations and requirements articulated in the policy will become effective on March 31, 2011.

SUBJECT: Clinical Trial Policy - Review, Enrollment and Tracking Process

APPROVED: John B. Mattingly, Commissioner

DATE: March 21, 2011

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IMPLEMENTATION RESPONSIBILITY: All Children's Services and Provider Agency Staff

PURPOSE: Every child in foster care who participates in a clinical trial must do so safely and appropriately. This policy provides clearly defined guidelines describing the process for reviewing clinical studies, requirements for consent and enrollment, and the procedures for subsequent tracking and monitoring of such studies. It specifies the responsibilities of foster care agencies and provides guidance to case planning and medical staff, so that every child in foster care who participates in a clinical trial does so in compliance with these guidelines.

SCOPE: This policy applies to all ACS and provider agency staff that provides foster care services. It replaces the *HIV Clinical Trial Policy* issued with *Bulletin 98-2*, and applies to all clinical trial enrollments, including those designed to treat HIV/AIDS and other medical conditions. This policy only applies to clinical trials involving medical intervention such as medication, surgery, or any invasive procedure or medical intervention. Trials involving behavioral and/or observational research are not covered by this policy and are reviewed by ACS Research Review Committee. This Policy is effective March 31, 2011.

POLICY: The Administration for Children's Services is responsible for seeing to it that quality, individualized medical care is provided to all children in foster care.[1] Our responsibility in this regard requires that we carefully consider and assess a health care provider's recommendation to enroll a child in a clinical trial.[2]

Children's Services will only permit a child in foster care to enter a clinical trial after each of the following provisions has been met:

1. The Institutional Review Board of the medical institution sponsoring the clinical trial has approved the clinical trial, and in doing so has determined that it falls into one of the following categories under federal law:

    a. Research not involving greater than minimal risk.[3]
    b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.[4]

[1] This policy applies to all children in foster care, including children placed through an Article 10 proceeding, PINS or JD proceeding, or voluntary placement agreement.
[2] Clinical Trial: A clinical trial (also clinical research) is a research study involving human volunteers to answer specific health questions. From NIH <clinicaltrial.gov>. For further information, see Appendix A.
[3] 45 CFR 46.404.
[4] 45 CFR 46.405(a)-(c)

2. An independent medical review team convened by Children's Services concludes that enrollment in the clinical trial offers the best available medical care for the particular child, in that there is a significant potential treatment benefit not available outside of the clinical trial, and this anticipated benefit outweighs any risks associated with the treatment.

3. The ACS Commissioner approves the enrollment following a detailed review process, as described below.

4. Informed consent[5] and permission[6] for enrollment in a clinical trial is provided by the child's parent or legal guardian, unless 1) a family court judge authorizes the proposed enrollment, or 2) parental rights have been terminated by surrender or involuntary termination of parental rights, allowing the Commissioner to give consent/permission as the child's legal guardian.

5. The child assents to participate in the clinical trial, if the child has the capacity to assent.[7]

In every case, the medical institution conducting the clinical trial will be required to assign the child an Independent Advocate[8] as a condition of the child's enrollment. ACS will expedite its internal processes and advocate for a timely decision in all requests for a child's participation in a clinical trial.

Children's Services will not approve participation of children in foster care in Phase I or Phase I/II clinical trials.

To assist in implementation of this policy, Children's Services will convene an Advisory Committee, which will include experts in pediatric HIV/AIDS, pediatric oncology, medical ethics, medical social work, and other areas of practice as needed. This panel will meet at least annually, and will be given regular reports regarding the implementation of the policy. The panel will assist Children's Services in identifying appropriate experts to serve as Independent Physicians for purposes of this review process.

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[5] Informed consent: No human research may be conducted in this state in the absence of the voluntary informed consent subscribed to in writing by the human subject. If the human subject is a minor, such consent shall be subscribed to in writing by the minor's parent or legal guardian. If the human subject is otherwise legally unable to render consent, such consent shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject. No voluntary informed consent shall include any language through which the human subject waives, or appears to waive, any of his legal rights, including any release of any individual, institution or agency, or agents thereof, from liability for negligence. N.Y. Pub. Health Law Article § 2442.

