

APPENDIX A

Survey Questionnaire

Survey of Investigator Experiences in Human Research



Welcome

Survey of Investigator Experiences in Human Research

The Institute for Social Research is conducting this survey on behalf of schools, colleges, and administrative offices on the Ann Arbor campus to hear from faculty, staff, and students about their experiences conducting human research, including the IRB application process and using eResearch, the types of information and support investigators would like when completing an IRB application, and attitudes about research practices.

To begin the survey, continue to the next page, review the information, and then check the box at the bottom of the page to indicate that you would like to participate.

Next

Consent Form

Survey of Investigator Experiences in Human Research

Invitation and Purpose

- The Institute for Social Research invites your participation in a survey about human subjects research. The survey asks you about how IRBs can better serve their customers in three areas:
 - The application review process and interacting with IRB staff.
 - Supporting the information needs of investigators.
 - Applying ethical practices in the research setting.
- Participation in the survey is an opportunity for you to convey your experiences regarding current research review and approval practices on campus and to represent the views of your community. This research also will serve as a model for other universities.

Procedures

- Your participation and the information you share is voluntary.
- You can skip any question you do not want to answer.
- Your participation will take about 15 minutes.
- You may end your participation at any time.

Risks and Benefits

- There are no risks or benefits to you from participating in this research.
- Your participation may lead to changes in the Ann Arbor campus IRB application and review process.
- Choosing not to participate in this research will not affect you in any way.

Research Findings

- Summary results and recommendations will be prepared and shared with persons associated with the Human Research Protection Program on the Ann Arbor campus, including IRBs, the Office of the Vice President for Research, the Office of Human Research Compliance Review, and the Office of the Executive Vice President for Medical Affairs.
- Access to the microdata is restricted to ISR project staff and will never be shared with others.

Confidentiality

- Your survey responses will be kept privileged and confidential.
- Your individual identity will never be disclosed in any research report.
- Your name will never be shared with anyone.

Your Rights

- Questions about your participation in this research can be directed to James Lepkowski at 936-0021/jimlep@umich.edu.
- Because this research could affect Ann Arbor campus IRB practices, the Flint Institutional Review Board reviewed and approved this research.
- Questions about your rights as a participant in research can be directed to:

May, 2008
Survey of Investigator Experiences in Human Research

Survey Research Center
University of Michigan

Institutional Review Board, Sally Conley
530 French Hall
303 Kearsley Street
Flint, MI 48502-1950
(810) 762-3383 / Email sjconley@umflint.edu

- I have read the consent form and would like to participate.

I. Experiences and Interactions with the IRB

The first set of questions is about your experiences with the Institutional Review Board (IRB) application process and your interactions with the IRB staff.

Several of the questions ask about your most recently approved IRB application where you are the principal investigator (PI) and not another study role like Co-PI. When we refer to your most recently approved application we mean the ORIGINAL application and any changes or requests for additional approval periods you may have made to that application.

A1 - rcontctirb:

First, did you ever CONTACT the IRB about your most recent application—either before or after it was approved—for any reason?

- 1 Yes
- 0 No

A2 - othercontactirb:

Did another study team member ever contact the IRB about your most recent application for any reason?

- 1 Yes
- 0 No
- 5 I am the only study team member
- 8 Don't know

A3 - rtrycontactirb:

Did you ever TRY TO CONTACT the IRB by telephone during normal business hours about your most recent application, but your call was not answered by a person and you did not leave a voicemail?

- 1 Yes
- 0 No

A4 - irbnoanswer:

A4 QUESTION TEXT IF LEGACY=0

Did you ever post a correspondence in eResearch or send an email to the IRB about your most recent application, but the IRB did not respond to your inquiry even though you expected a response?

A4 QUESTION TEXT IF LEGACY=1

Did you ever send an email to the IRB about your most recent application, but the IRB did not respond to your inquiry even though you expected a response?

- 1 Yes
- 0 No

ASK A5 IF A1=1, OTHERWISE GO TO A7

A5:

When you contacted the IRB about your most recent application, was it about:

(Check all that apply)

A5 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

IF LEGACY=1, SKIP CONTACTIRBREASON01-04

- rcontactirbreason01** The meaning of questions/terms in eResearch.
 - rcontactirbreason02** Finding IRB-approved documents in eResearch.
 - rcontactirbreason03** Attaching documents in eResearch.
 - rcontactirbreason04** Technical question about eResearch.
 - rcontactirbreason05** Whether your research needed IRB approval.
 - rcontactirbreason06** The type of IRB review for your research (exempt, expedited, or full board).
 - rcontactirbreason07** Adverse Event (AE) or Otherwise Reportable Incident or Occurrence (ORIO).
 - rcontactirbreason08** Consent forms or the consent process.
 - rcontactirbreason09** Inserting a header or footer into a document (i.e., the fields updated by the IRB after a document is approved).
 - rcontactirbreason10** Following up to a question or request from the IRB.
 - rcontactirbreason11** Update on the status of my application.
 - rcontactirbreason12** Other (*please specify in the box below*) **(rcontactirbother)**
-

A6:

How did you contact the IRB?

