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## **Guidance: Enrolling Maryland Foster Care Children in Research**

Investigators who seek to enroll children who are clients of the Maryland State Department of Human Resources (DHR), Social Services Administration (SSA), in research must comply with the DHR Circular Letter SSA #08-25, dated April 17, 2008. The letter specifies the procedure for submitting a research application for consideration by the Research Review Board (RRB).

Only minimal risk studies; or studies that pose more than minimal risk but offer the prospect of direct personal benefit to the participant will be considered for approval. (45 CFR 46.404 and 45 CFR 46.405 studies) Investigators should complete the "Department of Human Resources Social Services Administration Child Welfare and Policy: Inclusion of Foster Children in Human Subjects Research or Research-Related Activities" form and submit it to: Ms. Amaza (Scottie) Reid, Assistant Attorney General in the DHR, Office of the Secretary, Attorney General's Office of the State of Maryland, at AReid2@dhr.state.md.us (use asreid54@aol.com if your email bounces back.)

## The SSA Review Process:

- The RRB review process for a project classified as 45 CFR 46.405 will take approximately 3 weeks to complete. The RRB review process for projects classified as 45 CFR 46.404 may take 3 – 6 weeks to complete. The RRB will notify the Director of the SSA of the review outcome. The Director makes the final decision on whether projects for which RRB approval is granted may include DSS clients.
- The Director will send written notification of the RRB outcome and SSA decision to the PI and the JHSPH IRB.
- In cases where the Director of the SSA agrees that DSS clients may be enrolled:
  - a A signed Memorandum Of Understanding will be executed by the PI, JHSPH, and SSA
  - b The Director will notify the duly authorized local department of social services agent who may sign the consent form for an individual client. For Baltimore City the authorized agent is Mr. Jim Becker; for other jurisdictions in Maryland, the authorized agent will need to be identified. When the duly authorized local department of social services agent signs a consent document to allow a DSS client to enroll in a human subjects research project, he/she will monitor the progress of the child during study participation. At the time a continuing review application is sent to the IRB, the IRB will forward a copy to the RRB to allow the DSS to fulfill its oversight responsibilities.