

DATA AND COLLECTION INSTRUMENTS FOR

EVALUATION OF OHRP EDUCATIONAL ACTIVITIES

Submitted by

Division of Education and Development
Office for Human Research Protections
Rockville, MD

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INSTRUMENT C: Initial Assessment Survey

(Audience: Attendees at OHRP Educational Events where general information about OHRP is provided)

INSTRUMENT C: Initial Assessment Survey

Dear Participant:

The educational event you are attending is funded by the Office for Human Research Protections (OHRP), Division of Education and Development. OHRP is engaged in:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or -supported human subject research;
- developing, monitoring, and exercising compliance oversight of HHS regulations for protection of human subjects
- providing clarification and guidance on involving humans in research;
- developing and implementing educational programs and resource materials; and
- promoting the development of approaches to enhance human subject protections.

Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

OHRP intends to use the information gathered from this form to improve the quality of these events.

Please return the completed form to the place designated by the event staff.

Thank you, your help is appreciated.

INSTRUMENT C: Initial Assessment Survey

Answer questions by checking the box or circle corresponding to the appropriate choice.

A. EDUCATIONAL EVENT EVALUATION

A1. Please indicate the degree to which you agree with the following statements about the OHRP education event you just attended. If the event included more than one presenter and/or program, please give the average rating for the entire event.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The topics were well-organized.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The depth of topic coverage was excellent.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The breadth of topic coverage was excellent.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In general, the presenter(s) was effective (e.g. knowledgeable, responsive, interesting, and used appropriate instructional techniques)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall the program(s) was of high quality.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training environment (temperature, acoustics, etc.) was comfortable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The content covered is relevant to my current job.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The difficulty level of the materials was appropriate to my knowledge level.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
For the amount of material covered, the session length was appropriate.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Overall, the OHRP educational event was effective.	○	○	○	○	○
I would recommend this educational event to colleagues with roles similar to mine in human research protections.	○	○	○	○	○

A2. What was your main reason for attending this OHRP educational event? **(Mark only one)**

- I wanted to learn straight from OHRP
- I wanted to obtain CMEs/CEUs
- My attendance was required by my institution
- I wanted to gain knowledge and develop my skills
- Other, specify: _____

A3. What type of OHRP educational activities have you attended or utilized in the past twelve months (aside from the current training)? **(Mark all that apply)**

- I have not participated in any other OHRP educational event in the past twelve months
- OHRP national conference (comprehensive two-day program)
- OHRP Regional Community Forum (one-day program)
- Presentation (OHRP staff participate in conferences, workshops and seminars sponsored by institutions, professional associations, private industry, patient advocacy groups and the federal government)
- Staff training workshop (OHRP staff train institution staff in human research protections)
- Quality assurance and quality improvement activity (OHRP staff conduct consultations with a host institution to improve the quality of human research protections program)
- Website (the OHRP website provides numerous resources regarding human research protections)
- On-line tutorial (an online module describing written assurances of human subject protections for Institutional Officials, IRB Administrator and IRB Chairs)
- Other, specify: _____

B. EXPECTED IMPROVEMENTS IN PRACTICE

B1. Were the following topics covered at the Educational Event and if they were, was your understanding of the topic improved as a result of the event?

	Topic Covered at Educational Event	If the topic was covered, please indicate the extent to which the OHRP educational event improved your understanding of the topic.			
		Improved Greatly	Improved Somewhat	Did Not Improve	Don't Know
History and ethical foundations of human subject protections	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
HHS regulations overview (45 CFR 46)	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Definition of human subjects research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Determining exempt research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Engagement in human subjects research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Composition of IRB (membership)	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB review: Initial review	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB review: Continuing review	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB review: Expedited review	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Policies and Procedures/Minutes/Records	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Informed consent	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Waivers of Informed Consent	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Documentation of Informed Consent	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Requirements for Emergency Research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Identifying Conflicts of Interest	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reporting unanticipated problems/adverse events	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Topic Covered at Educational Event	If the topic was covered, please indicate the extent to which the OHRP educational event improved your understanding of the topic.			
		Improved Greatly	Improved Somewhat	Did Not Improve	Don't Know
Noncompliance	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Federal Wide Assurance	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving coded private information	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving biological specimens, storage/repositories	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving data and data storage	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pregnant women and fetuses in research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prisoners in research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Children in research	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other vulnerable populations	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Privacy/Confidentiality issues	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
International research involving human subjects	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP Quality Improvement Activities	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP Activities Update	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____ _____	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____ _____	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B2. Think about the topics you just rated and please indicate the extent to which you agree with the following statements:

Participating in this OHRP educational event ...	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
... increased my awareness of issues surrounding human research protections.	○	○	○	○	○
...increased my interest in the subject matter.	○	○	○	○	○
... helped me to consider how I/my institution can improve human research protections.	○	○	○	○	○

B3. What was the single best section of the OHRP educational event?