(Check all that apply)

A6 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

IF LEGACY=1, SKIP RCONTACTIRBWAY01

rcontactirbway01 Email within eResearch.

rcontactirbway02

IF LEGACY=1 QUESTION TEXT FOR RCONTACTIRBWAY02 = Email.

IF LEGACY=0 QUESTION TEXT FOR RCONTACTIRBWAY02 = Email that originated outside of eResearch.

rcontactirbway04 Telephone.

rcontactirbway05 In person with an appointment.

rcontactirbway06 In person without an appointment.

rcontactirbway07 Other (*please specify*)
(rcontactirbwayother) _____

A7: ASK ALL

Which two ways do you prefer to communicate with the IRB?

(*Check two items*)

ALLOW UP TO 2 SELECTIONS FROM FIRST 7 CHOICES

A7 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

IF LEGACY=1, SKIP COMMUNIPREF01

communipref01 Email within in eResearch.

communipref02

IF LEGACY=1 QUESTION TEXT FOR COMMUNIPREF02 = Email.

IF LEGACY=0 QUESTION TEXT FOR COMMUNIPREF02 = Email that originates
outside

of eResearch.

communipref04 Telephone.

communipref05 In person with an appointment.

communipref06 In person without an appointment.

communipref07 Other (*please specify*) (**communiprefother**)

communipref09 Prefer staff handles communication with the IRB.

communipref08 No preference.

A8 - irbcontactr:

Did the IRB ever contact you about your most recent application—either before or after it was approved—for any reason?

1 Yes

0 No **GO TO QUESTION A10**

A9:

How did the IRB contact you?

(*Check all that apply*)

A9 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

IF LEGACY=1, SKIP IRBCONTRACTRWAY01

irbcontractrway01 Email within eResearch and sent to my regular email inbox.

irbcontractrway02

IF LEGACY=1 QUESTION TEXT FOR IRBCONTACTRWAY02 = Email.

IF LEGACY=0 QUESTION TEXT FOR RBCONTACTRWAY02 = Email that originated outside of eResearch.

irbcontactrway04 Telephoned, left voice mail.

irbcontactrway05 Telephoned, conversation with me by telephone.

irbcontactrway06 Telephoned, conversation with support staff in my area.

irbcontactrway07 Other (*please specify*)

(irbcontactrwayother) _____

A10 – whoentered:

IF LEGACY=1

When preparing your most recent IRB application, who entered information into the application BEFORE IT WAS SUBMITTED to the IRB for review?

IF LEGACY=0

When preparing your most recent IRB application, who entered information into the eResearch application BEFORE IT WAS SUBMITTED to the IRB for review?

- 1 Only I entered the information.
- 2 Only others entered the information.
- 3 Both others and I entered the information.

A11 - whoconsent:

Who drafted consent forms and recruitment materials BEFORE THE APPLICATION WAS SUBMITTED to the IRB for review?

- 1 Only I did.
- 2 Only others did.
- 3 Both others and I did.
- 4 No consent form or recruitment material needed.

IF A1=1, ASK A12a-d; OTHERWISE EVALUATE A13 CHECKPOINT

A12:

Think about ALL OF THE INTERACTIONS you had with the IRB for your most recent application. To what extent do you agree or disagree with each of the following statements?

	Strongly agree (4)	Somewhat agree (3)	Somewhat disagree (2)	Strongly disagree (1)
timelyanswer				
	The IRB staff responded to my questions in a timely manner.			

- knowledgeable** The IRB staff was knowledgeable.
- respectful** The IRB staff treated me respectfully.
- approachable** The IRB staff was approachable.

A13 CHECKPOINT: IF STUDENT=1 ASK A13a-c; OTHERWISE GO TO A14

A13:

The next few questions ask about the faculty advisor for your most recent application. To what extent do you agree or disagree with each of the following statements?

	Strongly agree (4)	Somewh at agree (3)	Somewhat disagree (2)	Strongly disagree (1)
advisorhelp				
	My faculty advisor helped me understand how to use eResearch.			
advisorreview				
	My faculty advisor reviewed my IRB application and gave me comments.			
advisorethics				
	My faculty advisor helped me understand the ethics of conducting research with human subjects.			

