DATA AND COLLECTION INSTRUEMENTS 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.

Event Number: YYYY-NNN OMB #########

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.	○	○	○	○	○
The depth of topic coverage was excellent.	○	○	○	○	○
The breadth of topic coverage was excellent.	○	○	○	○	○
In general, the presenter(s) was effective (e.g. knowledgeable, responsive, interesting, and used appropriate instructional techniques)	○	○	○	○	○
Overall the program(s) was of high quality.	○	○	○	○	○
The training environment (temperature, acoustics, etc.) was comfortable.	○	○	○	○	○
The content covered is relevant to my current job.	○	○	○	○	○
The difficulty level of the materials was appropriate to my knowledge level.	○	○	○	○	○
For the amount of material covered, the session length was appropriate.	○	○	○	○	○

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	☐	○	○	○	○
HHS regulations overview (45 CFR 46)	☐	○	○	○	○
Definition of human subjects research	☐	○	○	○	○
Determining exempt research	☐	○	○	○	○
Engagement in human subjects research	☐	○	○	○	○
Composition of IRB (membership)	☐	○	○	○	○
IRB review: Initial review	☐	○	○	○	○
IRB review: Continuing review	☐	○	○	○	○
IRB review: Expedited review	☐	○	○	○	○
IRB Policies and Procedures/Minutes/Records	☐	○	○	○	○
Informed consent	☐	○	○	○	○
Waivers of Informed Consent	☐	○	○	○	○
Documentation of Informed Consent	☐	○	○	○	○
Requirements for Emergency Research	☐	○	○	○	○
Identifying Conflicts of Interest	☐	○	○	○	○
Reporting unanticipated problems/adverse events	☐	○	○	○	○

	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	☐	○	○	○	○
Federal Wide Assurance	☐	○	○	○	○
IRB issues involving coded private information	☐	○	○	○	○
IRB issues involving biological specimens, storage/repositories	☐	○	○	○	○
IRB issues involving data and data storage	☐	○	○	○	○
Pregnant women and fetuses in research	☐	○	○	○	○
Prisoners in research	☐	○	○	○	○
Children in research	☐	○	○	○	○
Other vulnerable populations	☐	○	○	○	○
Privacy/Confidentiality issues	☐	○	○	○	○
International research involving human subjects	☐	○	○	○	○
OHRP Quality Improvement Activities	☐	○	○	○	○
OHRP Activities Update	☐	○	○	○	○
Other (specify): _____ _____	☐	○	○	○	○
Other (specify): _____ _____	☐	○	○	○	○

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

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)**

  - O Scientific member
  - O Nonscientific member
  - O Non-affiliated member
  - O 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:

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- providing clarification and guidance on involving humans in research;
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Completion of the feedback form is voluntary. **All information gathered from the form is anonymous.** No individual responses are reported.

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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.	○	○	○	○	○
The depth of topic coverage was excellent.	○	○	○	○	○
The breadth of topic coverage was excellent.	○	○	○	○	○
In general, the presenter(s) was effective (e.g. knowledgeable, responsive, interesting, and used appropriate instructional techniques)	○	○	○	○	○
Overall the program(s) was of high quality.	○	○	○	○	○
The training environment (temperature, acoustics, etc.) was comfortable.	○	○	○	○	○
The content covered is relevant to my current job.	○	○	○	○	○
The difficulty level of the materials was appropriate to my knowledge level.	○	○	○	○	○
For the amount of material covered, the session length was appropriate.	○	○	○	○	○

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
- ☐ 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)
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- ☐ 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.	○	○	○	○	○
…increased my interest in the subject matter.	○	○	○	○	○
… helped me to consider how I/my institution can improve human research protections.	○	○	○	○	○

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:

_____
_____
_____

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

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)**

  - O Scientific member
  - O Nonscientific member
  - O Non-affiliated member
  - O 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)

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.	○	○	○	○	○
Overall, the OHRP educational event was effective.	○	○	○	○	○
Participating in the OHRP educational event improved my ability to carry out human research protections.	○	○	○	○	○

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")	○	○	○	○
Processing and Determining Exempt Research	○	○	○	○
Process, Content, and Documentation of IRB Review	○	○	○	○
Informed Consent Process	○	○	○	○
Reporting Unanticipated Problems and Noncompliance	○	○	○	○
Determining status and procedures related to research involving biological specimens and data	○	○	○	○

