

TO: WCSU University Senate President
FROM: Norine Jalbert, Patricia O'Neill, Tara Kuther, Robin Flanagan
Psychology Department
DATE: May 10, 2004
SUBJECT: Motion re: WCSU Human Subject Review Committee and Research & Development Committee

Thank you for placing our questions regarding the Human Subject Review Committee on the Senate agenda. We now recognize that the questions represent a larger issue than can be effectively dealt with in one Senate meeting, so we would like to propose the following motion:

That the WCSU University Senate direct the Research and Development Committee to:

- (1) amend its bylaws to include the responsibility of overseeing the Human Subjects Review Committee (also referred to as the IRC and IRB) and IACUC [alternatively, the Senate could treat each committee as *de facto* independent committees and ask them to carry out these tasks) ;
- (2) develop a clear statement of the membership of the committees, terms of office, and method of selecting members;
- (3) develop a procedure, consistent with other Senate committees, to be followed before changing any policies and procedures;
- (4) insure that the subcommittees and its members be listed in the annually published Senate Committee Roster
- (5) present its proposal as soon as possible in the Fall, 2004 semester, but not later than the December, 2004 Senate meeting

In the meantime, we are also requesting that the forms and procedures that are currently printed in the Faculty Handbook for Human Subjects research (pp.156-164; dated August, 2002 and August, 2003) shall remain in effect until the Bylaws and procedural issues are resolved.

email correspondence on this Senate agenda item (NOT a complete history)

5/5/04

Vijay,

Believe it or not, I decided to spend some time this afternoon actually updating the pages in my Faculty Handbook (partly because I couldn't ever be sure that I had the most current paperwork I was looking for). Anyway, I have a question about materials dealing with research (faculty, student, informed consents, etc.). There have been a lot of updates and, in fact, Margaret Leahey just issued an email (4/26/04) that another set of revised guidelines has been placed online. My question is this: NONE of these updates indicate that the material went through the committee approval process or the University Senate. This appears to be contrary to past practice (as the oldest forms in this area that I had in my faculty handbook indicated the date of R&D Comm approval, Senate approval and Admin. approval. I have no particular objection to the revisions that have been made

(since I haven't studied them carefully yet) but I do object to the apparent breach of procedure. I don't believe it's appropriate to have one office or one person changing forms so often with no public discussion and discourse among the parties concerned. I am requesting that the Senate investigate this matter. Thanks, Norine

5/6/04

Vijay,

I thought I would double check the R& D Committee bylaws (page 51) to see if it somehow slipped past me that they have created some procedures for IRB that allowed for the one-person decision making that's been going on. Worse than slipping by me is the fact that the R&D responsibilities don't include anything about the IRB committee. This seems like a major oversight ---- I KNOW historically that the R&D Comm. served as the IRB then later created a separate, I thought, subgroup to serve as IRB. What now appears to exist is a "Human Subjects Review Committee" (page 155) that seems to be nowhere included in the governance process. In fact, I couldn't find any indication of what the membership is, who selects the members, what their terms are, to whom they answer, etc. For all I know it could still be an R&D subcommittee but then the committee has failed to amend their bylaws or insert anything in the Faculty Handbook that informs us. Heck, there's not even a listing of the Human Subjects Review Committee membership on the annual Senate Committee Roster. I think it makes sense that the comm. would consist of members from depts. that do human subject research, but it still should fall somehow under the faculty governance system, so that faculty have the opportunity to provide input into policy and procedures.

Norine

5/6/04

Vijay -

Bringing the IRB under Senate governance is critical, I agree. More important, perhaps, is a discussion of how such an oversight has occurred. I've been aware of it for a few years.

Several years ago I ran into problems in gaining approval for my own research. Much of the feedback I received from the IRB was inappropriate in the sense that it didn't reflect current federal regulations on research with human participants. For example, the committee initially suggested that I obtain parental permission for students (all of whom are over age 18) to participate. Given that I have participated in an NSF funded ethics education group for 6 years and have published on issues related to research with human participants, I readily questioned the IRB's decisions.

I met with Gene (Phil Lom, then Psych Dept chair, accompanied me) and I raised the issues Norine has mentioned (i.e., how are individuals appointed to the IRB; where to find a committee roster). At that point, the response was that the IRB was a subcommittee of R&D; however, in response to our discussion, Gene noted the need to possibly appoint individuals to serve.

Since then, the IRB has become even more shrouded in mystery and several editions of new forms/procedures, each more elaborate than the last, have emerged. None of which have been presented to the Senate.

Tara

5/7/04

Terry:

RE: Institutional Review Board and Institutional Animal Care and Use Committee
(Faculty Handbook, page 155)

Can you tell me-

1. Who are the members of the IRC and IACUC?
2. How did they get to be members (elected; appointed; if appointed, by whom?)
3. Who are the Chairs?
4. Do the IRC and IACUC have bylaws or any other governing documents? Where are they?
5. To whom do they report?
6. Are there minutes of their meetings and annual reports? Where can I get them?

Thanks.

Vijay.

5/7/04

. . . What I am questioning is the fact that there is nothing in the Faculty Handbook that allows me to figure out where all the IRB paperwork changes are originating. Given that the IRB was/is a subset of the R&D Committee and therefore under the governance system of the University Senate, I took my question directly to the Senate President. Over my 25+ years at WCSU, I have always taken pride in the fact that I work at an institution where most policies and procedures are clearly articulated in either the collective bargaining agreement and/or the faculty handbook. The fact that the IRB evolved into an entity that "slipped off the Senate radar" is the major impetus to my inquiry. In principle and pretty much in practice, all of the Senate committees have published bylaws which include responsibilities, membership, procedures, annual reporting obligations, etc. Generally speaking, changes in policy, procedures, etc. must be approved by the responsible committee then by the Senate then by the administration. This doesn't appear to be the case with the paperwork originating from Margaret Leahey's office, and that's my fundamental problem.

Now, there is the second issue of the content of the changes which I have mentioned in earlier messages on this matter and which others in the department have articulated. In my mind, these are secondary to the first problem. If the first problem hadn't occurred, then faculty would have had an opportunity to discuss, debate and perhaps influence the procedures that were being proposed--at the committee level and at the Senate level. There's a lot that can be said about this second issue, but I don't want to get sidetracked at this time from what I consider to be the fundamental problem, i.e., that the R&D Committee has somehow created a sub-committee that operates outside of the faculty governance procedures.

Let me finally also state that I am not trying to cast blame on the R&D Committee, the Senate, or anyone else --- things do have a habit of falling through the cracks. I do vaguely remember that R&D moved to create a subcommittee but had not attended to the fact that it did so without going through the Senate. Now that this omission has become

apparent to me, however, I felt it to be my responsibility to bring it to the attention to the Senate which is the body responsible for faculty governance. . . .

Norine