[6] Federal regulations (45 CFR 46.402(c)) define the term "Permission" as "the agreement of parent(s) or guardian to the participation of their child or ward in research."

[7] Capacity to assent applies to children under 18 when someone else's consent is needed to allow the child to receive the procedure, medication, or clinical trial. The child's physician and/or mental health provider will advise CFH regarding the child's capacity to assent for the clinical trial enrollment. The child's age, stage of development and intellectual capacity will be considered in making this determination.

[8] Regarding advocates, Federal regulations (45 CFR 46.409(b)) state that "[o]ne individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role of advocate or member of the IRB) with the research, the investigator(s), or the guardian organization."

I Initiation of Medical Review

1. Whenever a parent, child (with capacity to assent), or physician proposes to enroll a child in foster care in a clinical trial, regardless of the nature of the clinical trial or the illness it is intended to treat, the foster care program director must promptly notify the ACS Office of Child and Family Health (OCFH) of the request. The foster care program director (or designee) must also inform the FCLS attorney of the proposal to enroll the child in a clinical trial and that a medical review will be conducted. The assigned FCLS attorney will provide an update to the child's attorney.

2. An OCFH nurse will be assigned to coordinate the medical review process, and will work closely with the case planning and medical staff involved in the child's care. The assigned nurse will be licensed to practice in New York State, and will have received training regarding the state (including NYS regulations regarding Informed Consent) and federal protections for children participating in research, as well as training regarding this policy.[9]

3. If parental rights have not been terminated or surrendered, but parent(s)/guardian(s) cannot be found, the case planner[10] must initiate and appropriately document reasonable efforts to locate a parent(s)/guardian(s). Where both parents' identities are known, reasonable efforts must be made to locate each parent and to engage both parents[11] in the process, especially if the parents live separately. One parent's consent is sufficient.

4. Reasonable efforts must include at least two personal visits to the parent(s)'/guardian(s)' last known address, one during and one after business hours. If those visits prove unsuccessful, within three business days of the second visit, the agency must send a letter by both regular and certified mail, which sets forth the need for the parent(s)/guardian(s) to give consent/permission to the clinical trial enrollment, to the parent(s)'/guardian(s)' last known address. The letter must be written in a language in which the parent/guardian is fluent. At least two telephone calls to the last known telephone number must also be made.

5. A member of the Family Permanency Services Shared Response Team must also conduct a search for the parent(s) in the New York City public assistance database. If the parent(s)'/guardian(s)' whereabouts remain unknown, the case planner must document her/his efforts to locate the parent(s)/guardian(s). Documentation must include all dates and methods for such efforts, properly

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[9] This training will include, but not be limited to, the National Institutes of Health program "Protecting Human Research Participants (PHRP)" offered at <http://phrp.nihtraining.com>, a free, web-based course presenting information about the rights and welfare of human participants in research. If this on-line training is no longer available, a suitable alternative will be identified. The assigned nurse will participate in updated training as frequently as is recommended by the training provider, in order to maintain a current training certificate.

[10] A case planner is an ACS or foster care agency caseworker who assesses the need for services and makes referrals to services that can allow parents to address the problems that led to placement. The case planner also schedules visits between the parents(s) and his/her child, and visits between siblings (if placed separately). The ACS or agency case planner supervises the foster home and is the person that plans with the parent(s) for the return of his/her child.

[11] In cases where a child was born to unmarried parents, only a consent father, as described in Domestic Relations Law (DRL) section 111(1) and applicable case law, can provide informed consent. If a child is born to a legal marriage or is adopted by two individuals (and rights have not been terminated or surrendered), then both parents (regardless of their sex) are able to give consent for their child's medical treatment.

signed and dated in the child's records and the progress notes in CONNECTIONS by the person conducting the efforts.

6. While reasonable efforts to locate the parent(s)/guardian(s) are being conducted, the medical review process may proceed, based upon the stated desire of the child (if s/he has capacity to assent) and the medical opinion of the treating physician. The clinical trial enrollment will not be permitted until a parent/guardian is found or reasonable efforts to locate the parent(s)/guardian(s) are completed (as described in this paragraph, above).

7. During initiation of the medical review process, the wishes of the parent(s)/guardian(s), foster parents[12] (if child is in family based care), and child with capacity to assent will be considered, along with the recommendation of the child's physician(s).

