



Award for Excellence in Human Research Protection
Founding sponsor: Office for Human Research Protections, US DHHS
2010 Application for Award

Purpose of Award

Health Improvement Institute (“Institute”) established the *Award for Excellence in Human Research Protection* to encourage and to recognize excellence and innovation in human research protection. The Office for Human Research Protections (of the U.S. Department of Health and Human Services) was the founding sponsor of the Award program.

Awards

The Institute has established three Award categories:

- Best Practice — given to a research institution, an unit, or an individual that has the best way, one of the best ways, or a proven way to achieve, or to contribute toward achieving, the protection that is the specified purpose of the practice
- Innovation — given to an individual (or a team) who has introduced an innovation in or a novel approach to the protection of human research subjects
- Life-time Achievement — given to an individual who has made significant contributions to the protection of human subjects of research over a continuous period of at least 20 years.

Judging

Award entries are evaluated by credentialed judges who volunteer their time to the Award program. The Judges Credentialing Committee determines whether or not a person who applies to become a judge meets established judge credentialing criteria. For each Award category, the Institute forms separate panels of credentialed judges, to the extent possible, to represent different aspects of the research enterprise (e.g., based on judges’ current position, geographic location, etc.). Judges evaluate Award entries against established Award criteria and record their evaluations on a structured form. The Institute recognizes applications judged to be excellent with an *Award of Excellence*. The most worthy application, if any, wins the *Annual Award* for the category. The Institute announces winners of Awards in December.

Award Advisory Board

Award Advisory Board (AAB) provides advice on all aspects of the Award program. The board consists of representatives of organizations that hold important roles in or related to the research enterprise, such as, research sponsors/funders, researchers/research institutions, human research protection professionals, research study participants, consumer or research participant advocates, and voluntary associations concerned with health care, diseases, treatments, and research. In addition, federal government liaisons serve as ex-officio representatives.

Award Steering Committee

Award Steering Committee (ASC) provides advice and feedback to the Award program coordinator and staff on operational matters, such as appointing members to implementing committees, improving the Award program structures, establishing policies and procedures, and drafting Award program materials.



Judges Credentialing Committee

The Institute invites and accepts applications to serve on the Judges Credentialing Committee (JCC) throughout the year. Members of Award Steering Committee evaluate applicants' qualifications against established JCC credentialing criteria. If credentialed, applicants serve on JCC to evaluate applications to become a judge for the Award program.

Who may apply?

Any institution or investigator who conducts research involving human beings, including medical and social science research, or who contributes to human research protection, is eligible to apply for an award; self-nomination is acceptable. We welcome applications from outside of the USA. Please refer to individual Award categories for specific eligibility criteria.

Entry deadline

Applications for a 2010 Award must be *received* by the Institute on or before September 27, 2010.

Entry fee

There is no fee for entering the Award competition.

Instructions for applying for an award

Please follow these steps:

- ❑ Determine for which Award you want to apply. *You may apply for any or all Award categories for any number of best practices or innovations, and/or nominate as many people as you like for the life-time achievement award. Self nomination is also acceptable.*
- ❑ Review the criteria for the Award to determine if you/your institution is eligible to apply. *Please do not hesitate to submit an application if you believe that a practice, innovation, or sum of life-time achievements meets or exceeds Award criteria.*
- ❑ Complete the Application Cover/Information Sheet or provide the required information in a word-processed document; key information to item numbers. See pages 1 and 2 of the application.
- ❑ Complete and sign the Attestation/Signature Page.

Note: The applicant must sign this form. You must complete a separate Application Cover/Information Sheet and Attestation/Signature Page for each Award for which you are applying. For example, if you are submitting 3 best practices, you must submit a complete and separate application for each one, including separate Application Cover/ Information Sheet and Attestation/Signature Page.

- ❑ On a word-processed document, answer each of the application questions for the award (listed on this document). Number sequentially each page of the application. The application form and attestation page are pages 1-3; answers to questions then begin on page 4. You may sequentially number "attachments" within each one (e.g., 1.1, 1.2, ... 2.1, 2.2, ... etc). Provide the following information, in the order listed, on each page of the application (and at least the first page of any "attachments"):
 - Award and year, for which you are applying (e.g., "AEHRP, Best Practice, 2008")
 - Name of applicant and affiliated organization (e.g., "A. Jones, XYZ Research Institute").



