Human Subjects Office (HSO)
Fall Service Survey
FY 2016-2017

The charts and tables below provide a snapshot of the responses to the HSO Service Survey.

During this reporting period, investigators received an invitation to complete a survey to assess their interaction and experience with the Human Subjects Office and IRB. The invitation was sent to investigators who received approval from the IRB office for new protocols, amendments, and continuing reviews. The PI or contact person was asked to complete the survey one time per invitation.

Below is a summary of the results from IRB Approvals for fall 2016.

**SURVEY PARTICIPANT DEMOGRAPHICS:**

I am a/an:

- Principal Investigator: 36%
- Investigator (not including students): 6%
- Student Investigator: 24%
- Study Coordinator: 34%

I have been involved in human subjects research for:

- Less than a year: 12%
- 1-2 years: 11%
- 2-10 years: 39%
- Over 10 years: 38%

**IRB PROCESS PERFORMANCE:**

<table>
<thead>
<tr>
<th>Item</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The IRB Staff are responsive.</td>
<td>135</td>
<td>120</td>
<td>79</td>
<td>79</td>
<td>6</td>
</tr>
<tr>
<td>The IRB Staff provide timely feedback.</td>
<td>104</td>
<td>102</td>
<td>72</td>
<td>72</td>
<td>5</td>
</tr>
<tr>
<td>The IRB Staff provide clear and helpful feedback.</td>
<td>104</td>
<td>102</td>
<td>72</td>
<td>72</td>
<td>5</td>
</tr>
<tr>
<td>The review of my submission by the IRB was of high quality.</td>
<td>104</td>
<td>102</td>
<td>72</td>
<td>72</td>
<td>5</td>
</tr>
<tr>
<td>Overall, I am satisfied with the IRB process.</td>
<td>104</td>
<td>102</td>
<td>72</td>
<td>72</td>
<td>5</td>
</tr>
</tbody>
</table>
CONTACTING THE HUMAN SUBJECTS OFFICE/IRB:

How often do you contact HSO staff with questions?

- Almost every week, 13%
- Almost every month, 22%
- Every few months, 37%
- Once or twice a year, 22%
- Never, 6%

Primary Method of Contact/Use of HSO Resources:

- Website
- Email the IRB office
- Call the IRB office
- Call/IM a specific staff member
- Email a specific staff member
Did you attend HSO Office Hours? If so, at what location?

<table>
<thead>
<tr>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>IU Health Methodist Hospital - Wile Hall (IN)</td>
</tr>
<tr>
<td>Lockefield Village (IN)</td>
</tr>
<tr>
<td>Wells Library (BL)</td>
</tr>
</tbody>
</table>

Have you attended HSO office hours?

- Yes: 20%
- No: 80%

Are you aware of HSO office hours, and their locations?

- Yes: 49%
- No: 51%

If you attended HSO Office Hours, how satisfied were you with the use of your time?

- Very Satisfied
- Satisfied
- Neither Satisfied nor Unsatisfied
- Unsatisfied
- Very unsatisfied

Satisfaction levels as follows:
- Very Satisfied: 6
- Satisfied: 10
HSO AVAILABLE TRAINING:

Are you aware of HSO training sessions?

Yes: 55%
No: 45%

Have you attended or scheduled a training session?

Yes: 42%
No: 58%

Have you attended or scheduled an HSO Training Session? If so, at what location?