B4. What was the greatest weakness with the OHRP educational event?

B5. What changes to the OHRP educational event would you recommend for future similar events?

B6. Would you recommend this OHRP educational event to others?

- Yes
- No, please explain:

C. PLEASE TELL US ABOUT YOURSELF

C1. What is your sex/gender?

- Male Female

C2. What is your ethnicity? **(Mark all that apply):**

- American Indian or Alaska Native Native Hawaiian or Other Pacific Islander
 Asian White
 Black or African American Other (Specify) _____
 Hispanic or Latino

C3. How old are you? ____

C4. What is your highest educational degree?

- High school
 Associate’s degree
 Some college
 Bachelor’s degree
 Master’s degree
 M.D.
 J.D.
 Other doctoral degree (Ph.D, Psy.D., Sc.D., etc.)
 Other, specify: _____

C5. What type of institution(s) do you work for? **(Mark all that apply)**

- Hospital
 Academic medical center
 University
 Private practice
 Research institute
 Other, specify:
-

C6. What type of human research is conducted in your institution? **(Mark all that apply)**

- Biomedical
 - Social/behavioral
 - None
 - Other, specify:
-

C7. For how many years have you been involved with human research?

- None
- Less than 1
- 1-4 years
- 5-9 years
- 10-14 years
- 15-20 years
- 20+ years

C8. How would you rate your depth of knowledge of human research protections?

- Very limited
- Elementary knowledge of regulations/principles
- Advanced knowledge in **some** areas of regulations/principles
- Advanced knowledge in **most** areas of regulations/principles

C9. Which of the following describes your current professional position(s)? **(Mark all that apply)**

- Faculty
 - Principal investigator
 - Research staff
 - IRB member, staff, administrator or chair
 - Institutional official
 - Compliance officer
 - Legal counsel
 - Clinical staff (nursing, other)
 - Physician
 - Administration
 - Public health official
 - Patient advocate
 - Student
 - Other, specify:
-

**C10. What is your primary role in human research protections at your institution?
(Please select only one primary role)**

- Institutional official (Assurance Signatory Official)
- Sponsor agency program official
- Institutional Review Board staff
- Institutional Review Board administrator/manager
- Institutional Review Board chair
- Institutional Review Board member

If you are an IRB Board member, which of the following do you represent on the board: **(Mark only one)**

- Scientific member
- Nonscientific member
- Non-affiliated member
- Don't know
- Principal investigator or co-investigator
- Research coordinator/data collection staff
- No active Role
- Other, specify: _____

THANK YOU FOR YOUR TIME!

INSTRUMENT C Mod: Initial Assessment Survey

(Audience: Attendees at OHRP Educational Events where education on a specific topic area related to OHRP activities is provided. Slight modification of Instrument C – 6.requests for ratings on general topics are excluded)

Dear Participant:

The educational event you are attending is funded by the Office for Human Research Protections (OHRP), Division of Education and Development. OHRP is engaged in:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or -supported human subject research;
- providing clarification and guidance on involving humans in research;
- developing and implementing educational programs and resource materials; and
- promoting the development of approaches to enhance human subject protections.

Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

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Please return the completed form to the place designated by the event staff.

Thank you, your help is appreciated.

INSTRUMENT C_MOD Initial Assessment Survey

Answer questions by checking the box or circle corresponding to the appropriate choice.

