Cases for 2006

Case 1 – Sharing Unpublished Data

Dr. Young is attending a conference in England where he meets Dr. Zenith. One night after a long session, Dr. Young and Dr. Zenith are socializing in a pub. After a few beers, Dr. Young tells Dr. Zenith what he has found out about the mop gene and its role in cardiac myopathy. A month later a friend informs Dr. Young that Dr. Zenith has just submitted a paper about the mop gene (and the results sound almost identical to what Dr.Young has found). Dr. Young is quite angry about the situation, especially because he now has to rush to submit a paper (initially he wanted to submit a more complete paper).

Was Dr. Zenith obligated to tell Dr. Young he was working on the same gene that evening in the pub?

Should Dr. Zenith have told Dr. Young he was submitting a paper about the mop gene? If so, at what point?

How should Dr. Young approach Dr. Zenith to discuss the situation?

Case 2 – Contradictory Results

Dr. Andrews recently published a paper in the New England Journal of Medicine (NEJM). Dr. Andrews and her postdoctoral fellows put substantial effort into making sure the study was complete and also carried out many experiments to address reviewers' comments. In the paper, Dr. Andrews acknowledges that the findings are contradictory to results published in the Journal of the American Medical Association (JAMA) by Dr. Benton. Two days after the paper is published online, Dr. Andrews receives a very aggressive email from Dr. Benton. In the one-page diatribe, Dr. Benton lists several reasons why Dr. Andrew's study is completely wrong.

How should Dr. Andrews respond?

What if Dr. Andrews and Dr. Benton are presenting back-to-back talks reporting these opposing results at an international conference. How should Drs. Andrews and Benton interact at the meeting?

Case 3 – Competing Offers

After much work, Dr. Lu and her colleague have successfully purified the "Mega-complex" and raised antibodies to some of the proteins. This work has not yet been submitted for publication, but Dr. Lu has presented the work at conferences. A few days ago, Dr. Lu received a phone call from Dr. James at Podunk University. Dr. James' group has results that indicate the Mega-complex has an important role in RNA silencing

and would like to collaborate with Dr. Lu and her postdocs to further examine the role (using their purified protein and antibodies). Dr. Lu is excited about this finding and quickly agrees to a collaboration. Then today Dr. Sam from Prestigious University called describing findings very similar to those of Dr. James, also wanting to collaborate.

How should Dr. Lu handle this situation? Would it be ethical for her to collaborate with both Dr. James and Dr. Sam?

Should Dr. Lu tell Dr. James that Dr. Sam has similar results and vice versa?

How should publications about the Mega-complex be handled?

Case 4 – Sharing Reagents and Assays

Dr. Smith, a new tenure-track investigator, publishes a paper that involves a number of plasmids and also makes use of a newly developed assay system that took him considerable effort to develop. Shortly after, he receives a request from a postdoc at another institution for both the plasmids and the assay system. Dr. Smith is concerned that the requesting postdoc wishes to conduct experiments that are similar to the ones he is pursuing. He therefore writes back and raises concerns about a possible overlap in research interest. The requesting investigator states that there is no overlap.

Dr. Smith decides that he must send the materials to the postdoc, with the understanding that their work would not overlap. A year later, a paper is published by the requesting scientist making use of the plasmids and assay system and "scooping" Dr. Smith. Does he have any recourse? Would the use of an MTA have helped prevent this situation?

If the requesting postdoc agrees that their interests overlap but insists on receiving the materials – "after all, they have been published" - does Dr. Smith have to send them?

If, on the other hand, the requesting postdoc agrees that their interests overlap and therefore withdraws the request, has Dr. Smith violated any rules by not sending the plasmids?

Six months later, the requesting investigator accuses Dr. Smith of violating the stated rules of the journal in which the results were published by not sending the materials. Did Dr. Smith's actions violate the rules? Are there comparable NIH rules? What could Dr. Smith do to prevent such an accusation?

Case 5 – Informed Consent

Dr. Jones' patient is an 81-year old woman with cancer. Her oncologist, Dr. Jones, has invited her to participate in a clinical trial testing a new treatment for her type of tumor.

Dr. Jones was present when Dr. Smith, the clinical investigator, obtained a signed informed consent from from Mrs. Franklin a few days ago. However, when Dr. Jones visited her in her hospital room today and asked if she was ready to begin the study tomorrow, she looked at him blankly and seemed to have no idea what he was talking about. The competence of his patient to give an ethically valid informed consent is in doubt.

What should Dr. Jones do?

- Mrs. Franklin may be an eligible research subject, and her participation may benefit her as well as other cancer patients. However, when clinical research consent is sought from impaired patients, the IRB is authorized by Federal Regulations [45 CFR 46.111 (b)] to protect the rights and welfare of research subjects who are temporarily or permanently impaired, by including "additional safeguards". There must be a careful evaluation of risks and benefits. These safeguards may include seeking a surrogate who can make decisions for the subject about his/her participation in research at the NIH.
- The Policy and Communications Bulletin for the NIH Clinical Center [M87-4 (rev)] outlines the NIH policy on the Consent Process in Research Involving Impaired Human Subjects.

- How might the situation differ if the clinical research were to test a treatment for cognitive impairment such as the memory loss Mrs. Franklin seems to have?
  - In this case, the IRB would have raised the issue of competence while reviewing the clinical protocol, and would have required that the investigator incorporate the appropriate safeguards into the consent process for all of the study subjects, which may have included the use of a Durable Power of Attorney for the consent process.

Code of Federal Regulations

45 CFR 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and

benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.