8. If the child is legally freed for adoption, the OCFH nurse will seek to identify and consult with a caring adult involved in the child's life, such as a long-term foster or pre-adoptive parent, a mentor, or a relative who visits the child frequently, regarding the child's needs and wishes.

9. Prior to such consultation, appropriate consent to release information regarding the child's health status and health care must be obtained, including the consent of the child, if she/he has capacity to consent, to the release of this otherwise confidential health information to the caring adult in the child's life. This caring adult will be consulted, but cannot give consent/permission for clinical trial participation.

10. Case management/planning staff must confirm that the principal investigator of the study (or a member of the research team), legal parent(s) or guardian (if available), foster parent(s) and child (if s/he has capacity to assent) have met or been provided a reasonable opportunity to meet to discuss the parameters, risks, and benefits associated with the proposed clinical trial enrollment.

11. This information must be provided in a language and manner that is accessible to the parent(s)/guardian(s), foster parent(s), and child, taking into account the parent(s)'/guardian(s)'/foster parent(s)' primary language, cultural background, and level of education. Though the foster parent(s) are included in this meeting, they are not authorized to give consent/permission for clinical trial participation. OCFH staff will assist in this process.

12. The Principal Investigator[13] will be asked to submit to OCFH a copy of the clinical trial protocol, IRB approval, and contact information for the IRB

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[12] A note regarding the role of foster and pre-adoptive parents: Foster and pre-adoptive parents cannot give consent or permission for enrollment in a clinical trial. However, they have a valuable perspective to contribute, as they provide a child's daily care, and are responsible for bringing children to medical appointments and administering medications. They are also in the best position to observe and report any side effects of medication. For all these reasons, it is important that the foster parent be consulted and informed both at the beginning and the completion of the review process.

[13] Principal Investigator: Qualified person who is designated by an applicant institution to direct a research project or program supported by the National Institutes of Health (NIH) and who usually writes the grant application. Principal investigators oversee scientific and technical aspects of a grant and the day-to-day management of the research. See nih.gov.

Chair. In addition, the OCFH nurse will contact the IRB chair, in order to inform her/him of Children's Services policy regarding enrollment of children in foster care in clinical trials, and to obtain a copy of the IRB minutes. The OCFH nurse will notify the IRB chair of the requirement that the child be appointed an independent advocate, and will request written confirmation of the medical institution's willingness to appoint such an advocate.

13. If a child in foster care has been enrolled in a clinical trial prior to placement, or prior to this review process, the case manager or foster care provider must initiate the review process by contacting OCFH as soon as s/he learns of the child's participation in a clinical trial. A medical review will be conducted, using the process and standards described in this policy. The child may continue to participate in the clinical trial during this review process, provided that the principal investigator furnishes documentation of appropriate, informed consent/permission for the enrollment, and of IRB approval by the institution conducting the trial.

14. Any concerns regarding the child's continued involvement in the clinical trial will be discussed with the child's parent(s)/guardian(s) and foster parent(s). If unresolved, the matter will be referred to the Family Court Legal Services (FCLS) for review to determine whether the case needs to be brought to Family Court.

15. If it is determined that the child should be removed from the clinical trial, the OCFH nurse will coordinate with the principal investigator, the child's primary care physician, and the agency's medical case management staff so that the child is transitioned out of the clinical trial in a safe and coordinated manner.

II Review of Institutional Review Board Minutes

1. An attorney from ACS' Office of the General Counsel (OGC) who is familiar with the federal and state regulations protecting human subjects of research will review the Institutional Review Board (IRB) approval and IRB minutes pertaining to the clinical trial under consideration.

2. The attorney will determine whether the Institutional Review Board placed the research in category 46.404 (Research involving no greater than minimal risk) or 46.405 (Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects).

3. The attorney will also verify that the IRB reviewed and approved the procedures for consent and assent proposed by the researchers, and will review any specific directives given to the researchers regarding the involvement of children in foster care in the clinical trial.

4. The OGC attorney will then inform the Director for Clinical Programs and Services (or the designated nurse) in OCFH of the results of the review.