- ❑ Provide complete yet concise answers to questions. State the question number and its short title; then provide answers. There are no page restrictions on applications. Generally, limit responses to individual questions to a single word-processed page.
- ❑ Use standard paper (e.g., in USA, 8-1/2"x11"; elsewhere, A4). Single-space responses. Use 1" (2.5 cm) margins all around (top/bottom; left/right). Use an appropriate type face and size, such as Times Roman or Univers 12 point. If "Attachments" are existing documents, there is no need to rekey or reprint them to conform to our standards; we'll accept them as they are (at applicant's risk for legibility).
- ❑ Attach any flowcharts, diagrams, tables, forms, etc, that support or supplement responses; label attachments sequentially and key them to questions. If relevant reports have been published (e.g., describing or evaluating a 'best practice'), please reference them, and attach a copy of each such report.
- ❑ *All applications, including attachments to be considered, must be in English.*
- ❑ Submit the original application and 6 copies (7 sets of hardcopy), plus a floppy disc or CD containing any WORD or PDF file you would like to be considered.
- ❑ All entries must be sent to the Institute prepaid, and received by the application deadline.

Contents of rest of packet

- Criteria/questions for
 - Best practice award ... 5 ~ 6
 - Innovation award ... 7
 - Lifetime achievement award ... 8
- Application Cover Sheet ... 9 ~ 10
- Attestation/Signature Page ... 11

For additional information, please visit www.hii.org, or call the Awards Coordinator at 301-320-0965, or send an email to hii@hii.org.

Health Improvement Institute

The Institute is a tax-exempt, 501(c)3 research and educational organization that gives national awards, conducts forums on emerging treatments, and undertakes other programs toward fulfilling its mission of enabling informed health care decision-making.

Award for Excellence in Human Research Protection

Best Practice Judging Criteria

The Annual Award for Best Practice will be given each year to the entry, if any, that judges consider most worthy of the award. Other entries may receive an Award of Excellence or Certificate of Merit based on judges' assessments. Criteria for evaluating applications for the Award are as follows.

Documented evidence that the practice submitted for an Award:

- Protects or contributes toward the protection of human subjects of research
- Is the best way, one of the best ways, or a proven way to achieve, or to contribute toward achieving, the protection that is the specified purpose of the practice (which is thus worthy of adoption by others)
- Meets or exceeds human research protection requirements (i.e., has tangible positive impact)
- If applicable, illustrates the use of quality assurance (including compliance self-assessment) methods and/or continuous quality improvement (CQI) principles to develop, check, or prove that a practice is the best practice
- Is replicable and can be (or has been) widely adopted or adapted
- Demonstrates leadership by example.

Questions to be answered by applicant

Q.1. Practice: What is the best practice for which you are applying for the Award? Please describe it in relevant details (e.g., purpose, objectives, methods, monitoring). If applicable, provide flowcharts, diagrams, etc. Note the institutions at which it is being used currently. If the best practice is embedded in, or is a document or product, please reference it, and provide a copy or, if not practical, provide the link to a website where it can be viewed.

Q.2. Genesis: What was the genesis of the practice? Please describe briefly any events that led to the redesign of an existing or the establishment of this new practice. For example, was the need for the practice identified by compliance self-assessment or continuous quality improvement (CQI) activities? If so, briefly describe the CQI activity that identified the need to redesign an existing or to establish this new practice.

Q.3. Experience: When was this redesigned or new practice first established, introduced, or implemented? If the practice has evolved over time, (e.g., as a result of CQI activities) please state the month and year the practice was first introduced. How successfully has the practice been implemented?

Q.4. Compliance: What human research protection regulations, accreditation standards, or institutional policies does the practice satisfy or address? Specify them by source and reference number, if any, and describe them briefly. Describe how the practice is consistent with these regulations, etc, and their intent. If the practice exceeds minimum regulatory requirements, describe in what ways.

Q.5. Protection of human subjects: How does the practice achieve or contribute toward the achievement of the protection of human subjects? To the extent applicable, document how it demonstrates a commitment by the institution to creating and/or maintaining a culture that exemplifies the central principles of humanity as a fundamental element of the research enterprise and to the welfare of research subjects, patients, and consumers.