<table>
<thead>
<tr>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Psychology and Brain Sciences (PBS)</td>
</tr>
<tr>
<td>Emerson Hall</td>
</tr>
<tr>
<td>Goodman Hall</td>
</tr>
<tr>
<td>Human Subjects Office, IUPUI Lockefield Building</td>
</tr>
<tr>
<td>In-house, Department Conference Room</td>
</tr>
<tr>
<td>In-house, Lab Meeting</td>
</tr>
<tr>
<td>IU Health University Hospital</td>
</tr>
<tr>
<td>IU Simon Cancer Center</td>
</tr>
<tr>
<td>IUPUI</td>
</tr>
<tr>
<td>IUS</td>
</tr>
<tr>
<td>Maurer Law School</td>
</tr>
<tr>
<td>Methodist Hospital</td>
</tr>
<tr>
<td>Methodist Hospital Library</td>
</tr>
<tr>
<td>Online Training</td>
</tr>
<tr>
<td>Oral Health Research Institute (OHRI)</td>
</tr>
<tr>
<td>Regenstrief Institute</td>
</tr>
<tr>
<td>Riley Outpatient Center (ROC)</td>
</tr>
<tr>
<td>School of Education</td>
</tr>
<tr>
<td>School of Optometry, Bloomington Campus</td>
</tr>
<tr>
<td>Social Science Research Commons (SSRC)</td>
</tr>
<tr>
<td>University Library</td>
</tr>
<tr>
<td>VA Hospital</td>
</tr>
</tbody>
</table>

If you attended an HSO Training Session, how satisfied were you with the use of your time?

<table>
<thead>
<tr>
<th>Satisfaction Level</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Satisfied</td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td></td>
</tr>
<tr>
<td>Neither Satisfied nor Unsatisfied</td>
<td></td>
</tr>
<tr>
<td>Unsatisfied</td>
<td></td>
</tr>
<tr>
<td>Very unsatisfied</td>
<td></td>
</tr>
</tbody>
</table>
How often do you use the HSO website?

- Daily: 2%
- Weekly: 15%
- Monthly: 20%
- A few times a year: 51%
- Never: 12%

How useful did you find the website?

- Very Useful: 14%
- Somewhat Useful: 49%
- Neutral: 19%
- Somewhat Inadequate: 10%
- Very Inadequate: 8%

How long did it usually take you to find the information you needed?

- Less than 5 minutes: 19%
- 5-10 minutes: 11%
- 11-20 Minutes: 22%
- More than 20 Minutes: 11%
- N/a I could not find the information: 11%
- 5-10 minutes: 37%
Simple amendments are taking much longer to get approval than before. It is very frustrating.

Nothing at this point.

IRB member did approve the studies quickly, but the actions of the staff member reviewing the IRB submissions is consisting of nothing but minor surveys or phone interviews, but it took several months just to get the application submitted. Was we got past the terms of when the submission should get sent to the IRB members. What’s sad is that both of the recent studies were expedited review studies wrong this point (who would know this better, the researcher or the staff member?). Moreover, I don’t see how that should make a difference in delay because the staff member replied that we should not be stating that our study was about personality. The staff member is categorically understanding the nature of the application or causing delays due to unnecessary comments. For example, the most recent submission was application prior to forwarding it to the IRB members. In the two recent submissions, unnecessary delays were caused by the staff member not understanding the nature of the application or causing delays due to unnecessary comments. For example, the most recent submission was delayed because the staff member replied that we should not be stating that our study was about personality. The staff member is categorically wrong this point (who would know this better, the researcher or the staff member?). Moreover, I don’t see how that should make a difference in terms of when the submission should get sent to the IRB members. What’s sad is that both of the recent studies were expedited review studies consisting of nothing but minor surveys or phone interviews, but it took several months just to get the application submitted. Was we got past the staff member, the IRB member did approve the studies quickly, but the actions of the staff member reviewing the IRB submissions is N/A

Nothing at this point.

Over the past several months, the response time seems to have drastically increased. It seems as though simple expedited studies and/or very simple amendments are taking much longer to get approval than before. It is very frustrating.
Overall I am very pleased with the assistance and feedback received from multiple members of the HSO staff. My only complaint is the timeline from submission to approval. There is no clear timeline on how long submissions should take for approval. This creates difficulty in planning recruitment activities since many times we are moving so quickly with our projects that we don't have months to wait.

Overall, the process went smoothly. The person whom I spoke with on the phone several times was patient and helpful. However, if I request to speak to a specific person when I call IRB, the person who answers says perhaps they can help. If I wish to speak to a specific person, I would appreciate being put through to that person. Also, the form is not real user friendly. I appreciate the quick turn-around time for approval.

