

From: [Bienenfeld, Tracy](#)
To: [Camp, Celeste](#)
Subject: FW: HHS 521 follow-up- 520s required
Date: Tuesday, February 25, 2014 4:24:40 PM

Hi Celeste,

Please see the below communication between myself and Robert 'Skip' Nelson.

Tracy Bienenfeld

Ethics & Integrity Staff

Food and Drug Administration

White Oak Building 1, Room: 4226

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<http://inside.fda.gov:9003/EmployeeResources/Ethics/FDAEthicsProgram/default.htm>

From: Nelson, Robert 'Skip'
Sent: Monday, September 20, 2010 8:57 AM
To: Bienenfeld, Tracy
Cc: Murphy, Dianne - OC; Tolino, Vincent R
Subject: RE: HHS 521 follow-up- 520s required

Tracy,

As my involvement on the two editorial boards is similar to that of being editor of AJOB Primary Research (an ethics journal), Dianne has approved my considering my editorial board involvement on all of these journals as part of my professional development. We will monitor the time commitment, and make sure that it does not exceed the appropriate amount for PD. I will not report them on my HHS 521 form in the future. Thanks.

Robert "Skip" Nelson, MD PhD

Pediatric Ethicist, Office of Pediatric Therapeutics

Tele: (301) 796-8665; Mobile: (240) 328-7146; Fax: (301) 847-8619

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Bienenfeld, Tracy

Sent: Wednesday, September 08, 2010 11:16 AM

To: Nelson, Robert 'Skip'

Cc: Murphy, Dianne - OC; Tolino, Vincent R

Subject: RE: HHS 521 follow-up- 520s required

Dr. Nelson,

If you are given permission to include the below activities as professional development, that is fine. You will no longer need to report them on your HHS 521: Annual Report of Outside Activity or fill out an HHS 520: Request for Approval of Outside Activity. I will make a note of the IRB Editorial Board in your file and will do so as necessary upon hearing from Ms. Murphy. If Dianne Murphy feels that you still need to seek approval for the other two Editorial Board activities, then you can complete the HHS 520s upon your return.

Thank you for your prompt response. Feel free to email or call me with any further questions.

Tracy Bienenfeld

Ethics & Integrity Staff

Food and Drug Administration

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From: Nelson, Robert 'Skip'

Sent: Wednesday, September 08, 2010 11:12 AM

To: Bienenfeld, Tracy

Cc: Murphy, Dianne - OC; Tolino, Vincent R

Subject: RE: HHS 521 follow-up- 520s required

Tracy,

I leave tomorrow morning for international travel (meetings in Vancouver and Singapore), returning September 20. I will take care of this as soon as I return. Although I remain on the Editorial Boards of

IRB and Accountability in Research, there has been no activity. My role on the American Journal of Bioethics has shifted and is now considered part of my professional development activity, and thus is not considered an outside activity. This approach was approved by my supervisor, Dianne Murphy, felt to be fine by Vince Tolino and Ann Wion. As the Editorial Board activity for these other two journals also involves bioethics (which is my job at FDA), perhaps the simplest approach is to also include these activities as professional development? I will be speaking with Dianne this afternoon about this approach.

Robert "Skip" Nelson, MD PhD

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From: Bienenfeld, Tracy

Sent: Wednesday, September 08, 2010 10:05 AM

To: Nelson, Robert 'Skip'

Subject: HHS 521 follow-up- 520s required

Good morning,

I am currently reviewing your HHS 521: Annual Report of Outside Activity. You reported participation and "renewal anticipated" for each of the following three activities:

- 1) Editorial Board; IRB: Ethics and Human Research
- 2) Editorial Board: American Journal of Bioethics
- 3) Editorial Board: Accountability in Research

Please submit an HHS 520: Request for Approval of Outside Activity for EACH of the three activities. Please ensure your supervisor and Office Director sign and provide comments and return it to our office for approval. I have attached the form below. Please complete it as soon as possible and return it to our office to ensure you are in compliance with the Ethics Regulations.

I would appreciate an update on the status of your HHS 520s within 7 business days of this email.

<< File: HHS-520.doc >>

Please feel free to email or call me with any questions.