A. EDUCATIONAL EVENT EVALUATION

A1. Please indicate the degree to which you agree with the following statements about the OHRP education event you just attended. If the event included more than one presenter and/or program, please give the average rating for the entire event.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The topics were well-organized.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The depth of topic coverage was excellent.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The breadth of topic coverage was excellent.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In general, the presenter(s) was effective (e.g. knowledgeable, responsive, interesting, and used appropriate instructional techniques)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall the program(s) was of high quality.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training environment (temperature, acoustics, etc.) was comfortable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The content covered is relevant to my current job.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The difficulty level of the materials was appropriate to my knowledge level.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
For the amount of material covered, the session length was appropriate.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Overall, the OHRP educational event was effective.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would recommend this educational event to colleagues with roles similar to mine in human research protections.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

A2. What was your main reason for attending this OHRP educational event? (**Mark only one**)

- I wanted to learn straight from OHRP
- My attendance was required by my institution
- I wanted to gain knowledge and develop my skills
- Other, specify: _____

A3. What type of OHRP educational activities have you attended or utilized in the past twelve months (aside from the current training)? (**Mark all that apply**)

- I have not participated in any other OHRP educational event in the past twelve months
- OHRP national conference (comprehensive two-day program)
- OHRP Regional Community Forum (one-day program)
- Presentation (OHRP staff participate in conferences, workshops and seminars sponsored by institutions, professional associations, private industry, patient advocacy groups and the federal government)
- Staff training workshop (OHRP staff train institution staff in human research protections)
- Quality assurance and quality improvement activity (OHRP staff conduct consultations with a host institution to improve the quality of human research protections program)
- Website (the OHRP website provides numerous resources regarding human research protections)
- On-line tutorial (an online module describing written assurances of human subject protections for Institutional Officials, IRB Administrator and IRB Chairs)
- Other, specify: _____

B1. Please indicate the extent to which you agree with the following statements:

Participating in this OHRP educational event ...	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
... increased my awareness of issues surrounding human research protections.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...increased my interest in the subject matter.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
... helped me to consider how I/my institution can improve human research protections.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B2. What was the single best section of the OHRP educational event?

B3. What was the greatest weakness with the OHRP educational event?

B4. What changes to the OHRP educational event would you recommend for future similar events?

B5. Would you recommend this OHRP educational event to others?

Yes

No, please explain:

C6. What type of human research is conducted in your institution? (**Mark all that apply**)

- Biomedical
 - Social/behavioral
 - None
 - Other, specify:
-

C7. For how many years have you been involved with human research?

- None
- Less than 1
- 1-4 years
- 5-9 years
- 10-14 years
- 15-20 years
- 20+ years

C8. How would you rate your depth of knowledge of human research protections?

- Very limited
- Elementary knowledge of regulations/principles
- Advanced knowledge in **some** areas of regulations/principles
- Advanced knowledge in **most** areas of regulations/principles

C9. Which of the following describes your current professional position(s)? (**Mark all that apply**)

- Faculty
 - Principal investigator
 - Research staff
 - IRB member, staff, administrator or chair
 - Institutional official
 - Compliance officer
 - Legal counsel
 - Clinical staff (nursing, other)
 - Physician
 - Administration
 - Public health official
 - Patient advocate
 - Student
 - Other, specify:
-

C10. What is your primary role in human research protections at your institution?
(Please select only one primary role)

- Institutional official (Assurance Signatory Official)
- Sponsor agency program official
- Institutional Review Board staff
- Institutional Review Board administrator/manager
- Institutional Review Board chair
- Institutional Review Board member

If you are an IRB Board member, which of the following do you represent on the board: **(Mark only one)**

- Scientific member
 - Nonscientific member
 - Non-affiliated member
 - Don't know
- Principal investigator or co-investigator
 - Research coordinator/data collection staff
 - No active Role
 - Other, specify: _____

THANK YOU FOR YOUR TIME!

INSTRUMENT D: Follow-up Assessment Survey

(Audience: Attendees at OHRP Educational Events where general information about OHRP was provided)

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including time for reviewing instructions and completing the feedback form. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, can be sent to [OHRP Clearance Officer; Paperwork Reduction Project (OMB #)]; Address. An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is #####.

Dear Participant:

You attended an Office for Human Research Protections (OHRP) educational event approximately three to six months ago, and feedback on the event content was requested at that time. Now that some time has passed, we would again appreciate your feedback on this educational event. We are particularly interested in whether you have been able to *apply the knowledge gained* from that course to your daily routine practices related to human research protections.

OHRP intends to use the information gathered from this effort to improve the quality of their educational events.

Please provide your feedback by completing the form at the following web site: http://_____. You may access the site either by pressing ctrl+ enter or by copying the web address and placing it in your browser. Completion of the form will take approximately six minutes and is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

Thank you, your help is appreciated.