Please please include the project title in your communications rather than just study # - this will really help keep these messages in order.

Response times suggest IRB staff address renewals/questions in the order they are received. This may mean that a question that takes one minute to answer are not replied to for a week or more.

Senta Baker is our contact and she is quick to respond and always willing to explain by phone - my preferred method of getting information.

Sharon Moran is very helpful. She answers the phone at IRB.

Thanks for prompt review.

Thanks for your help with research.

The IRB review process has been consistently horrible. They have made it very difficult to get even expedited and minimal risk studies approved. They have delayed research processes and thus timely completion of program milestones. They have made it nearly impossible to work with undergraduate RAs who have limited time to dedicate to a research project. They absolutely make me want to stop doing research at IUPUI.

The IRB reviews are very detailed and good, but response time and availability are poor.

The IRB staff is amazing! Very helpful and always provide timely advice! I think it would be very helpful to consider allowing 'umbrella' protocols. In most of my protocols, I use the same non-invasive tests and it would be helpful to be able to combine several of my protocols. Sometimes their feedback is inconsistent from proposal to proposal, and that sometimes they get hung up on really minor issues. Nonetheless, they are very responsive and helpful.

The KC IRB system is bad. The major problem is that there is no clear workflow when submitting a protocol for review. Ask where things are with my submission.

The online submission process could be more clear. I appreciate that we received prompt comments regarding our submission, but some of them seemed to no understand what we had submitted.

The only thing that is problematic is each reviewer seems to want different things. It makes each submission difficult.

Goodness the staff is good, but really, Kuali isn't making my job easier - in fact I add hours of work to every single submission because of it. Yes, I've done the trainings, and yes, I get help. But the fact that a PhD educated tenured professor struggles with this should be telling that the system is too complicated.

The people at the IRB are great! I never feel like any question I ask is too dumb!

The routing notifications are all study numbers - I know my studies by title. All to often I need to figure out which study is being referred to. If the number and an identifier could both be placed. It would help. Too many clicks to go back to find what study is the topic.

The so-called smart form is a nightmare. Because it is so disjointed, it is far to easy to overlook key elements.

The staff are generally great - however the IRB process has been somewhat slow lately.

Through the website. Without them, I could not complete the IRB task, which I was completely independent in completing BEFORE the website. I see the benefits of the website now that I have used it and received feedback from the IRB staff. I just guess the amount of calls and emails to IRB have increased. I know I have to connect more often.

The website change - where we have to search with IRB protocol number instead of having our studies pop up is very inconvenient. Be easier to know upfront.

Very happy that they get back to you in a timely manner.

Very helpful and efficient.

Website is unhelpful and I can never find it (seriously) or what I need.

My questions. The quality of review has improved a lot in the last 5+ years. What would help me is more guidance on the website about what types of documentation errors on consent/asset/authorizations should be handled by NTF only, correcting the problem, reporting, etc. with examples.

Available online, e.g. a missing date on a consent should be ......

While the new system (on line approvals) is efficient, there are times when it's difficult to identify which protocol I am reviewing when only the protocol number is provided. Including study title would help tremendously.

(Blank)

Failure. The IRB staff is not accurate in giving notices of due dates for test completions, and it takes an inordinately long time to resolve, and staff claiming that they were interns who were given poor instructions by higher staff. It seems to me that IRB staff needs to consider the time expended by faculty trying to meet requirements to participate in clinical trials and this means using a system that makes sense and is efficient and not foisting without first checking instructions on 'interns' to incorrectly inform faculty and research staff regarding due dates for test.
I say I am not aware of the HSO hrs/locations but I do know there are hrs/location and would check at a point of contact or at least could call center.
I'm not concerned about the office hours since I use e-mail without need for an immediate reply.

