Commissioner's Institutional Review Board (IRB)

Pertinent Information:

- *All studies involving human subjects or records pertaining to them should be assumed to require IRB review until determined otherwise. If there is any question if IRB review is required, the question should be submitted in writing to the IRB Chairperson.*
- DDS policy complies with federal regulations regarding the protection of human subjects where biomedical or behavioral research is conducted
- *Striving for balance: Protect individuals served by DDS versus permit research*

Areas of Oversight:

1) Research proposals
2) Investigational drugs

Cohorts:

- Research involving anyone in the following three DDS clusters:
  - Older than age three (otherwise OEC IRB)
  - Intellectual disability or Prader-Willi syndrome
  - Autism spectrum disorder (DDS IRB currently reviews for Autism Division of the Department of Social Services).

IRB Membership:

- At least five standing members
- Membership appointments are usually two years
- Participation in meetings may occur at intervals sufficient for research reviews and ongoing business of the committee to be completed. There are generally four meetings annually.
- Decisions based on majority vote
- Need quorum at meetings (minimum of half plus one)
- Members are selected based on diverse backgrounds, experience, and expertise:
  - Agency and non-agency
  - Scientist and non-scientist
  - Both genders
  - Experience with I/DD
- Invited guests may come to meetings as content experts
- Principal investigators only attend meetings at the request of the IRB Chair to respond to questions

Meetings:

- Not open to the public
- No expectation of transparency since research involves professional work products ("trade secrets")
- *Process is private, but the product is public*

- Activities recorded through detailed minutes

Jurisdiction:

- DDS IRB has jurisdiction over approval of activities categorized as research involving human participants.
- The DDS IRB may accept the actions taken by a collaborating institution that also operates under federal status.
- *Policy states that another DDS body may not approve research proposals that have been disapproved by the Commissioner's IRB.*

IRB Chair:

- Meets with Commissioner regarding member appointments and renewals, as well as research and investigation drug approvals or disapprovals.
- Recruits qualified member successors as needed
- Reviews pending proposals
- Prepares resource materials
- Registers IRB with federal Department of Health and Human Services

Application:

- IRB procedure applies to all researchers, including DDS employees or agents performing designated activities or exercising delegated authority. This includes contractors or their staff and other non-DDS researchers (e.g., faculty, graduate students, and undergraduate students)

Review Levels:

- Initial review:
  - Proposals inquire about risk-to-benefit analysis, informed consent, selection and recruitment of participants, privacy and confidentiality, and research design.
  - *Research cannot commence until after the DDS IRB has confirmed that human participants are sufficiently protected by the protocol.*

- Expedited reviews require full application materials to be submitted. *The IRB chair will not comment on inquiries about the possibility of an expedited review before receiving and reviewing an application.*

- Continued reviews:
  - Done at least once annually to ensure safeguards or more frequently in cases of increased risk.
  - Sanctions may be imposed in various forms, such as contingent, suspended, or terminated approval.
  - It is expected that adverse events will be reported as soon as they occur.

General Criteria for Approval includes:

- Risks to participants are minimized
- Risks are reasonable in relation to benefits

- Selection is equitable
- Documented informed consent is sought from participant or legal representative
- Data collection and monitoring
- Protection of confidentiality
- Safeguards against coercion and undue influence

Possible Review Outcomes:

- Disapprove
- Approved "as is"
- Approved if revisions are made
- Approved under conditions

Investigational Drugs:

- Relates to (1) Request for administration of a non-FDA approved medication; or (2) the off-label use of an FDA-approved medication.
- *Screening with the DDS Regional Health Service Director is recommended prior to contacting the IRB.*
- Reviews: Full IRB, IRB subcommittee, IRB member, or IRB Chair
- IRB makes recommendation to the Commissioner to approve or disapprove. An official letter is generated from the Commissioner's Office.
- Planning and Support/Treatment Team, often the delegating licensed nurse, submits information (see "Request for Approval to Use an Investigational Drug" form), which includes the following:
  - Research articles on the medication. Most often information about the efficacy of clinical trials on the condition are submitted.
  - Copies of the individual's medical records relevant to the issue
  - Current medication orders if applicable
  - Description of clinical symptoms
  - Proposed route of medication administration
  - Determination of individuals who will administer medication
  - Documentation in letter format that the medical provider asserts medical necessity (i.e., to achieve standard of care)
  - Implications of use, potential adverse effects, and risks of proposed medications
  - Method of medical monitoring and clinical oversight (approved by regional DDS Health Service Director or their designee)
  - Any supporting data or other information
- Guardian's powers (plenary or limited) regarding experimental medication is found in CGS 45a-677 (e) (6). Guardians must have approval from IRB.
- The Commissioner may issue a waiver for non-licensed DDS medication-administration certified staff to give non-FDA medications (by administering a non-FDA medication without a Commissioner's waiver these staff would be out of compliance with their certification).

Retention of Records:

- Maintained a minimum of three years