



MAY 27 2010

TO: Michael M. Gottesman, M.D., DDIR
John I. Gallin, M.D., Director, Clinical Center
Daniel L. Kastner, M.D. PhD, DDICR
Holli Beckerman-Jaffe, J.D., Senior Policy Officer, NEO

FROM: Deputy Director, NIH
NIH Deputy Ethics Counselor

SUBJECT: Expedited Review of Select Clinical Protocols

The NIH Ethics Community Protocol Working Group presented a proposal to model conflict of interest review of select clinical protocols on the Expedited Review process used by the Institutional Review Board.

For studies where there is no financial or commercial interest, such as for screening, training and some types of natural history research, the IC Deputy Ethics Counselor (DEC) will now review and sign the Personal Financial Holding (PFH) clearance with nominal review of individual financial interests of the PI and AIs listed on the PFH.

The DEC will make the determination for all appropriate studies with close scrutiny of Natural History protocols, to ensure they meet the appropriate criteria. Once a protocol has received Expedited Review status, the PI will not be required to submit further PFH forms for review unless there is a substantive change of status. Additional details for the IC DEC's will be forthcoming.

Raynard S. Kington, M.D., PhD.

DECISION

The DEC of each NIH IC can review and approve clinical protocols using an Expedited Review process for conflict of interest.

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|--------|----------------------------------------------|--------------------------------------|---------------|--------------------|
| DDIR: | Approved <input checked="" type="checkbox"/> | Disapproved <input type="checkbox"/> | Date 5/28/10 | M. Gottesman |
| CC: | Approved <input checked="" type="checkbox"/> | Disapproved <input type="checkbox"/> | Date 6/1/10 | J. Gallin |
| DDICR: | Approved <input checked="" type="checkbox"/> | Disapproved <input type="checkbox"/> | Date 6/3/10 | D. Kastner |
| NEO: | Approved <input checked="" type="checkbox"/> | Disapproved <input type="checkbox"/> | Date 05/28/10 | H. Beckerman-Jaffe |