**Why have you not attended or scheduled a training session?**

Been in Research For twenty years
Conflicting scheduling
did not have a protocol when they were offered
Did online training
Didn't feel a need to
Didn't feel I needed to
didn't feel like I needed to
Directly contact the staff
don't have the time
had students attend
have not had a chance
have not had free time in work day to attend training.
haven't needed it
I've just started seeing the e-mails about it this semester. I'm fairly comfortable with the process right now, so I don't feel the need to attend.

Lack of availability in my schedule
Limited time in schedule
my research staff have
n/a

New to my position
No need
No particular reason
No time.
None relevant to me at the moment.
not needed
Not needed
not needed at this time
Not needed...do training on line
not sure
Not sure
not sure why

On line trainings meet my current needs
Other staff members have attended for our group
Others from our center have attended on the center's behalf.

Prior training
prioritization of available time
research assistants usually attend
Scheduling conflicts
teaching/researching/meetings at times of training
time
Time of day
Time, but I will look into it.
timing, conflicts
too busy to travel over, takes too much time out of my day, and I need to be at Methodist
Too busy.
typically ask staff to attend
very very busy
(blank)

Additional comment/suggestions regarding HSO Training Sessions:
navigate the system.
I think a 'most common errors' class/email (with how to fix them) would be good.
Never was made aware of them.
not at IU, thereby making it difficult to attend sessions or visit office.
Perhaps trainings would be less needed if Kuali was navigable by intelligent human beings.
thanks for doing a great job
Where do I find info on the HSO training sessions?
Would be nice to have training sessions on not just where to find the questionnaires, but how to answer the questions. New coordinators in particular don't know what is a summary safe gaurd let alone understand that a questionnaire replaces it now.
(blank)

I would visit the HSO website more if:
?
a tutorial was available on how to navigate the site
As I become more active in research (I am a second year phd student)
content was better integrated with KCIRB
Didn't find answers online
easier to navigate
Easier to use
email reminders
fewer categories and easier search options....i don't know, but it's not very helpful in currnet form.
good for now
had more specific information, but this may not be realistic, some of the situations I've had are somewhat unique I think
HSO website is fine, but the IRB application website is a total disaster and should be radically redesigned and conceptualized.
I actually knew the website
I am not sure what would drive my use or yeild more frequent website visits
I can find information easily.
I can find what I need sooner
I could find information more easily.
I could find the information I need more easily
I could find things more easily.
I did more research
I did more research needing human subjects approval.
I didn't have direct contact to a pre-reviewer or reviewer.
I didn't have help from my staff to handle this
I even knew where it was
I felt I needed to
I found it more useful
I had a particular need to.
I had additional need
I had more occasion to use it
I had more questions
I had more research time
I had questions.
I haven't tried as my questions are generally specific to one study/one IRB staff
I just prefer to talk to someone it solves my questions faster
I knew it would get the IRB process moving faster. I have to deal with a particular person regardless, so the website is less useful.
I knew more about it.
I knew more about it.
I knew what my questions truly were.
I need to find out more info on research.
I needed it more.
I needed more information.
I needed more information.
I needed to.
I needed to do so.
I needed to.
I needed to.
but I use it when I need it regardless.
i needed to...
i needed to....
I only visit on an as needed basis.
I really haven't visited the website. I'll try to look at it more.
I refer to it first all of the time.
I still have trouble finding information via tabs.
I use it often.
I use it quite frequently.
i used it more often, i guess.
I want to dig new information.
I was more involved in research.
I would do a study that is ethically more demanding or requires full review.
if doing more research than currently doing.
If I had less specific study-related questions.
If I needed further assistance.
If I needed to but I typically have other resources available.
If I was aware of it.
If it were not so confusing.
If needed.
If the IU SOPs for human subjects research were made into a searchable web version you need.
I'm getting more familiar with it, so I'm not sure.
information is better categorized.
information is customized to my field(s).
Information was easier to find.
Information wasn't written in human subject jargon.
it could be organized in a clearer manner.
it didn't look so intimidating.
it had information on it I felt compelled to use. Right now, I don't frequently have much use for it.
it had information pertaining to my own branch campus; the offerings geographically based in Indianapolis are not accessible to me.
it had more information on how to get started submitting the IRB the first time.
it is better organized with clearer guiding links to specific sections separately.
it is easier to navigate and find what I need.
it is more user friendly.
it is user-friendly.