INSTRUMENT D: Follow-up Assessment Survey

Answer questions by checking the box or circle corresponding to the appropriate choice.

A. EVENT ATTENDED

Location of the OHRP educational event

Host institution: _____

Title: _____

City: _____

State: _____

Date of the OHRP educational event

__ __ / __ __ / __ __
MM DD YY

(Filled out in advance)

**A1. Did you complete OHRP's Initial Assessment Survey at the time of the event?
(Mark only one)**

- Yes
- No
- Don't know

B. FOLLOW-UP ASSESSMENT

B1. Please indicate the degree to which you agree with the following statements:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The OHRP educational event was relevant to my current job.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall, the OHRP educational event was effective.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Participating in the OHRP educational event improved my ability to carry out human research protections.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

C. RECENT IMPROVEMENTS IN PRACTICE

C1. The following is a list of human research protection practices; did you make any changes in the below practices as a result of the OHRP educational event?

	Changes Made	No Change Made	Not Applicable	Don't Know
Application of Threshold Regulatory Definitions (i.e., “research” “human subjects” “engagement”)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Processing and Determining Exempt Research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Process, Content, and Documentation of IRB Review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Informed Consent Process	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reporting Unanticipated Problems and Noncompliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Determining status and procedures related to research involving biological specimens and data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Changes Made	No Change Made	Not Applicable	Don't Know
Application of Subpart B	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Application of Subpart C	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Application of Subpart D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Institutional Policies and Procedures for Human Subject Protections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____ _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

D. ENABLING AND CONSTRAINING FACTORS

D1. Which of the following factors have enabled or constrained your ability to make changes in your practices related to human research protections following the OHRP educational event?

	ENABLED CHANGE (mark all that apply)	NEUTRAL	CONSTRAINED CHANGE (mark all that apply)
The attitudes of your institution's human research protections leadership.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The amount of funding available for your institution's human research protections program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The knowledge gained at the OHRP educational event.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The degree of support from peers in your institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The level of staffing available for your institution's human	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	ENABLED CHANGE (mark all that apply)	NEUTRAL	CONSTRAINED CHANGE (mark all that apply)
research protections program.			
The amount of time available to make changes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, Specify: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D2. Please list any additional comments regarding factors that have enabled or constrained your ability to make changes in your practices related to human research protections:

D3. What do you remember best about the OHRP Educational event?

E7. For how many years have you been involved with human research?

- None
- Less than 1
- 1-4 years
- 5-9 years
- 10-14 years
- 15-20 years
- 20+ years

E8. How would you rate your depth of knowledge of human research protections?

- Very limited
- Elementary knowledge of regulations/principles
- Advanced knowledge in **some** areas of regulations/ principles
- Advanced knowledge in **most** areas of regulations/ principles

E9. Which of the following describes your current professional position(s)? **(Mark all that apply)**

- Faculty
 - Principal investigator
 - Research staff
 - IRB member, staff, administrator or chair
 - Institutional official
 - Compliance officer
 - Legal counsel
 - Clinical staff (nursing, other)
 - Physician
 - Administration
 - Public health official
 - Patient advocate
 - Student
 - Other, specify:
-

**E10. What is your primary role in human research protections at your institution?
(Please select only one primary role)**

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- Institutional Review Board administrator/manager
- Institutional Review Board chair
- Institutional Review Board member

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- Scientific member
- Nonscientific member
- Non-affiliated member
- Don't know
- Principal investigator or co-investigator
- Research coordinator/data collection staff
- No active Role
- Other, specify: _____

THANK YOU FOR YOUR TIME!

INSTRUMENT D_Mod: Follow-up Assessment Survey

(Audience: Attendees at OHRP Educational Events where education on a specific topic area related to OHRP activities was provided.)

INSTRUMENT D: Follow-up Assessment Survey

Dear Participant:

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OHRP intends to use the information gathered from this effort to improve the quality of their educational events.

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Thank you, your help is appreciated.

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INSTRUMENT D: Follow-up Assessment Survey

Answer questions by checking the box or circle corresponding to the appropriate choice.