ASK ALL

A14 - irbaskchanges:

When your most recent application was **ORIGINALLY** approved, did the IRB approve it without asking you to make changes, or did the IRB approve it **ONLY** after you made changes they requested?

- 0 The IRB **DID NOT** ask me to make any changes. **GO TO QUESTION A18**
- 1 The IRB **DID** ask me to make changes.

A15:

What changes did the IRB ask you to make?

(Check all that apply)

A5 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

irbchangestype01

IF LEGACY=1 QUESTION TEXT FOR IRBCHANGESTYPE01 = Change answers to questions in the application.

IF LEGACY=0 QUESTION TEXT FOR IRBCHANGESTYPE01 = Change answers to questions in the eResearch application.

- irbchangestype02** Disallow a request for an exemption.
- irbchangestype03** Request an exemption.
- irbchangestype04** Submit a consent form.
- irbchangestype05** Change the text in a consent form.
- irbchangestype06** Change the informed consent process.
- irbchangestype07** Add a header or footer to a document (i.e., the fields updated by the IRB after a document is approved).
- irbchangestype08** Submit a questionnaire.
- irbchangestype09** Change the text in a questionnaire.
- irbchangestype10** Submit recruitment material (flyers, newspaper ads, letters, email reminders) or change recruitment material.
- irbchangestype11** Submit oral scripts used in research.
- irbchangestype12** Submit approval notifications from other IRBs.
- irbchangestype13** Submit notices from schools, businesses, or other institutions allowing research to be conducted at these locations.
- irbchangestype14** Complete or renew PEERRS certification.
- irbchangestype15** Clarify or change the use of payments or incentives.
- irbchangestype16** Clarify or change the use of deception.
- irbchangestype17** Other (*please specify in the box below*) **irbchangetypeother** _____

A16 – whochanges:

Who made the changes or additions requested by the IRB? That is, who updated the application or made changes to documents before your application was approved?

- 1 Only I made the changes.
- 2 Only others made the changes.
- 3 Both others and I made the changes.

A17:

Think about ALL THE CHANGES OR ADDITIONS the IRB asked you to make before your recent application was approved. To what extent do you agree or disagree with each of the following statements?

		Strongly agree (4)	Somewhat agree (3)	Somewhat disagree (2)	Strongly disagree (1)
reasonable	Changes requested by the IRB were reasonable.				
clear	Changes requested by the IRB were				

- explained** clear.
Ethical reasons underlying the changes were explained by the IRB.
- improvenext** Changes requested by the IRB will improve my next application.
- suggestions** The IRB gave suggestions on how to improve the research design.
- researchdelay** Time responding to the IRB's requests for changes delayed the start of research.
- researchharder** Changes requested by the IRB made it harder to achieve research goals and objectives.
- betterprotection** Changes requested by the IRB improved the protection of research participants.

A18:

Think about when your recent application was **ORIGINALLY** approved. To what extent do you agree or disagree with each of the following statements?

	Strongly agree (4)	Somewhat agree (3)	Somewhat disagree (2)	Strongly disagree (1)
timelyanswer1 The IRB reviewed the application in a timely manner.				
respectintegrity The IRB respected the integrity of the research.				

A19 - timeapproval:

How many **WEEKS** did it take between the time you submitted the **ORIGINAL** application to the IRB for review and the time it was approved?

Number of weeks

A20 - satisfaction:

Consider **ALL** of the interactions you had with the IRB for your most recent application. Overall, how satisfied were you with the application review and approval process?

- 4 Very satisfied
- 3 Somewhat satisfied
- 2 Somewhat dissatisfied
- 1 Very dissatisfied

A21 - amendment:

Have you ever submitted an "Amendment" to make changes to your most recent application?

1 Yes
0 No

A22 – evercontinuing:

Have you ever submitted a “Scheduled Continuing Review” to renew ANY application for another period of time because you were nearing the end of an approval period for a research project?

1 Yes
0 No **GO TO QUESTION A24**

A23 - irbaskrchanges:

When you submitted a “Scheduled Continuing Review”, did the IRB ask you to change your approved application by completing an amendment before your research could be renewed for another period of time?

1 Yes
0 No

A24:

Think about all of the human subject applications you submitted to an ANN ARBOR CAMPUS IRB, even if you submitted just one application. Please indicate whether you agree or disagree with each of the following statements.

