Attachment 3 H - M:

TEMPLATE LETTERS

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Attachment 3H - Adult Query of Candidate Interest

Dear ,

You have been recommended by as a potential Board member for the NCI Central Institutional Review Board (CIRB). If you are not familiar with the project, it is an NCI Initiative that was established to eliminate redundant local IRB reviews of phase 3 Cooperative Group trials while maintaining high standards of human subjects protections.

The Board meets twice a month via an internet enhanced conference call. Each meeting lasts approximately 3-4 hours and occurs on the first and third Thursday of the month at 9:00 am ET. There is also an educational meeting every year that occurs in person. Board related travel for the educational meeting is covered and a per diem is provided. Board members serve two-year terms and receive an honorarium for volunteering their time. You may refer to the NCI CIRB website at www.ncicirb.org for more information.

The reason you are being considered is there is an opening for a .

If you are interested in participating, please send me a current copy of your CV. If you are not able to serve at this time but are interested in this opportunity in the future, please provide a date when you believe you will be available so that we may contact you again in the future.

I look forward to your reply. If you have any questions, please feel free to contact me.

Thank you,
Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative
National Cancer Institute, NIH
6130 Executive Boulevard Room 6102
Bethesda, MD 20892
goldberj@mail.nih.gov
ph 301-496-0510
fax 301-480-2642
www.ncicirb.org

cc: NCI CIRB Project Officer
CIRB Administrator

Attachment 3I – Pediatric Query of Candidate Interest

Dear ,

You have been recommended by as a potential Board member for the NCI Central Institutional Review Board (CIRB). .If you are not familiar with the project, it is an NCI Initiative that was established to eliminate redundant local IRB reviews of COG phase 2, 3 and pilot trials while maintaining high standards of human subjects protections

The Board meets once a month via an internet enhanced conference call. Each meeting will last approximately 3-4 hours and occurs on the second Thursday of each month at 11:00 am ET. There is also an educational meeting every year that occurs in person. Board related travel for the educational meeting is covered and a per diem is provided. Board members serve two-year terms and receive an honorarium for volunteering their time. You may refer to the NCI CIRB website at www.ncicirb.org for more information.

The reason you are being considered is there is an opening for a .

If you are interested in participating, please send me a current copy of your CV. If you are not able to serve at this time but are interested in this opportunity in the future, please provide a date when you believe you will be available so that we may contact you again in the future.

I look forward to your reply. If you have any questions, please feel free to contact me.

Thank you,
Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative
National Cancer Institute, NIH
6130 Executive Boulevard Room 6102
Bethesda, MD 20892
golderj@mail.nih.gov
ph 301-496-0510
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www.ncicirb.org

cc: NCI CIRB Project Officer
CIRB Administrator

Attachment 3J – Confirming Candidate Qualifications and COI

Dear ,

Thank you for your interest in becoming a Board member for the NCI CIRB. There are certain criteria that a person must meet in order to serve on the CIRB as well as information we feel is helpful in assessing each candidate for the Board.

Please provide your response to the following:

1. Do you currently have internet access and are you comfortable using a computer for all communications and meetings?
2. Have you ever served on an IRB?
3. Are you currently sitting on an IRB that is a member of the CIRB Initiative? If yes, does the panel you sit on review these CIRB studies or does your IRB Chair do the facilitated review for them?
4. Do you have significant holdings in drug companies that would result in frequent recusals from voting?
5. Do you have any conflicts based on your review of the CIRB Conflict of Interest Policy included at the end of this e-mail?

After we confirm that your answers will not impede you from serving on the Board, a staff member will contact you regarding member orientation and education.

Thanks again for your interest. If you have any questions, please contact me.

Thank you,
Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative
National Cancer Institute, NIH
6130 Executive Boulevard Room 6102
Bethesda, MD 20892
goldberj@mail.nih.gov
ph 301-496-0510
fax 301-480-2642
www.ncicirb.org

cc: NCI CIRB Project Officer
CIRB Administrator

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. While your participation is completely voluntary, to participate in the NCI CIRB, completion of this form is required. Data collected as part of the NCI CIRB review is private and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be kept private under the Privacy Act and will be presented only in statistical or summary form.

6.0 Conflict of Interest of CIRB Members

The purpose of this policy is to ensure that all deliberations of the Adult and Pediatric NCI's CIRB affecting participants in research projects are conducted by members whose overriding interest is the protection of those participants. At the same time, the policy is not intended to unnecessarily deny the CIRB the benefit of the expertise of any of its members in such deliberations.

When it is determined that any member has an existing conflict of interest in a study before the CIRB, that member shall be absent throughout the deliberations concerning that study and voting, except when the Chair or a majority of the members not conflicted shall request that member's presence for the purpose of responding to questions. If such a member has been requested to remain in the meeting to respond to questions, they will be absent for the final deliberation and vote. A member with a conflict of interest cannot be assigned as a reviewer.

6.1 Definition of a Conflict of Interest

6.1.1 A member or her/his immediate family member (spouse, significant other or dependent child) or a person in a direct supervisory or reporting relationship with the member has a primary role in the oversight, design or conduct of the project or has a role in the analysis or management of the data. This includes but is not limited to:

6.1.1.1 serving on a governing body or any significant supervisory committee of the Cooperative Group that submitted the protocol under consideration, such as a Disease Committee, the Board of Directors, or a Data Monitoring Committee of the Cooperative Group or

6.1.1.2 serving as a Study Chair of a currently active study or

6.1.1.3 working at the same institution as the Study Chair

6.1.2 A member or immediate family member has a financial interest of $10,000 or more in any of the agents/devices/enterprises involved in the study under consideration, or in any direct competitor of such an enterprise. (Ownership interests arising solely from investment in a company by a mutual, pension or other institutional investment fund over which the IRB member does not have control shall not be included as a conflict of interest or deemed such.).