B. EVENT ATTENDED

Location of the OHRP educational event

Host institution: _____

Title: _____

City: _____

State: _____

Date of the OHRP educational event

__ __ / __ __ / __ __
MM DD YY

(Filled out in advance)

A1. Did you complete OHRP's Initial Assessment Survey at the time of the event?
(Mark only one)

- Yes
- No
- Don't know

B. FOLLOW-UP ASSESSMENT

B1. Please indicate the degree to which you agree with the following statements:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The OHRP educational event was relevant to my current job.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall, the OHRP educational event was effective.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Participating in the OHRP educational event improved my ability to carry out human research protections.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

C. RECENT IMPROVEMENTS IN PRACTICE

C1. The following is a list of human research protection practices; did you make any changes in the below practices as a result of the OHRP educational event?

	Changes Made	No Change Made	Not Applicable	Don't Know
Institutional Policies and Procedures for Human Subject Protections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Administration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Membership	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Minutes and Records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____ _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

D. ENABLING AND CONSTRAINING FACTORS

D1. Which of the following factors have enabled or constrained your ability to make changes in your practices related to human research protections following the OHRP educational event?

	ENABLED CHANGE (mark all that apply)	NEUTRAL	CONSTRAINED CHANGE (mark all that apply)
The attitudes of your institution’s human research protections leadership.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The amount of funding available for your institution’s human research protections program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The knowledge gained at the OHRP educational event.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The degree of support from peers in your institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The level of staffing available for your institution’s human research protections program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The amount of time available to make changes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, Specify: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D2. Please list any additional comments regarding factors that have enabled or constrained your ability to make changes in your practices related to human research protections:

D3. What do you remember best about the OHRP Educational event?

E. PLEASE TELL US ABOUT YOURSELF

E1. What is your sex/gender?

- Male
- Female

E2. What is your ethnicity? **(Mark all that apply):**

- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Asian
- White
- Black or African American
- Other (Specify) _____
- Hispanic or Latino

E3. How old are you? ____

E4. What is your highest educational degree?

- High school
- Associate's degree
- Some college
- Bachelor's degree
- Master's degree
- M.D.
- J.D
- Other doctoral degree (Ph.D, Psy.D., Sc.D., etc.)
- Other, specify: _____

E5. What type of institution(s) do you work for?

- Hospital
 - Academic medical center
 - University
 - Private practice
 - Research institute
 - Other, specify:
-

E6. What type of human research is conducted in your institution? (**Mark all that apply**)

- Biomedical
 - Social/behavioral
 - None
 - Other, specify:
-

E7. For how many years have you been involved with human research?

- None
- Less than 1
- 1-4 years
- 5-9 years
- 10-14 years
- 15-20 years
- 20+ years

E8. How would you rate your depth of knowledge of human research protections?

- Very limited
- Elementary knowledge of regulations/principles
- Advanced knowledge in **some** areas of regulations/ principles
- Advanced knowledge in **most** areas of regulations/ principles

E9. Which of the following describes your current professional position(s)? **(Mark all that apply)**

- Faculty
- Principal investigator
- Research staff
- IRB member, staff, administrator or chair
- Institutional official
- Compliance officer
- Legal counsel
- Clinical staff (nursing, other)
- Physician
- Administration
- Public health official
- Patient advocate
- Student
- Other, specify: _____

E10. What is your primary role in human research protections at your institution? **(Please select only one primary role)**

- Institutional official (Assurance Signatory Official)
- Sponsor agency program official
- Institutional Review Board staff
- Institutional Review Board administrator/manager
- Institutional Review Board chair
- Institutional Review Board member

If you are an IRB Board member, which of the following do you represent on the board: **(Mark only one)**

- Scientific member
- Nonscientific member
- Non-affiliated member
- Don't know
- Principal investigator or co-investigator
- Research coordinator/data collection staff
- No active Role
- Other, specify: _____

THANK YOU FOR YOUR TIME!

INSTRUMENT E: Survey of Institution Representatives

(Audience: Individuals who are directly involved in human research protection activities)

Dear Respondent:

The Office for Human Research Protections (OHRP) is engaged in:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or -supported human subject research;
- developing, monitoring, and exercising compliance oversight of HHS regulations for protection of human subjects;
- providing clarification and guidance on involving humans in research;
- developing and implementing educational programs and resource materials; and
- promoting the development of approaches to enhance human subject protections.

Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

OHRP intends to use the information gathered from this form to identify outstanding training needs and to assess the quality of current training activities at the institutional level.

Please return the completed form in the enclosed, self-addressed, stamped envelope.

Thank you, your help is appreciated.