		Strongly agree (4)	Somewhat agree (3)	Somewhat disagree (2)	Strongly disagree (1)
irbhurdle	The IRB process is a hurdle to clear in order to conduct research.				
irbally	The IRB is an ally in my research.				
irbmission	The IRB understands its mission.				
irbscope	The IRB acts within the scope of its mission.				
irbuseful	The IRB as it currently functions serves a useful purpose.				
irbaddition	IRB review of research adds to the protection of human subjects.				
irbmorestrict	The IRB interprets federal regulations more strictly than is necessary to protect human subjects.				
peerrsrating	PEERRS certification contributes to my understanding of human research ethics.				
IF IRB=1 ASK A24i; EVALUATE SECTION II CHECKPOINT					
ancillary	I am familiar with the ancillary review process.				

SECTION II CHECKPOINT: IF LEGACY=1 GO TO SECTION III

II. eResearch

The next set of questions is about your experiences with the IRB application process using eResearch.

B1 - applydifficulty:

First, how easy or difficult would you say it is to complete a new application in eResearch—not including the “Amendment” process or the “Scheduled Continuing Review” process?



- 5 Very easy
- 4 Easy
- 3 Neither easy nor difficult
- 2 Difficult
- 1 Very difficult

B2:

How did you become familiar with using the eResearch system?

(Check all that apply)

B2 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED



- familiarways01 Created an application in the eResearch “Sandbox.”
- familiarways02 Clicked on the  Help or  symbols, or other links in the eResearch application.
- familiarways03 Used the FAQs or other links on the eResearch homepage.
- familiarways04 Asked a colleague for advice.
- familiarways05 Asked support staff in my area for advice.
- familiarways06 Contacted the eResearch Help Desk (MAIS).
- familiarways07 Contacted IRB staff.
- familiarways08 Referred to information on the IRB’s website (not the eResearch website).
- familiarways09 Attended a course or lecture offered by an IRB or other unit on campus.
- familiarways10 Other *(please specify)*
(familiarwaysother) _____

B3:

When you have a question about preparing or changing an eResearch application, which of the following, if any, have you used to answer your questions?

(Check all that apply)

B3 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED



- answerways01** Created an application in the eResearch “Sandbox.”
- answerways02** Clicked on the  Help or  symbols, or other links in the eResearch application.
- answerways03** Used the FAQs or other links on the eResearch homepage.
- answerways04** Asked a colleague for advice.
- answerways05** Asked support staff in my area for advice.
- answerways06** Contacted the eResearch Help Desk (MAIS).
- answerways07** Contacted IRB staff.
- answerways08** Referred to information on the IRB’s website (not the eResearch website).
- answerways09** Attended a course or lecture offered by an IRB or other unit on campus.
- answerways10** Reviewed previously approved applications.
- answerways11** Other (*please specify*)
(answerwaysother) _____

B4:

Next, what sources of information, if any, have you used to get familiar with the content required in informed consent forms?

(Check all that apply)

B4 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- consentsources01** Clicked on the  Help or  symbols, or other links in the eResearch application.
- consentsources02** Used the FAQs or other links on the eResearch homepage.
- consentsources03** Asked a colleague for advice.
- consentsources04** Asked support staff in my area for advice.
- consentsources05** Contacted the eResearch Help Desk (MAIS).
- consentsources06** Contacted IRB staff.
- consentsources07** Referred to information on the IRB’s website (not the eResearch website).
- consentsources08** Used IRB-approved or recommended templates.
- consentsources09** Reviewed previously approved consent forms.

consentsources10 Attended a course or lecture offered by an IRB or other unit on campus.

consentsources11 Other (*please specify*)
(consentsourcesother) _____

B5:

When preparing or changing your most recent application, did you experience any of the following TECHNICAL ISSUES with eResearch?

(Check all that apply)

B5 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

techproblem01 Browser incompatibility with eResearch.

techproblem02 Difficulty navigating within the application.

techproblem03 Difficulty attaching documents.

techproblem04 Difficulty adding a header or footer to a document (i.e., the fields updated by the IRB after a document is approved).

techproblem05 System crash, loss of mouse, screen freezing.

techproblem07 Slow response time.

techproblem08 Losing information entered by not saving it.

techproblem09 Losing information due to the eResearch time-out feature.

techproblem10 Difficulty submitting the application to the IRB once completed.

techproblem11 Other (*please specify in the box below*) **(techproblemother)** _____

B6:



When you completed or changed your most recent application, did you experience any of the following NON-TECHNICAL ISSUES with eResearch?

(Check all that apply)

B6 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

notechproblem01 Not understanding the relevance of some questions.

notechproblem02 Not understanding the meaning or definition of terms or phrases in required questions.

notechproblem03 Not finding relevant answers to your questions in the  Help or the  functions in eResearch.

notechproblem04 Not being able to complete the application within a reasonable amount of time.



notechproblem05 Other (*please specify in the box below*)
(notechproblemother) _____

B7:

The items in the list below describe some of the features in the eResearch system. Which of the following, if any, do you think could be enhanced or changed to make the eResearch system easier to use?