6.1.3 A member or immediate family member within two years before the deliberations receives any compensation from any enterprise involved in the protocol under consideration, or from any direct competitor.

6.1.4 A member or immediate family member has a proprietary interest in the research, such as a licensing agreement, copyright, patent or trademark.

6.1.5 A member is a Cooperative Group investigator and has either:

6.1.5.1 identified a prospective subject for the study, or
6.1.5.2 enrolled a subject in the study or
6.1.5.3 performed or directed research interventions and interactions with the subject. Item 6.1.5.3 does not apply to other physicians who may be involved in the care of the patient, such as cross-over attendings, surgeons or radiotherapists.

6.1.6 A member has potential to gain academic or career advancement based upon participation in the study.

6.1.7 A member has an interest (financial or non-financial) that the CIRB or the CIRB member believes conflicts with or biases his/her ability to objectively review a study.

6.1.8 Each CIRB member is responsible for disclosing potential or actual conflicts of interest to the appropriate NCI CIRB Coordinator as soon as possible. This disclosure should occur prior to the scheduled CIRB meeting, or at the beginning of the CIRB meeting, if not declared previously. If a CIRB member has questions regarding a potential conflict, the member must disclose the potential conflict to the appropriate NCI CIRB Coordinator, who will forward the information to the appropriate CIRB Conflict of Interest Subcommittee for evaluation. If the Subcommittee does not have sufficient time to evaluate, the convened CIRB will make the determination.

6.1.9 A copy of this policy shall be posted as a reference document on ePanel© and the Chair shall call attention to the policy at the beginning of each meeting. An entry in each meeting's minutes will reflect adherence to this policy.

6.2 Conflict of Interest Subcommittee

6.2.1 The purpose of the Conflict of Interest (COI) Subcommittee is to review potential conflicts of interest as disclosed by members when the member is not certain as to whether the disclosed relationship constitutes a conflict of interest requiring the member's absence from the deliberations and vote.

6.2.2 The COI Subcommittee is composed of a subset of CIRB members who are appointed by the CIRB Chair. It is recommended that the three members be an ethicist, a scientific reviewer, and a patient advocate.

6.2.3 Members with uncertainty regarding potential conflicts shall disclose the pertinent facts of the potential conflict in writing to the NCI CIRB Coordinator. The disclosure shall be submitted by the NCI CIRB Coordinator to the CIRB Conflict of Interest Subcommittee for a determination prior to the CIRB meeting.

6.2.4 The COI Subcommittee will review all such disclosures and render a decision regarding whether or not the disclosure constitutes a conflict of interest. Members with conflicts under consideration by the COI Subcommittee will not be named as primary reviewers.

6.2.5 The COI Subcommittee will present a written report of its review no later than the beginning of such meeting where research in which the potential conflict exists will be reviewed.

6.2.6 The CIRB must accept the determinations of the COI Subcommittee unless the determination was not unanimous or if the member alleged to have the conflict appeals the Subcommittee's determination.

6.2.7 If a conflict or potential conflict affecting an item on the agenda for a convened meeting is disclosed too late for Subcommittee consideration, the issue shall be dealt with directly by the CIRB as a committee of the whole.

6.2.8 If a potential conflict is disclosed by a member of the COI Subcommittee and sent to the Subcommittee for review, the CIRB Coordinator shall designate a CIRB member not so conflicted to replace the disclosing COI Subcommittee member for the conflict determination.

Attachment 3K – Notification of Selection to Serve on NCI CIRB

Dear ,

We are pleased to notify you of your appointment to the NCI CIRB!

John Horigan, NCI CIRB Administrator, will be contacting you within the next 10 days to begin the orientation process. He will serve as your primary contact during this process and will work with you to complete all of the necessary documents and orientation activities. We look forward to working with you.

Sincerely,
Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative
National Cancer Institute, NIH
6130 Executive Boulevard Room 6102
Bethesda, MD 20892
goldberj@mail.nih.gov
ph 301-496-0510
fax 301-480-2642
www.ncicirb.org

cc: NCI CIRB Project Officer
CIRB Administrator

Attachment 3L – Notice of Rotation Off

Dear

We have begun the process of retiring members who approaching completion of their tenure or have served beyond their tenure so that new members have the chance to serve.

We do not have a precise date yet for your rotation off the Board. The Operations Office is working with the new appointees to determine dates, but I will get back to you once a date is established.

OR

Your last meeting will be

Thank you for your time and your contributions to the CIRB.

John Horigan
NCI CIRB Administrator

NCI CIRB Adult/Pediatric Chair

cc: Head, Central IRB Initiative

Attachment 3M – Thank You to Retiring Members and Acknowledgment of Resignation

Dear ,

On behalf of the NCI CIRB Initiative, we want to thank you for your service and dedication to upholding high standards of human subjects protections. It is the diligence of our Board members that makes it possible for this Initiative to continue to accomplish its goals. It has been a pleasure working with you and we wish you success in the future.

Regards,

Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative

NCI CIRB Adult/Pediatric Chair

cc: CIRB Administrator