Public reporting burden for this collection of information is estimated to average 6 minutes per response, including time for reviewing instructions and completing the feedback form. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, can be sent to [OHRP Clearance Officer; Paperwork Reduction Project (OMB #)]; Address. An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is #####.

INSTRUMENT E: SURVEY OF INSTITUTION REPRESENTATIVES

Answer questions by checking the box or circle corresponding to the appropriate choice.

A. EDUCATIONAL EXPERIENCE

A1. In fulfilling your human research protections responsibilities, have you used the following education resources? If so, how useful were they?

	Did you use this resource?			<i>If yes, how useful was it?</i>		
	Yes	No	Not Available	Very Useful	Somewhat Useful	Not Useful
Other individuals in my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training developed by my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Handbooks, guidelines, and/or standard operating procedures developed by my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Model consent form(s) or consent form checklist developed by my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Protocol content checklist developed by my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Human research protection guidelines for investigators developed by my institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other written material developed by my institution (specify): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other internal resources (specify): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Books	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Newsletters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Journals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP IRB Guidebook	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP Telephone Consultation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP e-mail box	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
“Investigator 101” CD Rom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other printed material (specify): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Code of Federal Regulations (online)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP website	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FDA website	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Forum (discussion group)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NIH Training Course	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Web resources (specify): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

A2. Please mark all the following activities that apply to you.

I have...

- Led a session at a national or regional meeting/workshop on human research protections (e.g., one sponsored by ARENA, PRIM&R, or SAR).
- Attended a national or regional meeting/workshop on human research protections.
- Served on a national or regional committee related to human research protections.
- Authored a paper or published article on human research protections.
- Submitted a poster session on human research protections.
- Developed training materials and/or SOPs on human subjects protections
- None of the above.

B. FORMAL OHRP EDUCATIONAL ACTIVITIES

B1. OHRP conducts educational activities related to human research protection. Which of the following, if any, OHRP educational activities did you attend or use during the past twelve months? **(Mark all that apply)**

OHRP Educational Activity	Did you attend or use this event/activity?			If yes, how useful was it?		
	Yes	No	N/A	Very Useful	Somewhat Useful	Not Useful
OHRP national conference (comprehensive two-day program)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP Regional Community Forum (one-day program)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Presentation (OHRP staff participate in conferences, workshops and seminars sponsored by institutions, professional associations, private industry, patient advocacy groups and the federal government)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Staff training workshop (OHRP staff train institution staff in human research protections)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality assurance and quality improvement activity (OHRP staff conduct consultations with a host institution to improve the quality of human research protections program)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Website (the OHRP website provides numerous resources regarding human research protections)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
On-line tutorial (an online module describing written assurances of human subject protections for Institutional Officials, IRB Administrator and IRB Chairs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B2. Other than in the past 12 months, have you *ever* participated in OHRP educational activities?

- Yes No

C. OPINIONS ABOUT EDUCATION NEEDS

For questions C1-C3, please share your personal opinions based on your experiences with human research protections.

C1. In your opinion, which audiences at **your institution** are most in need of human research protections education? (**Mark all that apply**)

- Institutional official
- Department chair
- Principal investigator or co-investigator
- Clinical research associates
- Data safety and monitoring committee members
- Institutional Review Board administrator
- Institutional Review Board chair
- Institutional Review Board members
- Institutional Review Board staff
- Research coordinator/data collection staff
- Other members of the research team
- Other, specify: _____
- None – all have adequate training

C2. From your viewpoint, what are the most effective modes for receiving human research protection education? (**Mark up to three**)

- Lecture/presentation
- Seminar, workshop
- Case studies
- Panel discussions
- Videoconference
- Teleconference
- Web-based training
- Multi-media (CDs, DVDs, Videotapes)
- Other, specify: _____

C3. Which of the following factors have enabled or constrained your participation in OHRP educational activities?

	ENABLED PARTICIPATION (mark all that apply)	CONSTRAINED PARTICIPATION (mark all that apply)	N/A or DON'T KNOW
The attitudes of your institution's human research protections leadership.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The amount of funding available for your institution's human research protections program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The level of staffing available for your institution's human research protections program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The amount of time available to make changes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, Specify: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C4. The following are general topics OHRP might include in training. Please rate how important it is to you to receive training on the following topics.