(Check all that apply)

B7 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- erchanges01** Creating different eResearch applications for different disciplines (e.g. biomedical versus social-behavioral sciences).
- erchanges02** eResearch “Sandbox.”
- erchanges03** Number of clicks to use the system.
- erchanges04** Arrangement of text and other visual features on a page.
- erchanges05** Order of questions that describes a research project.
- erchanges06** Answers to questions in the  or the  functions.
- erchanges07** Entering information into the application.
- erchanges08** Navigating among sections in the application.
- erchanges09** Information describing the status of my application.
- erchanges10** Knowing where to find IRB-approved research materials (consent forms, questionnaires, recruitment material, etc.).
- erchanges11** Posting or reading correspondence in eResearch.
- erchanges12** Speed of eResearch when continuing from one page to another.
- erchanges13** Additional FAQs.

B8 – erchangesother:

Are there any other ways in which the eResearch system could be enhanced or changed to make it easier for you to use?

III. Information on Human Subjects Research

C1 - classesattend:

IRBs and other units on the ANN ARBOR CAMPUS offer courses, classes, lectures, brownbags, or informational sessions on topics related to human subjects research. Have you ever attended sessions like these?

- 1 Yes **GO TO QUESTION C4**
- 0 No

C2 - offerfamiliar:

How familiar are you with sessions like these?

- 1 Not familiar at all **GO TO QUESTION C8**
- 2 Not very familiar **GO TO QUESTION C8**
- 3 Somewhat familiar
- 4 Very familiar

C3:

Which of the following are reasons you DID NOT ATTEND sessions like these?

(Check all that apply)

C3 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- noattendreason01** Scheduling conflict.
- noattendreason02** Offered at inconvenient times.
- noattendreason03** Didn't have time to attend.
- noattendreason04** Inconvenient location.
- noattendreason05** Topics not relevant to immediate needs.
- noattendreason06** Topics already known.
- noattendreason07** Didn't like the presentation format.
- noattendreason08** Other *(please specify)* **(noattendreasonother)** _____

GO TO QUESTION C8

C4:

Which IRB, department, or other unit on the ANN ARBOR CAMPUS sponsored the session(s) you attended?

(Check all that apply)

C4 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- whoclasses01** IRBMED - the IRB that reviews biomedical research.
- whoclasses02** IRB Behavioral Sciences - the IRB that reviews social and behavioral research.

- whoclasses03** IRB Health Sciences - the IRB that reviews health research.
- whoclasses04** OVPR - the Office of the Vice President for Research.
- whoclasses05** MICHHR - the Michigan Institute for Clinical and Health Research.
- whoclasses06** Dental School.
- whoclasses07** DRDA - the Division of Research Development and Administration.
- whoclasses08** Other (*please specify*)
(whoclassesother) _____

C5:

Think about all the courses, lectures, brownbags, or informational sessions you have attended on the ANN ARBOR CAMPUS about human subjects research. Which of the following topics were covered?

(Check all that apply)

C5 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- topicscovered01** Federal regulations.
- topicscovered02** Preparing informed consent documents.
- topicscovered03** Adverse Event (AE) or Other Reportable Information and Occurrences (ORIO) reporting.
- topicscovered04** Working in eResearch.
- topicscovered05** History of research ethics.
- topicscovered06** Belmont principles, research ethics (e.g., autonomy, beneficence, and justice).
- topicscovered07** Good clinical practice.
- topicscovered08** Writing human subjects sections of grant proposals (e.g., NIH).
- topicscovered09** University practices and policies when conducting human subjects research.
- topicscovered10** IRB practices and policies.
- topicscovered11** Documentation of the research process.
- topicscovered12** Protecting the identity and confidentiality of subjects or data security.
- topicscovered13** Conflict of interest.
- topicscovered14** HIPAA.
- topicscovered15** INDs or IDEs.
- topicscovered16** Sponsor investigator status.
- topicscovered17** Other (*please specify*)
(topicscoveredother) _____

C6 – classesuseful:

In general, how useful would you say these sessions were?

- 4 Very useful
- 3 Somewhat useful
- 2 Not very useful
- 1 Not at all useful

C8:

How interested would you be in learning more about each of the following topics in research with human subjects?