III Medical Review Process

1. OCFH then convenes a medical review team. Participating in the medical review team is:
   - An independent physician who is a specialist in the area of treatment that is being considered for the child. The independent physician will be selected based on her/his range of expertise in the appropriate field of practice, and ability to provide an independent judgment. The independent physician will:
     - review the clinical trial protocol[14];
     - consult with the principal investigator of the clinical trial; and
     - review the child's medical history.

     If needed, the independent physician and/or the OCFH nurse will consult with additional medical specialists familiar with the proposed treatment and/or the child's condition.

     The independent physician cannot be affiliated with the medical institution seeking to enroll the child in the clinical trial. He/she will also be asked to complete an ACS self-disclosure form listing direct and indirect financial ties to pharmaceutical companies manufacturing the medications, treatments or devices being evaluated in the clinical trial that may influence or be perceived to influence his/her recommendation for clinical trial participation.

     If a relationship to an involved pharmaceutical company is disclosed or uncovered, this will be considered a potential conflict of interest and the physician will be replaced by another independent physician who will undergo the same vetting process;

   - The OCFH nurse who has reviewed the child's medical history and consulted with the case planner, case manager (if applicable), and legal parent/guardian or advocate;

   - The foster care program staff member who has been working with the child most closely and is aware of psychosocial issues that may affect the child's adherence to the medical regimen;

   - A member of the medical case management[15] staff from the foster care program; and

   - The child's primary care physician. If the child's primary care provider is also the principal investigator for the clinical trial, a generalist

[14] A clinical trial protocol is a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

[15] Medical case manager: agency staff member responsible for tracking medical appointments and needs of any child in foster care. Tracking responsibilities are based on state regulations and OCFS and ACS policies.

pediatrician, as well as the child's primary care physician will be included in the medical review team.

2. The review may be conducted in person or via conference call, if necessary, to expedite the review process. The independent physician presents a summary of the clinical trial protocol and the OCFH nurse presents a summary of the child's medical history and the wishes of the parent/guardian or advocate and child with capacity to assent as well as the foster parent(s) support or lack of support for the child's participation.

3. The medical review team then determines whether participation in the clinical trial is appropriate treatment for the child, given his/her specific medical history, and meets Children Services' standard of offering a significant potential treatment benefit to the child not available outside the clinical trial, while posing a concomitant minimal risk of harm to the health or safety of the child.

4. Factors to consider in making this determination include:
    a. the child's current medical status and medical history;
    b. the child's prognosis with and without the recommended medical treatment;
    c. the probability of treatment adherence by the child;
    d. the outcomes of prior research and clinical experience with the recommended treatment;
    e. the availability of alternative treatments; and
    f. the phase of the trial.

5. Where the clinical trial offers a significant potential treatment benefit, but includes random assignment to a control group as part of the study design, the medical review team must determine whether children in the control group will receive care that meets or exceeds the standard of care offered outside the study, and whether there are additional benefits to participation in the clinical trial, even for those children assigned to the control group.

6. If the Medical Review Team recommends enrollment, they will also provide specific recommendations regarding the type and frequency of monitoring that would be appropriate for the duration of the child's enrollment in the clinical trial. These recommendations may include a schedule for reconvening the Medical Review Team to evaluate the child's progress following enrollment in the clinical trial.

7. If parental rights have not been terminated or surrendered and the medical review team concludes that the enrollment is **not** recommended, the case planner and/or case manager will meet or provide a reasonable opportunity to meet with the parent(s)/guardian(s), and foster parent(s) to explain the team's decision and the reason for the decision, unless reasonable efforts to locate the parents have been unsuccessful and the parents cannot be found.

8. The child's attorney will also be invited to this meeting. If it is known that the child's attorney will be joining the meeting, the FCLS attorney must be informed about the meeting as well.

9. If the child has capacity to assent, s/he is included in this meeting. If the parent(s)/guardian(s) agree with the Medical Review Team's decision and the child with capacity to assent agrees with the determination the OCFH nurse is notified.

10. If the parent cannot be found, or declines to participate, a meeting will be held with the foster child with capacity to assent, and the foster or pre-adoptive parent to discuss the determination of the medical review team.

11. Once it is determined that the parent(s)/guardian(s), child with capacity to assent, and child's attorney agree with the Medical Review Team's decision not to recommend the enrollment, the OCFH nurse notifies all parties of the final decision.