	Changes Made	No Change Made	Not Applicable	Don't Know
Application of Subpart B	○	○	○	○
Application of Subpart C	○	○	○	○
Application of Subpart D	○	○	○	○
Institutional Policies and Procedures for Human Subject Protections	○	○	○	○
Other (specify): _____ _____	○	○	○	○

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.	☐	☐	☐
The amount of funding available for your institution's human research protections program.	☐	☐	☐
The knowledge gained at the OHRP educational event.	☐	☐	☐
The degree of support from peers in your institution.	☐	☐	☐
The level of staffing available for your institution's human	☐	☐	☐

	ENABLED CHANGE (mark all that apply)	NEUTRAL	CONSTRAINED CHANGE (mark all that apply)
research protections program.			
The amount of time available to make changes.	☐	☐	☐
Other, Specify:_____ _____	☐	☐	☐

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

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)**

  - O Scientific member
  - O Nonscientific member
  - O Non-affiliated member
  - O 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:

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.

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.	○	○	○	○	○
Overall, the OHRP educational event was effective.	○	○	○	○	○
Participating in the OHRP educational event improved my ability to carry out human research protections.	○	○	○	○	○

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	○	○	○	○
IRB Administration	○	○	○	○
IRB Membership	○	○	○	○
IRB Minutes and Records	○	○	○	○
Other (specify): _____ _____	○	○	○	○

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.	☐	☐	☐
The amount of funding available for your institution's human research protections program.	☐	☐	☐
The knowledge gained at the OHRP educational event.	☐	☐	☐
The degree of support from peers in your institution.	☐	☐	☐
The level of staffing available for your institution's human research protections program.	☐	☐	☐
The amount of time available to make changes.	☐	☐	☐
Other, Specify:_____ _____	☐	☐	☐

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)**

  - O Scientific member
  - O Nonscientific member
  - O Non-affiliated member
  - O 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.

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?			*If yes,* how useful was it?		
	Yes	**No**	**Not Available**	**Very Useful**	**Somewhat Useful**	**Not Useful**
Other individuals in my institution	☐	☐	☐	○	○	○
Training developed by my institution	☐	☐	☐	○	○	○
Handbooks, guidelines, and/or standard operating procedures developed by my institution	☐	☐	☐	○	○	○
Model consent form(s) or consent form checklist developed by my institution	☐	☐	☐	○	○	○
Protocol content checklist developed by my institution	☐	☐	☐	○	○	○
Human research protection guidelines for investigators developed by my institution	☐	☐	☐	○	○	○
Other written material developed by my institution (specify): _____ _____ _____	☐	☐	☐	○	○	○

Other internal resources (specify): _____ _____ _____	☐	☐	☐		○	○	○
Books	☐	☐	☐		○	○	○
Newsletters	☐	☐	☐		○	○	○
Journals	☐	☐	☐		○	○	○
OHRP IRB Guidebook	☐	☐	☐		○	○	○
OHRP Telephone Consultation	☐	☐	☐		○	○	○
OHRP e-mail box	☐	☐	☐		○	○	○
"Investigator 101" CD Rom	☐	☐	☐		○	○	○
Other printed material (specify): _____ _____ _____	☐	☐	☐		○	○	○
Code of Federal Regulations (online)	☐	☐	☐		○	○	○
OHRP website	☐	☐	☐		○	○	○
FDA website	☐	☐	☐		○	○	○
IRB Forum (discussion group)	☐	☐	☐		○	○	○
NIH Training Course	☐	☐	☐		○	○	○
Other Web resources (specify): _____ _____ _____	☐	☐	☐		○	○	○

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)	☐	☐	☐		○	○	○
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): _____ _____	☐	☐	☐		○	○	○

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.	☐	☐	☐
The amount of funding available for your institution's human research protections program.	☐	☐	☐
The level of staffing available for your institution's human research protections program.	☐	☐	☐
The amount of time available to make changes.	☐	☐	☐
Other, Specify:_____ _____	☐	☐	☐

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	○	○	○	○
HHS regulations overview (45 CFR 46)	○	○	○	○
Definition of human subjects research	○	○	○	○
Determining exempt research	○	○	○	○
Engagement in human subjects research	○	○	○	○
Composition of IRB (membership)	○	○	○	○

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

Training Topic	Importance of Topic			
	High	**Med**	**Low**	**Don't Know**
OHRP Quality Improvement Activities	○	○	○	○
OHRP Activities Update	○	○	○	○
Other (specify): _____ _____	○	○	○	○
Other (specify): _____ _____	○	○	○	○

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)**:
  - o Scientific member
  - o Nonscientific member
  - o Non-affiliated member
  - o 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: _____