		Very interested (4)	Somewhat interested (3)	Not very interested (2)	Not at all interested (1)	Not sure (8)
learnincentives	Incentives and payments in research.					
learndeception	Deception in research.					
learnchildren	Research with children.					
learnvulnerable	Research with other vulnerable persons.					
learninterna- tional	Research in an international setting.					
learnorganizing	Organizing research records.					
learnpools	Student subject pools.					
learnoralhis- tory	When ethnography and oral history projects are subject to IRB review.					
learnconsent	Writing informed consent documents.					
learnidentity	Protecting the identity of research participants in primary data collection.					
learnconflict	Conflicts of interest in human subjects research.					
learnsecondary	Protecting the identity of research participants when using secondary data sets.					
learnhuman- subjects	When persons not involved in research become human subjects.					
learnethics	Research ethics and history; function and mission of IRBs.					
learnminimi- zing	Minimizing the number of changes requested by the					

- learnhipaa**
learnindide IRB.
HIPAA regulations.
Food and Drug
Administration (FDA) IND
and IDE regulations.
- learnaeorio** Adverse Events (AE) and
Other Reportable
Information and Occurrences
(ORIO).
- learnsponsorpi** FDA obligations for
sponsored investigations.
- learneresearch** Using eResearch more
effectively.
- learncriteria** Criteria IRBs use to review
and approve research.
- learnfaculty-
role** The faculty advisor role in
mentoring student research.
- learnexempt** When research does not need
IRB approval or is exempt.
- learncertifi-
cates** Using Certificates of
Confidentiality to protect the
privacy of human subjects.

C9 - learnother:

Are there other topics in human subjects research you want to learn more about? If yes, please describe below.

ASK C10 IF AT LEAST ONE ITEM IN C8 WAS "NOT VERY INTERESTED," "SOMEWHAT INTERESTED", OR "VERY INTERESTED" OR TEXT IN C9; ELSE GO TO QUESTION C11

C10:

When you need information on topics in research with human subjects who should provide this information?

infopreference

- 1 IRB staff.
- 2 No preference.
- 3 Other group or person (*please specify*)

(infopreferenceother) _____

C11 - learnprefways:

Some people prefer to learn information by attending a lecture and others like to read information when they have time. What are your preferred ways to learn about topics in research with human subjects?

(Check up to three items)

C11 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

PROGRAMMER NOTE: LIMIT CHOICES TO 3 ITEMS—"OTHER" COUNTS AS 1 CHOICE

- | | |
|-------------------------------------------------------|----------------------------------------|
| learnprefways01 | Classroom lecture setting. |
| learnprefways02 | Workshop/seminar. |
| learnprefways03 | Brownbags. |
| learnprefways04 | Conferences on specific topics. |
| learnprefways05 | Webcasts. |
| learnprefways06 | On-line tutorials. |
| learnprefways07 | Reading printed material. |
| learnprefways08 | Viewing DVD/CD-ROM. |
| learnprefways09 | Podcasts. |
| learnprefways10
(learnprefwaysother) | Other <i>(please specify)</i>
_____ |

C12 - reguinfosource:

If you had a question about how REGULATIONS affect your human subjects research, to which of the following, if any, would you go for answers?

(Check all that apply)

VALUE LABELS FOR C12 ARE: 1=CHECKED; 0=NOT CHECKED

- | | |
|-------------------------|--------------------------------------------------------------------|
| reguinfosource01 | IRBMED staff. |
| reguinfosource02 | IRB Behavioral Sciences staff. |
| reguinfosource03 | IRB Health Sciences staff. |
| reguinfosource04 | Research colleagues in my area. |
| reguinfosource05 | Support staff in my area. |
| reguinfosource06 | Persons I know who are current IRB board members. |
| reguinfosource07 | Persons I know who are former IRB board members. |
| reguinfosource08 | Michigan Institute for Clinical and Health Research (MICHR) staff. |
| reguinfosource09 | Michigan Center for Oral Health Research (MCOHR) staff. |

reguinfosource10 Other (*please specify*)
(reguinfosourceother) _____

C13 - visitohrp:

How often have you visited the website hosted by the Office for Human Research Protections (OHRP) as displayed below?

- 1 Never
- 2 Rarely
- 3 Often
- 4 Very often

SHOW IMAGE OF OHRP HOMEPAGE: [HTTP://WWW.HHS.GOV/OHRP/](http://www.hhs.gov/OHRP/)

C14 - visithrpp:

How often have you visited the University's Human Research Protection Program (HRPP) website hosted by the OVPR as displayed below?