Training Topic	Importance of Topic			
	High	Med	Low	Don't Know
History and ethical foundations of human subject protections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
HHS regulations overview (45 CFR 46)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Definition of human subjects research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Determining exempt research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Engagement in human subjects research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Composition of IRB (membership)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Training Topic	Importance of Topic			
	High	Med	Low	Don't Know
IRB review: Initial review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB review: Continuing review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB review: Expedited review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB Policies and Procedures/Minutes/Records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Informed consent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Waivers of Informed Consent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Documentation of Informed Consent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Requirements for Emergency Research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Identifying Conflicts of Interest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reporting unanticipated problems/adverse events	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Noncompliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Federal Wide Assurance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving coded private information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving biological specimens, storage/repositories	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IRB issues involving data and data storage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pregnant women and fetuses in research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prisoners in research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Children in research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other vulnerable populations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Privacy/Confidentiality issues	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
International research involving human subjects	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Training Topic	Importance of Topic			
	High	Med	Low	Don't Know
OHRP Quality Improvement Activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OHRP Activities Update	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (specify): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

D. PLEASE TELL US ABOUT YOURSELF**D1.** What is your sex/gender?
 Male Female
D2. What is your ethnicity? (**Mark all that apply**):
 American Indian or Alaska Native Native Hawaiian or Other Pacific Islander
 Asian White
 Black or African American Other (Specify) _____
 Hispanic or Latino
D3. How old are you? (**in years**) _____

D4. What is your highest educational degree?

- High school
- Associate's degree
- Some college
- Bachelor's degree
- Master's degree
- M.D.
- J.D.
- Other doctoral degree (Ph.D, Psy.D., Sc.D., etc.)
- Other, specify: _____

D5. What type of institution do you work for?

- Hospital
- Academic medical center
- University
- Private practice
- Research institute
- Other, specify: _____

D6. What type of human research is conducted in your institution? **(Mark all that apply)**

- Biomedical
- Social/behavioral
- Data/specimens
- Epidemiological
- Other, specify: _____

D7. For how many years have you been involved with human research?

- None
- Less than 1
- 1-4 years
- 5-9 years
- 10-14 years
- 15-20 years
- 20+ years

D8. How would you rate your depth of knowledge of human research protections?

- Very limited
- Elementary knowledge of regulations/principles
- Advanced knowledge in **some** areas of regulations/ principles
- Advanced knowledge in **most** areas of regulations/ principles

D9. Which of the following best describes your current professional position? **(Mark all that apply)**

- Faculty
- Principal investigator
- Research staff
- IRB member, staff, administrator or chair
- Institutional official
- Compliance officer
- Legal counsel
- Clinical staff (nursing, other)
- Physician
- Administration
- Public health official
- Patient advocate
- Student
- Other, specify: _____

D10. What is your primary role in human research protections at your institution? **(Please select only one primary role)**

- Institutional official (Assurance Signatory Official)
- Institutional Review Board administrator/manager **(Please answer D11 below)**
- Institutional Review Board chair **(Please answer D12 below)**
- Institutional Review Board member **(Please answer D13 below)**
 - If you are an IRB Board member, which of the following do you represent on the board **(Mark only one)**:
 - Scientific member
 - Nonscientific member
 - Non-affiliated member
 - Don't know
- Principal investigator or co-investigator **(Please answer D14 below)**
- Research coordinator/data collection staff **(Please answer D14 below)**
- Other, specify: _____

Please answer the following questions that pertain to your primary role only. For example, if your primary role is IRB chair, you only need to answer question D12.

D11. If your primary role is Institutional Review Board administrator/manager, please answer the following questions:

a) What is the total number of IRBs you administer? _____

b) We would like you to think back over the most recently completed year. This might be a calendar year, the academic year, or a state- or institutionally-specified fiscal year. If your institution is not annualized, please use calendar year 2004.

In the most recently completed record year, how many protocols were submitted to your IRB for initial review and, if applicable, for determination or confirmation of exempt status?

Number of protocols submitted _____

c) Is this number an actual number or an estimate ? **(Please check one)**

D12. If your primary role is Institutional Review Board chair, please answer the following questions:

a) We would like you to think back over the most recently completed year. This might be a calendar year, the academic year, or a state- or institutionally-specified fiscal year. If your institution is not annualized, please use calendar year 2004.

In the most recently completed record year, how many protocols were submitted to your IRB for initial review, continuing review, and, if applicable, for determination or confirmation of exempt status?