IV Legal Review Process

1. If the medical review team recommends enrollment, the parent(s) [whose rights have not been terminated]/guardian(s) agree, and the child with capacity to assent concurs, the issue is referred by OCFH to the General Counsel for review to determine if the clinical trial enrollment meets legal standards in the area of parental consent/permission and assent of the child (where the child has capacity to assent).

2. An attorney from the Office of the General Counsel (OGC) will review whether reasonable efforts have been adequately made based on documents submitted by OCFH. If the consent-related documentation is completed before the medical review, OCFH will send the documents to the OGC attorney for review at any time prior to or during the medical review.

3. If the parent(s)/guardian(s) cannot be located after reasonable efforts to locate them have been made, or if the parent(s)/guardian(s) are unwilling to offer their opinion, OCFH consult with FCLS to determine the need to bring the matter to Family Court for resolution, following the Commissioner's review of the Medical Review Committee's recommendation.

4. If there is a difference of opinion between the parent(s)/guardian(s) and/or child with capacity to assent and the medical review team, every effort should be made to resolve the issue by working with the parent(s)/guardian(s) and/or child to confirm that they understand the risks and benefits of the treatment, and the alternatives available to the child, providing a second opinion if requested, and exploring reasonable, medically sound alternatives.

5. Notwithstanding these efforts, if there is disagreement between Children's Services and the parent(s)/guardian(s), child, or law guardian, all parties will be free to pursue the matter in court. OCFH will consult with FCLS to determine the need to bring the matter to Family Court for resolution, following the Commissioner's review of the Medical Review Committee's recommendations, if no other party already has done so.

6. If the clinical trial enrollment does not meet legal standards, OCFH notifies the case planner, case manager, attorney for the child, and principal investigator. The case planner then notifies the parent(s)/guardian(s), foster parent(s) and, if applicable, the child of the decision and the process ends.

7. If there is disagreement between Children's Services and parent(s)/guardian(s), child, or attorney for the child, all parties will be free to pursue the matter in court. OCFH will consult with FCLS to determine the need to bring the matter to Family Court for resolution, if no other party already has done so.

V Commissioner's Determination

1. If the clinical trial enrollment is recommended by the medical review team, and meets legal standards, the case is forwarded to the Commissioner, who reviews the recommendations of the medical review team and the General Counsel, and makes the final decision about whether the child should be allowed to participate in the clinical trial.

2. If the Commissioner concurs with the recommendations and parental rights have been terminated or surrendered, the Commissioner signs the informed consent/permission as legal guardian for the child. If the Commissioner concurs with the recommendations and parental rights have *not* been terminated or surrendered, the Commissioner sends a letter to the principal investigator, case manager, and case planner informing them of his/her conclusion.

3. The case planner then informs the parent(s)/guardian(s), foster parent(s), and child (if appropriate) of the Commissioner's decision. The parent(s)/guardian(s) then sign the consent, and the child, if capable, assents to the clinical trial.

4. If the parent(s)/legal guardian(s) objects or cannot be located, OCFH will consult with FCLS to determine the need to bring the matter to Family Court for resolution, and the Commissioner will sign the informed consent/permission if the court authorizes the Commissioner to consent to such enrollment.

5. If the Commissioner concludes that enrollment in a clinical trial is *not* in the child's best interest regardless of whether parental rights have been terminated/surrendered or not, s/he sends a letter to the principal investigator, case manager, and case planner informing them of his/her decision.

6. If there is disagreement between Children's Services and the parent(s)/guardian(s), child, or attorney for the child all parties will be free to pursue the matter in court. OCFH will consult with FCLS to determine the need to bring the matter to Family Court for resolution, if no other party already has done so.

VI Clinical Trial Enrollment and Tracking

1. If a child in foster care enrolls in a clinical trial, the principal investigator or a member of his/her medical research team meets with the parent(s)/guardian(s), foster parent(s), and, if applicable, with the child who has capacity to assent to review the parameters of the clinical trial, including anticipated benefits, potential risks and treatment regimen, as described in the consent form.

