From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, December 10, 2002 2:00 PM
To: [purged]
Subject: RE: Capacity to Consent

Dear [purged], I apologize for the delay in responding to your question (below). I encourage you to read, if you have not already done so, the National Bioethics Advisory Commission's report on "Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity", dated December 1998. It is available on the Internet at: http://www.georgetown.edu/research/nrcbl/nbac/pubs.html In addition, you may want to contact Dr. David Shore, who is Associate Director of Clinical Research at the National Institute of Mental Health, National Institutes of Health. His e-mail address is: ds125k@NIH.gov. I believe that between these two resources you will find the information you need. I hope this is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program

-----Original Message-----
From: [purged]
Sent: Wednesday, October 30, 2002 5:00 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Capacity to Consent

Dear Sir/Madam:
I am a certified clinical research coordinator working in a psychiatric hospital. While the issue of capacity to consent for psychotic patients is not new, we have recently instituted a process that seems to cross over the line and hamper the potential subject's right to participate. Can you give me some guidelines for how to assess capacity to consent for patients who have not been deemed legally incompetent?