



**Award for Excellence in Human Research Protection
Judge Application Form**

*Please complete and fax this form to 301-320-0978 (or email to award@hii.org)
Submit CV, resume, and/or brief biographical sketch highlighting relevant qualifications & experience.*

Name: _____
 Organization: _____
 Position/Title: _____
 Address: _____

 Telephone: _____ Fax: _____ Email: _____

- I would like to be a member of the Judges Credentialing Committee (JCC): Yes No
- I would like to judge the following award categories (*check all that apply*):
 Best Practice Innovation Life-time Achievement

1. Please check the one category that is most applicable:

1.1 Present organization:

- | | |
|--|---|
| <input type="checkbox"/> Accrediting organization | <input type="checkbox"/> Law firm |
| <input type="checkbox"/> Consumer advocacy organization | <input type="checkbox"/> Research performer - center/institute/university |
| <input type="checkbox"/> Drug/device manufacturer | <input type="checkbox"/> Research sponsor/funder |
| <input type="checkbox"/> Government/regulatory agency | <input type="checkbox"/> Voluntary health association (e.g., Red Cross) |
| <input type="checkbox"/> Healthcare facility (e.g. hospital) | <input type="checkbox"/> Other, please specify below:
_____ |
| <input type="checkbox"/> Health plan/insurer | _____ |
| <input type="checkbox"/> Health trade association (e.g., AHA, BIO, PHARMA) | _____ |
| <input type="checkbox"/> Health professional association (e.g., AMA, ANA) | |
| <input type="checkbox"/> Independent consultant/Individual | |

1.2 Present role in research enterprise:

- | | |
|---|--|
| <input type="checkbox"/> Administrator (of research institution/center) | <input type="checkbox"/> Proposal/study reviewer – science |
| <input type="checkbox"/> Consumer/research participant advocate | <input type="checkbox"/> Public relations/communications professional |
| <input type="checkbox"/> Consultant to IRB/HRP program | <input type="checkbox"/> Regulator (e.g., government) |
| <input type="checkbox"/> Educator/trainer | <input type="checkbox"/> Social scientist (who studies the enterprise) |
| <input type="checkbox"/> HRP compliance officer/auditor | <input type="checkbox"/> Study administrator/coordinator |
| <input type="checkbox"/> HRP professional/IRB staff | <input type="checkbox"/> Study monitor/auditor/evaluator |
| <input type="checkbox"/> HRP QI/CQI committee member | <input type="checkbox"/> Study staff |
| <input type="checkbox"/> Investigator/researcher | <input type="checkbox"/> Surveyor accrediting organization |
| <input type="checkbox"/> IRB/ethics committee member | <input type="checkbox"/> Other, please specify below:
_____ |
| <input type="checkbox"/> Journal reviewer (ethics/science) | _____ |
| <input type="checkbox"/> Proposal/study reviewer – ethics | _____ |

(Please complete next page...)



2. Research experience

2.1 For how many years have you been actively involved in the human research enterprise (excluding years that you were not fully involved)?

2.2 How many of the last 5 years have you been actively involved in the human research enterprise in a role relevant to the protection of people who participate in research studies? _____

2.3 What type of human research have you done, and for how many years (excluding years that you were not fully involved)? *Check all that apply*

- None
- Behavioral research, surveys, etc; _____ years
- Clinical (biomedical) research; _____ years
- Other, specify below; _____ years

3. **Certifications** - Which of the following types of certification (given by a recognized professional body) do you hold? *Check all that apply*

- Investigator
- IRB professional
- Research administrator
- Other relevant certification, specify

None

4. Human research protection (HRP) training

4.1 In the past 5 years, which of the following types of formal training (e.g., regarding federal regulations) have you completed successfully?

Check all that apply

- Investigator
- Institutional official
- IRB member
- IRB staff/support
- Research staff (including, e.g., CRO)
- Surveyor (for HRP accreditation)
- Training of trainers
- Other, specify: _____
- None

4.2 Have you received formal training in the last 5 years or are you knowledgeable about current federal regulations pertaining to:

- Protecting human subjects of research?
 Training in last 5 yrs Knowledgeable No
- Assuring the integrity of research?
 Training in last 5 yrs Knowledgeable No

5. **Human research protection experience** - In the past 5 years, in which of the following ways have you protected human subjects of research?

Check all that apply

- Conflict of interest committee
- Consumer/participant advocate
- Consultant to IRB/HRP program
- Educator/trainer (in HRP)
- HRP compliance officer/auditor
- HRP program oversight
- HRP QI/CQI committee
- Investigator/researcher
- IRB/ ethics committee – member
- IRB/HRP program – staff
- Journal reviewer (ethics/science)
- Proposal/study reviewer – ethics
- Proposal/study reviewer – science
- Regulator (government)
- Scientific integrity committee
- Study administrator/coordinator
- Study monitor/auditor/evaluator
- Study staff
- Surveyor (accrediting organization)
- Other, specify: _____
- None

6. **Adverse professional events** - In the last 5 years, have you been, or are you currently, involved with any event that could call into question your suitability to be a judge (e.g., adverse action regarding quality of care, professional conduct, research integrity, etc)?

Yes; explain below No

7. **Comments** – including any other relevant qualifications or experience, explanations of adverse professional events, etc. *If necessary, attach additional page.*

Signed: _____ Date: _____

Printed name: _____

Award for Excellence in Human Research Protection **Judges Credentialing/Selection Criteria**

Definitions & notes

- *Credentialing criteria* refer to the qualifications and experiences of individuals to be judges. The Judges Credentialing Committee (JCC) assesses applications based on these criteria.
- *Selection criteria* refer to guidelines for forming panels of judges (from among credentialed judges) to evaluate Award applications.
- Separate panels are established to evaluate applications for each category of Award. Multiple panels may be established for the same category of Award if the volume of applications warrants.
- All judges who evaluate applications for an Award must complete a Declaration of Interest Form (DIF) pertaining to each application that they judge.
- In each Award category, judges assess the applicant's contributions to human research protection, select applicants who have demonstrated excellence, and select the year's best contribution, if any, to human research protection to receive the Annual Award.

Credentialing criteria

Documented evidence that the applicant:

- Is actively engaged in the research enterprise in a role relevant to the protection of human subjects of research, e.g., working to assure and/or improve human research protection, and/or the integrity or quality of biomedical and/or behavioral (including psychological) research involving human subjects
- Has at least 5 continuous years experience, or at least 10 years total experience, in the research enterprise in a role relevant to the protection of human subjects
- Possesses thorough knowledge of current federal requirements for protecting human subjects and assuring the integrity of research, including HIPAA, has undergone applicable training regarding these subjects, and, preferably, has experience with Institutional Review Boards (IRBs) or equivalent committees and/or with other human subject protection functions
- Has sufficient specific qualifications and experiences necessary to evaluate applications for one or more of the categories of Award, e.g., for innovation award judging panel, made or contributed to innovation in human research protection
- Does not have, or has had in the past 5 years, any event that might weaken the applicant's suitability to be a judge
- Once credentialed, professional performance as a judge (e.g., prompt and appropriate completion of evaluation of Award applications) permits recredentialing.

Selection criteria

Each panel consists of 3-5 credentialed judges, selected, to the extent possible, to represent relevant diversity with respect to the research enterprise, including, for example:

- Type of organization (e.g., sponsor, research institution, government/regulatory agency, consumer advocacy organization)
- Role (e.g., investigator, IRB member, ethicist, HRP professional)
- Professional background
- Region of the country.