Number of protocols submitted _____

b) Is this number an actual number or an estimate ? **(Please check one)**

D13. If your primary role is Institutional Review Board member, please answer the following question:

a) In total, how many years have you served on this or any other IRB? **(Please include IRB service at other institutions)**

Number of years _____

D14. If your primary role is principal investigator, co-investigator, research coordinator or data collection staff, please answer the following questions:

a) In the past three years, how many research projects with human subjects have you worked on?

Number of projects _____

c) Is this number an actual number or an estimate ? **(Please check one)**

THANK YOU FOR YOUR TIME!

Introductory Letters and Emails

INSTRUMENT C & C_Mod: Initial Assessment Survey

Dear Participant:

The educational event you are attending is funded by the Office for Human Research Protections (OHRP), Division of Education and Development. OHRP is engaged in:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or -supported human subject research;
- developing, monitoring, and exercising compliance oversight of HHS regulations for protection of human subjects;
- providing clarification and guidance on involving humans in research;
- developing and implementing educational programs and resource materials; and
- promoting the development of approaches to enhance human subject protections.

Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

OHRP intends to use the information gathered from this form to improve the quality of these events.

Please return the completed form to the place designated by the event staff.

Thank you, your help is appreciated.

INSTRUMENT D and D_Mod: Follow-up Assessment Survey

Dear Participant:

You attended an Office for Human Research Protections (OHRP) educational event approximately three to six months ago, and feedback on the event content was requested at that time. Now that some time has passed, we would again appreciate your feedback on this educational event. We are particularly interested in whether you have been able to *apply the knowledge gained* from that course to your daily routine practices related to human research protections.

OHRP intends to use the information gathered from this effort to improve the quality of their educational events.

Please provide your feedback by completing the form at the following web site: http://_____. You may access the site either by pressing ctrl+ enter or by copying the web address and placing it in your browser. Completion of the form will take approximately six minutes and is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

Thank you, your help is appreciated.

INSTRUMENT E: Survey of Institution Representatives

Dear Respondent:

The Office for Human Research Protections (OHRP) is engaged in:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or -supported human subject research;
- developing, monitoring, and exercising compliance oversight of HHS regulations for protection of human subjects;
- providing clarification and guidance on involving humans in research;
- developing and implementing educational programs and resource materials; and
- promoting the development of approaches to enhance human subject protections.

Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

OHRP intends to use the information gathered from this form to identify outstanding training needs and to assess the quality of current training activities at the institutional level.

Please return the completed form in the enclosed, self-addressed, stamped envelope.

Thank you, your help is appreciated.

Confidentiality Pledge

As a member of the JBA evaluation team, I recognize the importance of maintaining the confidentiality of data collected and of assuring the right of privacy of persons cooperating in this evaluation activity. To establish safeguards for all involved, I agree to abide by the following principles of conduct:

- 1) All information that is collected by me (or other project team members) from participants is confidential. All participants must be informed that their responses to interviews and survey questions will be kept confidential and are for statistical purposes only. All data (and all copies) are property of the project and are not to be shared with anyone. I will not permit any unauthorized person, including members of my own family, to see any completed documents or forms. I will only discuss information obtained about a respondent with authorized project staff.
- 2) I agree to treat as confidential and proprietary to the evaluation any and all instruments, materials, and documentation provided or accessed during the course of my service on this evaluation activity. I agree not to copy or duplicate any materials without written permission from the Principal Investigator. I agree to safeguard all study materials and to exercise extreme care to protect them from access by unauthorized persons.
- 3) I agree to conduct myself at all times in a manner that will obtain the respect and confidence of all participants and other persons with whom I may come into contact in connection with this project. I agree to report any breach of confidentiality to my supervisor immediately.
- 4) I understand that all data collected for this study are the property of OHRP and will not be used for any purpose without prior written permission

By signing below, I acknowledge that I have read and understand the assurances that will be provided to participants. I understand that I am prohibited by both the law and this agreement from disclosing any confidential information which has been obtained by this study to anyone other than an authorized member of JBA or OHRP. I understand that any willful and knowing disclosure in violation of the Privacy Act of 1974 (5 U.S.C. 552a) is a misdemeanor and is punishable by a fine of up to \$5,000. I agree to abide by the terms of the assurances of confidentiality set forth here.

Staff Name: _____

(PLEASE PRINT)

Signature: _____