2. This information must be provided in a language and manner that is accessible to the parent(s)/guardian(s), foster parent(s) and child, taking into account the parent(s)'/guardian(s)' and foster parent(s) primary language, cultural background, and level of education. The parent(s')/guardian(s)' consent/permission and the child's assent are indicated by their signing of the form.

3. Where practicable, the review of the clinical trial protocol with the parent(s)/guardian(s) and foster parent(s) should take place in one meeting, although the foster parent(s) cannot give consent/permission for the enrollment.

4. The principal investigator gives a copy of the signed consent to the parent(s)/guardian(s), if applicable, and foster parent(s), and sends copies of the consent form to OCFH and to the case planner.

5. ACS will provide the principal investigator with a Letter of Agreement (LOA) outlining the standards pertaining to wards of the state participating in clinical trials. This LOA must be signed and returned to ACS prior to the child commencing participation in the clinical trial.

6. OCFH will maintain a file regarding the clinical trial enrollment, including:
    a. a description of the clinical trial;
    b. confirmation of IRB approval from the medical institution conducting the trial;
    c. the IRB minutes;
    d. a copy of the signed consent form;
    e. the name, affiliation, and contact information for the Independent Advocate assigned by the institution conducting the research;
    f. documentation of reasonable efforts to locate the parent(s)/guardian(s), if applicable;
    g. a summary of the medical review team's discussion and conclusions, and a list of review team participants;
    h. a curriculum vitae and financial self-disclosure form completed by the independent physician; and
    i. copies of all correspondence related to the clinical trial review process.

7. Both a child folder and a clinical trial folder will be maintained. The child folder will contain any and all information concerning the child's enrollment and progress in a clinical trial. Also included will be all preliminary

information such as measures to reach the parents(s)/guardian(s) and deliberations regarding enrollment. The clinical trial folder will be filed under the number and name of the clinical trial; no information about a specific child will be included in that folder.

8. These records will be maintained in addition to the child's electronic case record, the child's medical file that is maintained by the case planning contract agency, as well as any files maintained by the institution conducting the clinical trial. Case-specific files regarding clinical trial enrollment of a foster child will be maintained by Children's Services for at least thirty years following the child's discharge from foster care and records of foster children later adopted will be sealed and permanently retained.[16]

9. The case planner and/or medical case management staff are expected to maintain regular communication with the research team, the child's Independent Advocate and the child's primary care physician, and to continually monitor the child's health care and well being. The frequency of such communication will be determined by the recommendations of the Independent Medical Review Team, but will be at least quarterly.

10. If recommended by the Medical Review Team, the Team may be convened as a monitoring body at specific points in time during the child's participation in a clinical trial, or may be reconvened in response to specific events, such as an adverse reaction, Data Safety and Monitoring Board finding, or other concern. If the Medical Review Team is reconvened after the child's enrollment, the child's Independent Advocate will be invited to the meeting.

11. Any concerns that arise regarding the child's continued participation in the clinical trial including concerns raised by the child's parent(s)/guardian(s), foster parent(s), or case planner must be immediately brought to the attention of both OCFH and the principal investigator of the clinical trial.

12. If the parent/guardian or child (who has the capacity to assent) after enrollment in a clinical trial communicates to a foster care agency employee or foster parent a desire to withdraw consent/assent, the foster care agency must immediately notify both the OCFH and the research team for the clinical trial, and should assist the parent/child in arranging a meeting with the research team to communicate their wishes. OCFH will contact the child's assigned FCLS attorney to verify the child's legal status.

13. The medical review team will be reconvened to review the situation, and to develop/review a plan for the child's transition to treatment outside of the clinical trial. If appropriate, the research team need not wait for this meeting to withdraw the child from the clinical trial, provided the legal right of the parent/guardian to withdraw consent has been verified.

14. If, notwithstanding these efforts, there is disagreement between Children's Services and the parent(s)/guardian(s), child, or child's attorney, all parties will be free to pursue the matter in court. OCFH will consult with FCLS to

[16] 18 NYCRR 428.10(a)(5)(i) and (iv).

determine the need to bring the matter to Family Court for resolution if no other party has already done so.

