



Office for Human Research Protections
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Jonathan J. Oviatt, J.D.
Chief Legal Officer
Mayo Clinic
Siebens 12
200 First Street SW
Rochester, MN 55905

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) - 5001

Dear Mr. Oviatt:

As you know, the Office for Human Research Protections (OHRP) conducted an on-site evaluation of human subject protection procedures at the Mayo Clinic (Mayo) from June 28, 2011 – June 30, 2011. The evaluation, conducted by three OHRP staff with the assistance of three consultants, included meetings with you, senior institutional officials, institutional review board (IRB) Chairs, IRB members, the administrative staff of the IRB and Department of Health and Human Services (HHS)-supported principal investigators who submit protocols to one or more of the Mayo IRBs. The evaluation also involved attending an IRB meeting. Lastly, the evaluation involved a review of IRB policies and procedures, IRB files for approximately 30 open protocols, the review of approximately 20 study amendments and the minutes of a number of IRB meetings held from March 2011.

During the OHRP site visit, the IRB chairs, members, and administrative staff displayed an enthusiastic and sincere concern for the protection of human subjects. In addition, we noted that investigators demonstrated a culture of respect for the IRB process. Moreover, as we indicated during the exit interview with you and others, we have observed that over the last few years there have been significant improvements in the Mayo human subjects protection program. We applaud Mayo for these improvements.

Please note that we did find a relatively minor procedural problem that should be rectified. Based on the interviews conducted during the on-site evaluation, information reviewed during the evaluation, and information included in a Mayo July 8, 2011 follow-up information letter, we note that Mayo does not have a written IRB procedure that adequately describes the procedures the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4)(ii).

As we indicated during our June 30, 2011 close out meeting with you and other Mayo officials, we could not locate a document outlining the above-referenced procedure. While we acknowledged that

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there was a verification statement in the Mayo Continuing Review Procedure, we noted that this was simply a statement. We explained that this document did not include any details regarding (a) the criteria used by the Mayo IRB for identifying which protocols need such verification; and (b) how the verification process would occur. Lastly, we explained that given the placement of the verification statement within the Continuing Review Procedure, it appeared to us that the Mayo IRB only considers utilizing a verification process at the time of continuing review.

We acknowledge that following our site visit Mayo revised its Continuing Review Procedure to include the criteria the Mayo IRB uses to determine which protocols require verification from sources other than investigator that no changes have occurred since last review. (We also acknowledge that Mayo IRB members use both the IRB Reviewer Checklist and the IRB Committee Member Worksheet – Continuing Review as guides for determine whether verification from other sources (sources other than the investigator) is needed.) We note that the revised Continuing Review Procedure does not address how the verification process will occur. Moreover, the revised procedure limits the timing of when a verification process can occur. Given these two outstanding issues, we recommend that Mayo revise its Verification Process Procedure or Continuing Review Procedure to adequately describe the procedures the Mayo IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4)(ii). We recommend that either of these revised procedures include: (a) the criteria the Mayo IRB will use to determine which protocols require verification from sources other than the investigator that no changes have occurred since last review; (b) the procedures for conducting the verification process, e.g., who will conduct the process, how will it be conducted, and how will verification process findings be reported; (c) a list of actions to be taken if the verification process reveals that the investigator has implemented changes to his/her research since last IRB review; and (d) clarification that the verification process can be initiated at any time, i.e., not just at the time of continuing review.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Bart Clarke, IRB Chair, Mayo Foundation IRB #1 - IRB - C
Dr. Joseph Lobl, IRB Chair, Mayo Foundation IRB #2 - Blue Friday
Dr. Rita Basu, IRB Chair, Mayo Foundation IRB #3 - Orange Thursday
Dr. R. Scott Wright, IRB Chair, Mayo Foundation IRB #6 - Wednesday
Mr. Gary Cseko, Mayo Clinic, Human Protections Administrator (HPA)
Dr. Kristina Borrer, OHRP