- 1 Never
- 2 Rarely
- 3 Often
- 4 Very often

**SHOW IMAGE OF UM HRPP HOMEPAGE:
[HTTP://WWW.RESEARCH.UMICH.EDU/HRPP/INDEX.HTML/](http://www.research.umich.edu/hrpp/index.html)**

C15 – a) visitirbmed b) visitirbbehavsci c) visitirbhealth:

How often have you visited each of the following University IRB websites?

a) The IRBMED Website displayed below.

- 1 Never
- 2 Rarely
- 3 Often
- 4 Very often

**SHOW IMAGE OF IRBMED HOMEPAGE:
[HTTP://WWW.MED.UMICH.EDU/IRBMED/](http://www.med.umich.edu/irbmed/)**

b) The IRB Behavioral Sciences Website displayed below.

- 1 Never
- 2 Rarely
- 3 Often
- 4 Very often

**SHOW IMAGE OF BEHAVIORAL SCIENCES IRB HOMEPAGE:
[HTTP://WWW.IRB.
RESEARCH.UMICH.EDU/IRB_BEHAVIORAL/NEW/IRB_BEHAVIORAL.HTML](http://www.irb.research.umich.edu/irb_behavioral/new/irb_behavioral.html)**

c) The IRB Health Sciences Website displayed below.

- 1 Never
- 2 Rarely

- 3 Often
- 4 Very often

SHOW IMAGE OF HEALTH SCIENCES IRB HOMEPAGE: [HTTP://WWW.IRB.RESEARCH.UMICH.EDU/IRB_HEALTH/NEW/IRB_HEALTH.HTML](http://www.irb.research.umich.edu/irb_health/new/irb_health.html)

IF C14=1 and C15a=1 and C15b=1 and C15c=1, GO TO C19

C16 – visitreason:

Think about all of the visits you made to any of the University’s IRB/HRPP websites. Why did you visit any of these sites?

(Check all that apply)

VALUE LABELS FOR C16 ARE: 1=CHECKED; 0=NOT CHECKED

visitreason01 Looking for information about informed consent.

visitreason02 Looking for guidance on other topics.

visitreason03 Looking for dates when an IRB Board meets.

visitreason04 Looking for IRB Board membership.

visitreason05 Looking for IRB contact information.

visitreason06 Other reason (*please specify*) **visitreasonother** _____

C17 - visitdifficult:

In general, how easy or difficult was it to find the information you were looking for?

- 4 Very easy
- 3 Easy
- 2 Difficult
- 1 Very difficult

C18 - websitesuseful:

You have indicated earlier that you visited the websites displayed below. Overall, how useful [was/were] [this/these] [site/sites]?

PROGRAMMER INSTRUCTION: USE “WERE” AND “SITES” IF RESPONSE CODES 2-4 CHECKED IN 2 OR MORE OF THE FOLLOWING QUESTIONS: C14, C15A, C15B, AND C15C; OTHERWISE USE “WAS” AND “SITE”

DISPLAY THE IMAGES OF WEBSITE(S) VISITED AT LEAST “RARELY” IN C14 and C15 AND ADD ABOVE THE IMAGE “The IRBMED Website,” or “The IRB Behavioral Sciences Website,” or “The IRB Health Sciences Website” respectively.

- 4 Very useful
- 3 Somewhat useful
- 2 Not very useful
- 1 Not at all useful

C19 - peerrseuseful:

Think about when you completed or renewed your PEERRS certification. How useful was the content to your research?

- 4 Very useful
- 3 Somewhat useful
- 2 Not very useful
- 1 Not at all useful

IV. Research Practices

D1 - selfchange:

Conducting research is dynamic and changes in research designs are common. Some people say the IRB should review all changes before they can be made. Others say it is not necessary for the IRB to review all types of changes after a research study has been approved.

Please check each type of change or event listed below, if any, that you should be able to make on your own AFTER a study has been approved without having to have the IRB review and approve the change.

(Check all that apply)

D1 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

- selfchange01 Changing punctuation in a consent form.
- selfchange02 Making a minor change to an expression in a consent form.
- selfchange03 Changing the order of questions in a questionnaire.
- selfchange04 Adding new attitude questions to a questionnaire.
- selfchange05 Removing questions in a questionnaire.
- selfchange06 Not reporting to an IRB that a co-investigator now works at another university.
- selfchange07 Not reporting to an IRB that a student has graduated and doesn't work on a project anymore.
- selfchange08 Increasing a payment by \$5 to participants to cover parking fees.
- selfchange09 Increasing the number of people recruited for a study by 25.
- selfchange10 Changing the time human subjects in biomedical research have follow-up appointments.
- selfchange11 Not reporting a complaint to an IRB from a subject about the time to complete a survey.
- selfchange12 Sharing a summary of research results with participants.
- selfchange13 Adding an intervention by measuring someone's height and weight.

selfchange14 Changing a contact telephone number in an advertisement.

