

Attachment 3 N - Q:
INTERNAL OPERATIONS

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Attachment 3N – Internal Plaque Order Form

Plaque Order Form

To be sent from NCI to Chris at damec@ors.od.nih.gov

Hello Chris,

Hope this finds you well. I have just been informed that we will need a plaque to honor a retiring CIRB member.

I would like to use the same specifications as previous certificates for previous CIRB members, the certificate style, font type, wording, layout and framing will be the same as follows:

- Certificate bond size 8.5 inches x 11 inches
- Double matted with red and white
- Gold wooden frame
- “National Cancer Institute” centered near the top in red
- “Presented to” in black and centered
- “ ” in the center in gold
- “For his/her Significant Contribution to the NCI Pediatric/Adult Central Institutional Review Board” in black
- Month Year – Month Year
- NIH logo in gold centered
- Signed by Dr. Niederhuber and Dr. Abrams, Associate Director, Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program – both signatures on file

Our CAN number is 8332942 and our AO is Jackie Robinson.

Please confirm receipt.

Thank you very much once again for your assistance.

Attachment 30 – Operations New Member Checklist

Operations Office Checklist for New Member Orientation

Nominee Name:

Step 1:

- Send Welcome Letter including:
 - Biosketch questionnaire
 - W9
 - NDA
 - Contact Information sheet
 - Meeting Schedule
 - Orientation Steps
- Mail Orientation Packet including:
 - Institutional Review Board Member Handbook (Amdur, R)
 - CIRB Meeting Schedule
 - Copy of DDHS regulations
 - Copy of FDA regulations
 - CIRB Operations Office Organizational Chart
 - Helpful URLs
 - CIRB Initiative Contact Information
 - Copy of Orientation Powerpoint
 - CIRB Administrator's business card.
- Update status to Nominee in MAT database _____
- Notify ePanel[®] for orientation. _____

Step 2

Collect:

- Completed contact information form
- Completed W9
- Completed Non-Disclosure Agreement (NDA)
- Certification of HSP training (CITI or NIH)
- Completed biosketch questionnaire, or pre-prepared biosketch.
- Headshot
- CV (if not up to date, or if not previously provided)

Schedule or Confirm the following:

- CIRB Operations Office teleconference Orientation
- ePanel[®] training.
- Observation meeting.

Step 3

- Confirm Humanitas Training and log in information
Date: _____
- Complete new member training orientation via teleconference
Date: _____
- Notify CIRB Chair of attendance at observational meeting
Date: _____
- Notify Board Coordinators
Date: _____
- Update MAT database status from nominee to premember
Date: _____

Step 4

- Confirm attendance at observational meeting
Date: _____
- Conduct observational meeting debrief if requested or warranted.

Step 5

- Confirm all prior steps are complete.
- Update OHRP registration adding new member.
Date: _____
- Update Mat database status from premember to member
- Notify Coordinators of status change
- Update CIRB website with:
 - Member name, degree and affiliation
 - Biosketch
 - Headshot
 - Contact Outreach to obtain log in info for CIRB participants' side.
- Add member to internal rosters as appropriate
- Add member to IRB Manager
- Add member to distribution lists
- Update minutes template

Attachment 3P – Educational Checklist for Member File

New Member Education Checklist—Areas members were trained in per CIRB Orientation Powerpoint

Member Name: _____

Orientation Presentation conducted by: _____

Ethical Decision Making Principles

- Belmont Report
- Nuremberg Code
- Declaration of Helsinki

Regulatory Elements

- OHRP and FDA roles in HSP
- 45 CFR 46
- 21 CFR 50 & 21 CFR 56
- Informed consent elements
- NCI Consent Template

Role as IRB member

- IRB decision making (how to vote, criteria for approval, etc)
- Procedures of the Board and Board members
- Responsibilities of the Board and Board members
- CIRB Member Orientation Manual
- IRB Member Handbook

Outside Training

- Completion of valid human subjects protections training module (NCI, CITI, etc)

Date all educational elements completed: _____

Attachment 3Q – Operations Checklist for Retiring Board Members

Member:

Step 1

- Notify member in advance (see attachment 14a)
- Try to provide final meeting date when possible

Step 2

- Confirm receipt of notice of rotation off.
- Confirm final meeting date.
- Notify Operations Office Staff
- Notify CIRB Chair and Vice Chair
- Add notice to agenda for final meeting

Step 3 (after final meeting)

- Remove as a reviewer (IRB Manager)
- Remove Member from "Board" Distribution/Email Lists
- Remove Member from ePanel
- Remove Member from website/access
- IRB Membership Roster
 - Send email to staff notifying them that new roster is ready
 - Update with OHRP

Step 4

- Forward plaque order to NCI