

**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](mailto: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<sup>®</sup> 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<sup>®</sup> 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