Q.6. Monitoring and evaluation/outcomes: What monitoring and/or evaluation is ongoing and/or has been completed to demonstrate the practice's effectiveness (including its sustainability) and/or its efficiency (including costs and burdens placed on research participants) compared to other effective

Award for Excellence in Human Research Protection

practices? If the institution monitors or evaluates the practice periodically, specify how often. Describe who performed the evaluation, methods, results to date (i.e., in the last 5 years), and any changes to the practice stemming from monitoring its cost and/or effectiveness (in terms of achieving the practice's objectives and the protection of human subjects). What comparative (benchmarking) assessments have been conducted that suggest the practice is a "best practice?" If benchmarked, describe who conducted the assessment, assessment methods, results, and any changes to the practice consequently. Describe the evidence that the practice actually assures or improves the protection of human research subjects.

Q.7. Innovation: In what ways, if any, is the practice innovative? For example, does the practice focus attention on a protection that is generally not undertaken? Does it provide a novel way of meeting an accepted requirement?

Q.8. Replicability: What types of institutions could adopt or adapt this practice? How adoptable or adaptable is it by these institutions? Describe what efforts, if any, are being or have been made to disseminate the practice and/or to provide technical assistance to other institutions interested in adopting or adapting it. If applicable, describe the required circumstances (e.g., institutional environment) and personnel, financial, and other resources necessary to replicate (i.e., plan, establish, implement, and monitor) the practice at another institution.

Q.9. Justification for Award: Why should this practice receive an Award of excellence and be judged a "best practice?" How does it demonstrate leadership by example? Summarize the main points made above. Add any others necessary to convince judges that this practice should receive this year's Award.

Award for Excellence in Human Research Protection

Innovation Judging Criteria

The Annual Award for Innovation will be given each year to the entry, if any, that judges consider most worthy of the Award. Other entries may receive an Award of Excellence or Certificate of Merit based on judges' assessments. Criteria for evaluating applications for the Award are as follows.

Report of work completed within the past 5 years that demonstrates:

- Innovation in or novel approach to the protection of human research subjects, including, for example, one that focused attention on the importance of protecting, shaped debate or advanced knowledge regarding how to protect human subjects of research
- Significant contribution, for example, to delineating the principles of, identifying the scope and/or criteria for, recognizing gaps in, providing potential solutions for, implementing program for and/or to improve, distinguishing and/or designing programs to determine best practices regarding, the protection of human subjects of research
- Material impact, for example, on public or professional opinion and/or debate, government regulations and/or initiatives, research institution policies and/or procedures (including continuous quality improvement programs), and/or human research protection realized in practice.

Note: The report may have been written by the nominee, a journalist reporting the nominee's work, or the nominee with a professional writer. A published research report (or one in press) that advances thinking about and/or knowledge regarding the protection of human subjects of research is eligible for the Award.

Questions to be answered by applicant

Q.1. Publication: Where and when was the (report of the) innovation published? Please provide one or more citations to published work, preferably in Index Medicus style; attach a copy of the article. Submit up to 3 articles regarding the innovation. If the innovation is embedded in, or is a document or product, please reference it, and provide a copy or, if not practical, provide the link to a website where it can be viewed.

Q.2. Innovation: What is the innovation for which you are seeking the Award? Please describe it completely yet concisely. Mention particularly to what the innovation pertained, for example, enriched understanding of, raised visibility of, shaped the debate regarding, advanced knowledge about, offered reforms and/or increased awareness of requirements for human research protection, and/or how to meet these requirements, including, for example, how to improve programs and activities intended to protect human subjects of research.

Q.3. Significance/contribution: What is the innovation's significance? How does (or did) it contribute toward protecting or advancing the protection of human subjects of research?

Q.4. Impact: What has been the innovation's impact to date? If the impact has been measured or evaluated, how was it measured or evaluated? If not measured yet, how could it be measured or evaluated? Please describe impact, in relevant detail, for example, on the public, health care researchers and/or practitioners, research institutions, research subjects, sponsors, and government; in such terms as programs, funding, policies, procedures, practices, knowledge, skills, attitudes, and/or motivation. Substantiate impact with reference to published reports. Please attach a copy of completed evaluations and/or any other evidence of the innovation's adoption and/or its effectiveness in protecting or advancing the protection of human subjects of research.

