IRBMED
UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

Serving as an Advocate for a Ward of the State Eligible for Participation in a Research Project

You have been asked to serve as an advocate for this child because federal law requires this when a *Ward of the State* is asked to participate in research where the risk level is more than minimal and the study either does not offer the subject a prospect of direct benefit or the study has blinded arms in which at least one arm of the study does not offer a prospect of direct benefit and the risk level if more than minimal.

Regulations require that the advocate not be associated in any way with the research, the investigator(s), or the guardian organization (except in the role of advocate or member of the Institutional Review Board (IRB)). You should also not serve as the advocate if you have a financial interest (such as stock ownership or a consultant relationship) in any company associated with the research. You cannot have a formal relationship with any of the investigators outside of work interactions, such as marriage or familial relationships. If such an association was overlooked in your assignment as an advocate, please inform the study team immediately so that another person can be assigned as advocate.

An advocate represents the individual child subject's interests throughout the child's participation in the research, not just at the time of entry into the study. An advocate must be an individual who has the background and experience to act in, and agrees to act in, the *best interests* of the child throughout the duration of the child's participation in the research.

How are you to act in the ward's 'best interest' when the research study may not offer a potential of direct benefit to the ward? The Department of Health and Human Services' (DHHS) Office of Human Research Protections (OHRP) offers this guidance:

1. Assure the child wants to participate, if the child is capable of providing such assurance.
2. To the extent possible, assure the child understands what will be required of him or her during the research.
3. If the IRB has required assent, accompany the child during the assenting process.
4. If the study includes multiple arms and is blinded (meaning subjects are randomized to different interventions and/or placebo) consider, and assist the child in considering, if the potential benefit of being randomized to an arm with benefit is worth the risks entailed in being randomized to the arm without benefit.
5. Evaluate the ongoing impact of the research study on the child. This can be done by phone or email, or by seeing the child during a study visit.

- This added protection is intended to ensure that the ward, who is particularly vulnerable, is not exploited, coerced, or subjected to undue influence or harm in the course of the research.

In addition, IRMBED asks that advocates do the following:

- Review the informed consent/parental permission form and any other documents provided to the guardian or ward for the study.
- Discuss your questions and concerns with the study team.
- Accompany the guardian during the permission discussion with the study team
  - If agreeing to the child's participation, sign the consent/permission document where room permits (the guardian will sign in the standard place for parent or guardian signature).
  - Complete section II of the *Ward of State–Advocate Checklist* whether agreeing or disagreeing.
- Contact the IRBMED if you have questions or concerns—irbmed@umich.edu or 763-4768. Weekends or after hours UMHS paging can contact an IRB chair to assist you.

Posted 2/29/08