



DATE: March 2, 2009

TO: Members and Staff of the Case Comprehensive Cancer Center

FROM: Mariesa Malinowski, Administrative Director, Case Cancer IRB

RE: Institutional Approval Process

The Offices of the Protocol Review and Monitoring Committee (PRMC) and the Case Western Reserve Cancer Institutional Review Board (Case Cancer IRB) have modified the institutional approval process to allow for simultaneous submission for most multicenter industry initiated cancer related research. This will allow for concurrent review of PRMC and Cancer IRB New Review applications.

The following types of cancer related research involving human subjects now qualify for the simultaneous and concurrent PRMC and Cancer IRB review process:

- NCI Cooperative group trials
- Compassionate Use Research
- Multicenter Industry Initiated Research

The following types of cancer related research involving human subjects will continue to require sequential submission to the PRMC and then to the Case Cancer IRB:

- Single site Industry Initiated Research
- Investigator Initiated Research
- Research in a consortium setting
- Bio-behavioral protocols

This change has been made in hopes to remove redundant steps in administrative processes that have previously caused delays in clinical trial activation. We want to thank you for your continued commitment in making a more efficient clinical trial review process for all participants of the Case Comprehensive Cancer Center.

Should you have any questions please contact me directly: Mariesa Malinowski at (216) 368-3771 or via e-mail at Mariesa.Malinowski@case.edu.

Sincerely,

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Administrative Director
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