Award for Excellence in Human Research Protection

Q.5. Role: Who were the innovators (i.e., the people who created or made the innovation for which you are applying for an Award)? What were individuals' roles in the innovation (e.g., design, implementation, communication, dissemination)? Please describe in relevant details. If applicable, refer to published reports.

Q.6. Justification for Award: Why should the reported thinking, research, action, etc, be considered innovative? How does it demonstrate leadership in protecting or advancing the well-being of people who participate in research? Summarize the main points made above. Add any others necessary to convince judges that this innovation should receive this year's Award.

Award for Excellence in Human Research Protection

Lifetime Achievement Judging Criteria

The Annual Award for Lifetime Achievement will be given each year to the entry, if any, that judges consider most worthy of the Award. Other entries may receive an Award of Excellence or Certificate of Merit based on judges' assessments. Criteria for evaluating application for the Award are as follows.

Documented evidence that the nominee:

- Has worked consistently and steadfastly to assure and/or to improve the protection of human subjects of research over a continuous period of at least 20 years
- Has made one or more outstanding contributions, or a series of significant contributions, to advance, to promote, or to assure, and/or improve, the protection of human subjects of research
- Whose work has had a demonstrable impact on protecting, advancing, and/or promoting the protection of human subjects of research, and/or has had far-reaching influence on assuring or improving such protection
- Has led or inspired the advancement of human research protection by example.

Note: The nominee must be alive at the time of the application, but need not be currently active professionally. Self-nomination and nomination by someone other than the nominee are both acceptable.

Questions to be answered about nominee

Q.1. Curriculum vitae: What positions did the nominee hold and/or what work did he or she perform during his or her professional career relevant to the protection of human subjects of research? Please provide a list of relevant positions (and when held) and/or work completed (and when done). For each listed position/work, please describe briefly its relevance, and, if applicable, the contribution made, to the protection of human subjects of research. If available, please attach the nominee's curriculum vitae. If the nominee has received awards for his/her work in human research protection, please list them and summarize the award citation (accomplishments underlying each award). Up to 3 references or letters of recommendation may be included but are not necessary; they cannot be a substitute for complete yet concise answers to questions.

Q.2. Contribution/Impact: What outstanding, and/or what series of significant, contributions (such as the introduction of or improvement to policies, procedures, and practices) has the nominee made to advance, to promote, or to assure and/or improve the protection of human research subjects? When, or over what period, were they made? Please describe each contribution, or series of contributions, in relevant detail. Please focus on contributions' impact or influence, for example, in terms of assuring and/or improving human research protection or guiding other people to do so. The focus of this question is the contributions that the nominee has made, and their impact (in contrast to Q.1., in which the focus is on showing that the nominee has worked continuously and steadfastly to assure or improve the protection of human subjects of research).

Q.3. Leadership: How has the nominee demonstrated leadership by example in advancing, promoting, assuring, and/or improving the protection of human subjects of research? How has he or she inspired others to do so? Please highlight the nominee's actions, who they influenced, how they were influenced, and to what effect.

Q.4. Justification for Award: Why should this nominee receive the Lifetime Achievement Award? How did the nominee demonstrate leadership by example? How does the nominee's career and/or the nominee's accomplishments demonstrate his or her dedication to human research protection? Summarize the main points made above. Add any others necessary to convince judges that this nominee should receive this year's Award.

Award for Excellence in Human Research Protection
2010 Application for Award

Contact information:

Name: _____

Position/Title: _____

Organization: _____

Address: _____

City: _____ State: _____

Zip Code: _____ Telephone: _____

Fax: _____ Email: _____

Award for which applying

I/We are applying for the following award (check one):

- Best Practice Innovation Lifetime Achievement

If applying for Best Practice Award: Is the best practice currently in use at the applicant's institution?

- Yes No Not sure. Is it currently in use at any other institutions? Yes No Not sure.

If applying for Innovation Award: Has the innovation been adopted (is it currently in use at the applicant's institution or elsewhere)? Yes No Not sure.