15. Federal standards for informed consent provide that clinical trial participants can withdraw consent at any time during their participation in a clinical trial. When this occurs for a child in foster care, careful planning and coordination must occur, to verify that the parent still has the legal right to consent or withdraw consent, and to support the child's timely access to appropriate treatment outside of the clinical trial. In addition, there should be an assessment of the circumstances around the withdrawal of consent, to verify that the child welfare staff and foster parent (if applicable) are effectively coordinating and communicating with the child's medical team, and that the parent is being appropriately included in medical decisions.

16. The principal investigator must immediately inform the case planner and OCFH of any complications and/or adverse reactions the child experiences while participating in the clinical trial, and of any findings by the Data Safety and Monitoring Board (if applicable), or changes to the protocol, so that continued participation can be assessed. Also, the principal investigator must alert the case planner and OCFH of the date the clinical trial is completed, and date and reason child leaves the clinical trial if termination precedes the expiration date anticipated in the original agreement, as stipulated in the letter of approval sent by the Commissioner.

17. OCFH will track all children participating in clinical trials and produce quarterly reports for the Commissioner's review. ACS will submit summaries on a quarterly basis to the New York State Office of Children and Family Services and the Advisory Committee. Summaries will consist of the child's progress in the trial and any problems encountered, but will not include individual identifying information.

VII Other Issues

1. Children placed into foster care under a voluntary placement, PINS petition, or JD petition, who are not freed for adoption, must have parental consent/permission for all non-routine, non-emergency medical treatment, including enrollment in a clinical trial. This policy applies to children who are placed in foster care voluntarily, through a PINS petition, or through a JD petition, who are not freed for adoption, and Commissioner's approval of the clinical trial enrollment is still required.

2. ACS does not approve enrollment in research protocols that have, as their sole purpose, increased general knowledge, and do not offer significant potential treatment to the child enrolled. If participation in such a study involves no more than minimal risk to the child, parent(s)/guardian(s) whose parental rights have not been terminated or surrendered may enroll their child in the study at their own discretion.

3. Although the ACS Research Review Committee Reviews such research proposals, the case planner/case manager must inform OCFH of any such enrollments as soon as s/he is made aware of the enrollment or as soon as plans for enrollment are discussed (whichever comes first), and provide a copy of the

signed consent forms to OCFH. Any concerns regarding the child's continued involvement in the research protocol will be discussed with the child's parent(s)/guardian(s), and, if unresolved, will be referred to FCLS for review.

4. ACS will not approve enrollment in any clinical trial that uses prizes or monetary incentives to entice children/parent(s)/guardian(s) to enroll. Reimbursement for expenses such as transportation to the trial site, care for the other children, and meals for the child and foster parent are acceptable.

For additional information on this policy, please contact Beatrice Aladin at Beatrice.aladin@dfa.state.ny.us or (212) 676-6481.

APPENDIX A

Glossary of Relevant Clinical Trials Terms
Source: ClinicalTrials.gov (http://clinicaltrials.gov/ct2/info/glossary)
Maintained by the U.S. National Institutes of Health

ADVERSE REACTION: (Adverse Event.) An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time (See **Side Effects**).

CLINICAL: Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

CLINICAL INVESTIGATOR: A medical researcher in charge of carrying out a clinical trial's protocol.

CLINICAL TRIAL: A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed. (See **Phase I, II, III,** and **IV Trials**).

CONTROL GROUP: The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo (See **Placebo** and **Standard Treatment**).

CONTROLLED TRIALS: Control is a standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.

DATA SAFETY AND MONITORING BOARD (DSMB): An independent committee, composed of community representatives and clinical research experts that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

ENROLLING: The act of signing up participants into a study. Generally this process involves evaluating a participant with respect to the eligibility criteria of the study and going through the informed consent process.

INSTITUTIONAL REVIEW BOARD (IRB): 1. A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin. 2. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants.

IRB: See **Institutional Review Board.**

PHASE I TRIALS: Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

PHASE II TRIALS: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

PHASE III TRIALS: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide and adequate basis for physician labeling.

PHASE IV TRIALS: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

PROTOCOL: A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

RISK-BENEFIT RATIO: The risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated.

SIDE EFFECTS: Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects (See **Adverse Reaction**).

STANDARD TREATMENT: A treatment currently in wide use and approved by the FDA, considered to be effective in the treatment of a specific disease or condition.

STANDARDS OF CARE: Treatment regimen or medical management based on state of the art participant care.