Thank you,

Tracy Bienenfeld

Ethics & Integrity Staff

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From: [Tolino, Vincent R](#)
To: [Nelson, Robert "Skip"](#)
Subject: RE: Question about Professional Development and Outside Activity
Date: Thursday, May 20, 2010 11:10:31 AM

I suppose if the official duty at Georgetown includes the hiring of the editorial assistant then you could be involved in that action, however, I think it is "cleaner" if it is the university that handles the money aspect of that action.

Vince Tolino
Director, Ethics and Integrity Staff
5600 Fishers Lane, Rockville, MD 20857
301-827-5514 (HFA-320)

From: Nelson, Robert 'Skip'
Sent: Thursday, May 20, 2010 10:32 AM
To: Tolino, Vincent R
Cc: Murphy, Dianne - OC
Subject: RE: Question about Professional Development and Outside Activity

Thanks, Vince. I will touch base again with Dianne and then contact Ann Wion. I am assuming that any support for the editorial assistant should then go directly to that person, and not through me (especially if this is an official capacity role). Or do you see this simply as an administrative issue based on convenience and accounting?

Robert "Skip" Nelson, MD PhD
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From: Tolino, Vincent R
Sent: Thursday, May 20, 2010 10:12 AM
To: Nelson, Robert 'Skip'
Cc: Murphy, Dianne - OC
Subject: RE: Question about Professional Development and Outside Activity

Hi Skip -

It appears that the journal is "owned" by the Taylor & Francis group and from what I see is not a separate organization with it's own officers. In other words, the Taylor & Francis group is a publishing company with a Board of Directors and that Board owns the Journal. With this assumption, it appears

that if you were to serve as Editor-in-Chief of the journal, you would not be assuming an officership position with Taylor & Francis such as President, Vice-President, Secretary, treasurer, nor would you be on a governing body of the organization. If this is correct, then the decision for you to serve on the journal is a management decision for this to be a part of your official duties. As such, you do not need outside activity approval as you will be serving in your official capacity.

Regarding the Kennedy Institute at Georgetown, it would have to be determined if this appointment is an official duty activity or one that you will do in your private capacity. Because the appointment at Georgetown is desired to facilitate the journal relationship, it makes sense for you to serve at Georgetown also in your official capacity. Therefore, no outside activity approval is needed.

I do suggest that you contact the Office of Chief Counsel (Ann Wion) for a determination that it is within the Agency's legal programmatic authority to assign you to this official duty position. Other than that, I don't see any ethical concerns.

Vince Tolino
Director, Ethics and Integrity Staff
5600 Fishers Lane, Rockville, MD 20857
301-827-5514 (HFA-320)

From: Nelson, Robert 'Skip'
Sent: Wednesday, May 19, 2010 4:00 PM
To: Tolino, Vincent R
Subject: Question about Professional Development and Outside Activity

Vince,

I have been asked to be Editor-in-Chief of a new journal called AJOB Primary Research (<http://www.tandf.co.uk/journals/uabr>). It is published by Taylor & Francis Group (<http://www.taylorandfrancisgroup.com/>). The focus of the journal is on empirical research in bioethics, and will be published quarterly. As I estimate that the time involved will be no more than 4 hours per week, Dianne Murphy and I would consider this activity to be appropriate as "professional development." However, I believe it should be thoroughly vetted by your office given that I would be assuming a leadership position with the journal. The position comes with a \$10,000 allowance to be able to hire an editorial assistant. I do not plan for any of this money to come my way. Rather I plan to see if the money can be used to hire a PhD graduate student or post-doctoral fellow through the Kennedy Institute of Ethics at Georgetown University. I would also like to seek an adjunct faculty appointment at Georgetown to facilitate this relationship.

My questions:

- (1) Are there any concerns about my having a relationship with a journal published by Taylor & Francis Group?
- (2) Similarly, are there any concerns about my having an adjunct appointment with the Kennedy Institute at Georgetown University?
- (3) Even if this is considered "professional development" activity, should I complete an "outside activity" form for each activity to make sure these two relationships are thoroughly vetted?

Thanks.

Robert "Skip" Nelson, MD PhD
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