D2:

Please indicate whether you agree or disagree with each of the following statements.

	Strongly agree (4)	Somewhat agree (3)	Somewhat disagree (2)	Strongly disagree (1)
rknowobligations	Research colleagues understand the ethical obligations in protecting human research participants from harm.			
rknowconflicts	Research colleagues know when conflicts of interest occur in doing human subjects research.			
irbimportant	The IRB serves an important role in the research process.			
irburdensome	In practice, it is burdensome for researchers to strictly follow IRB-approved protocols.			
mentoringprogram	There is an effective student mentoring program in my department that teaches students about ethical obligations when conducting human subjects research.			
rknowreview	Research colleagues understand when a research project involving human subjects needs to be reviewed by the IRB.			

enoughpossibilities There are sufficient opportunities to learn about responsible research practices at the University.

rcknowaeorio Research colleagues understand what an Adverse Event and Other Reportable Information and Occurrence are.

rcknowirbmembers Research colleagues know IRB committee members to contact with questions about human subjects research.

irbhelpprotect The IRB helps me protect human subjects from harm in my research.

evaluateimportant It is important to evaluate the extent to which investigators adhere to IRB-approved protocols.

D3 - familiarohrcr:

How familiar are you with the mission of the Office of Human Research Compliance Review (OHRCR) on the Ann Arbor campus?

- 1 Not familiar **GO TO SECTION V**
- 2 Somewhat familiar
- 3 Very familiar

D4:

Which of the following activities do you think are part of the Office's mission?

(Check all that apply)

D4 VALUE LABELS: 1=CHECKED; 0=NOT CHECKED

ohrcrmission01 Approve IRB applications.

ohrcrmission02 Oversight of the IRB.

ohrcrmission03 Helping investigators understand federal regulations.

ohrcrmission04 Handling investigator's conflict of interest issues.

ohrcrmission05 Assist the Office of the Vice President for Research (OVPR) in the investigation of possible noncompliance with federal regulations.

ohrcrmission06 Develop University policies that protect human subjects.

ohrcrmission07 Review research projects for compliance with federal regulations.

V. Demographics

The last set of questions is about you and your position at the University.

E1 - gender:

Are you...

- 1 Male
- 2 Female

E2 - age:

How old are you?

Years

E3 - nativeenglish:

Is English your native language?

1 Yes → GO TO QUESTION E4

0 No

languageorigin: What language did you speak growing up? _____

E4 - role:

What is your primary role at the University of Michigan?

(Select one)

- 1 Student: Undergraduate
- 2 Student: Masters/Professional Program (e.g., business, law)
- 3 Student: Doctoral/Postdoctoral
- 4 Lecturer, Instructor, Research Investigator
- 5 Faculty: Professor
- 6 Faculty: Associate Professor
- 7 Faculty: Assistant Professor
- 8 Faculty: Emeritus
- 9 Staff
- 10 roleother: Other (please specify) _____

E5 - numapplications:

IF LEGACY=1

How many different IRB applications, not including requests for changes or for additional approval periods, have you submitted to the IRB where you assumed the role of principal investigator?

IF LEGACY=0

Since you began using eResearch, how many different IRB applications, not including requests for changes or for additional approval periods, have you submitted to the IRB where you assumed the role of principal investigator?

Number of different applications [in eResearch]

IF E4=1, 2, OR 3 ASK E6; ELSE GO TO E7

E6 - yearsstudying:

How many years in total have you been at the University studying towards your current degree or training?

Years GO TO QUESTION E8

E7 - yearsfacultystaff:

How many years have you been a faculty/staff member at the University of Michigan?

Years

ASK ALL

E8 - yearsresearch:

All together, how many years have conducted human subjects research at the University of Michigan or elsewhere?

__ __ years

E9 - comments:

Finally, use the space below to make any additional comments.

wantresults

If you would you like to receive a summary of the survey results please check the box.

Please click the “submit results” button to complete the survey.

TEXT FOR THE THANK YOU MESSAGE IF R COMPLETED THE SURVEY

Thank you very much for participating in the survey.

We value people like you who are willing to give their time to further research practices at the University of Michigan.

TEXT FOR MESSAGE IF R DID NOT COMPLETE SURVEY

To complete the survey and return to where you left off, just click on the link in the email invitation you received. All surveys must be completed by December 20.

We value people like you who are willing to give their time to further research practices at the University of Michigan.

Legend:

Color

Red

Green

Yellow

Explanation

Section titles of the questionnaire; not shown to respondents

Variable names; not shown to respondents

Instructions for programmer; not shown to respondents