If applying for Best Practice Award or Innovation Award: Which of the following categories best characterizes the area of human research protection (HRP) practice or innovation?

- | | |
|--|--|
| <input type="checkbox"/> Institutional responsibilities (for HRP), including, e.g., oversight, priorities | <input type="checkbox"/> Participation of populations affected by research in its design and/or evaluation |
| <input type="checkbox"/> Conflict of interest management | <input type="checkbox"/> Relationships with external organizations, compliance, accreditation, etc |
| <input type="checkbox"/> Education/training of investigators regarding HRP | <input type="checkbox"/> Development/application of HRP regulations, requirements, etc |
| <input type="checkbox"/> Scientific adequacy/integrity | <input type="checkbox"/> Development/training of professionals for HRP field |
| <input type="checkbox"/> IRB structure/operations (evaluation and monitoring of research proposals and studies) | <input type="checkbox"/> Development/use of tools (forms, publications, etc), software, systems |
| <input type="checkbox"/> Evaluation of risks/benefits, and their distribution, including, e.g., selection/recruitment of subjects, privacy/confidentiality | <input type="checkbox"/> Funding for HRP |
| <input type="checkbox"/> Informed consent process/documentation | <input type="checkbox"/> Information for participants/public |
| <input type="checkbox"/> QA/QI/Continuous quality improvement | <input type="checkbox"/> Other, specify below: |

**Award for Excellence in Human Research Protection
2010 Application for Award - Continued**

Please select one category in each column:

Applicant's present organization:

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

Present role in research enterprise:

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

Answers to questions

Please attach word-processed answers to the questions for the Award for which you are applying, according to the instructions in the application packet.

Award for Excellence in Human Research Protection **Attestation/Signature Page**

Release

By submitting this application, I affirm that I have examined the application for an Award, including any "attachments," and certify that:

- The information submitted is truthful, and that nothing has been omitted that would cast doubt on the truthfulness of the materials submitted.
- None of the information included in the application, including any "attachments," is confidential, proprietary, or trade secret.
- I am authorized, and/or have permission, to disclose the information in this application and to authorize Health Improvement Institute to use all of the information it contains in the Institute's programs, including, but not limited to, use in publicity, marketing, workshops, and publications, whether or not I/we receive an Award.
- I release Health Improvement Institute, its directors, officers, and staff from any liability for disclosure of the information contained in this application.
- *Only for Best Practice Award or Innovation Award:* The concept or work presented is original, and it does not infringe on any statutory or consumer law copyright, proprietary right, or any other right of any party.

Attestation

I am submitting this application on behalf of (check only one):

Individual (including self-nomination) "Team" Institution.

If checked "team" or institution: I certify that I am a duly authorized representative of the "team" or institution for purposes of submitting this Award application.

I certify that the Award application, including answers to questions and any "attachments" (such as flowcharts, diagrams, etc), are substantially complete and correct and true in all relevant details.

Signed/date: _____

Printed name: _____

Disclosure policy

Health Improvement Institute will circulate the application to award judges for evaluation. If judges rate the application excellent, it will receive an *Award of Excellence*, and, if the best and most worthy, the *Annual Award* in the category. The Institute will publicize Awards. Such publicity may include release of the applicant's name, affiliation, etc, information in the application, and answers to questions, in whole or in part, including any information in "attachments." The Institute may use any or all of the information in the application, whether or not the applicant received an *Award of Excellence*, for program purposes, including, but not necessarily limited to, publicity, marketing, workshops, and publications. The Institute does not release the name of applicants who did not receive an *Award of Excellence* or *Certificate of Merit*, unless the applicant agrees or such release is required by law.

Awards

Volunteer judges evaluate answers to Award questions submitted in the application for an Award against established criteria. Health Improvement Institute recognizes applications judged to be meritorious with a *Certificate of Merit*. Applications judged to be excellent receive an *Award of Excellence*; recipients receive a certificate and may purchase a plaque. The most worthy entry, if any, wins the *Annual Award* for the category; the winner receives a certificate and plaque proclaiming the Award. Winners of the *Award of Excellence* and the *Annual Award* may use the

Award for Excellence in Human Research Protection
2010 Application for Award - Continued

Award logo on their website, in print, and other media. The Institute's decision about giving an Award and the level of the Award given is final.