exactly the forms and templates for submission were required to submit for this process. It is massively unhelpful, there is a lot of information there.
it provided specific info about whom to contact regarding studies; e.g. biobehavioral contact J. Doe.
lost).
it was better organized. It seems to be organized not for the end user but for the HSO.
it was easier to find pertinent information.
it was easier to find the info and tutorials I need.
it was easier to navigate.
it was easier to read.
it was easier to use
It was laid out more clearly.
It was more clearly laid out - focused on getting clear short answers to researchers.
it was more streamlined... it's not too easy to navigate through it and find the info I need.
it was more user friendly
It was more user friendly - designed from the perspective of the user.
it was more user friendly (particularly new to KC user friendly)
it was needed/necessary
it was organized by user function
it was up to date and organized in a logical manner
it was useful
It was user friendly. I can never find what I'm looking for easily
It was clearer.
just to ask a staff member.
It were more intuitive and answers were easier to find.
it were more streamlined
it were more user friendly
it were more user friendly and I could find what I needed fast. It is usually quicker to contact a person and ask.
it were more user friendly.
it were more user friendly; the menu options are not intuitive
it were necessary.
IT WERE PRODUCTIVE
It would be helpful to have search option to find what I need.
Items were needed
Material was more clearly broken down by type of research (human subjects, exempt, etc.)
MAYBE if it had a better search function.
note screen shots of KC system?
more user friendly
Most recently, I would have found it useful to have a page dedicated to exempt research and determining whether amendments were necessary.
N/A
N/A - I use it whenever I'm doing an IRB submission
NA
needed
Needs walk through on how to use KC IRB. Preferably with screenshots.
NO COMMENT
no response
not certain
Not sure
Not sure
nothing
organized better
provided clear information on where to find things
samples of the kc forms and questionnaires were provided on the web site, directions on using KC, etc.
searching was easier
The guidance document was broken down in chapters. It is very long and very difficult to search if you don't use the terms in the document
The information about the different levels of review and what is required for each was more explicit
The information was clear.
the information was clearer, especially for submissions from IU Health staff
The IRB meeting calendar was more user friendly
The layout were better!
The research staff could pick who reviews our submissions.
the submission process needs to be streamlined. Kuai sucks.
The templates and forms and the protocol decision tree were not as cluttered with info
There were hot-links for the most used items (like the conflict of interest form)
there were more detailed decision trees related to types of submissions.
beginning study procedures)
they had a chat live option
User friendly and clearer.

User interface were more user friendly

was better organized to common tasks that need to be done.

was easier to navigate

website is ok, it's the Kuali Coelus system that is unnecessarily confusing and inaccessible.

well, I think it is useful; I just don't know it that well right now

you had simple, step by step instructions relevant to Kuali (e.g., to submit a study closures, go to this tab, click on this, etc.. )

(Blank)

**Additional comments/suggestions regarding the HSO website:**

Can be more user friendly

research done.

I generally only go to the website to obtain the latest documents at a point of submission or amendment.

minutes figuring out how to open it again.

I have trouble with students accessing the consent forms and knowing what forms go with what type of project. I am only able to figure it out because I've had previous experiences. Please update your website.

I'm not sure I've ever been to the website actions.

It seems like there is so much to know to properly navigate the website. Somehow it needs to be simplified and streamlined.

My response to the question should have skipped me out of the 2nd and 3rd. I had to input made-up values to continue.

n/a

Please continue to keep in mind those of us who do not conduct drug or device trials.

Simplify the webpage.

Some information provided on the website needed to be clarified by a staff member

Metrodora/Pharm-Olam study.

The process is laborious and confusing. Again, very hard to understand what documents I needed to submit as part of the IRB process.

There is a large amount of content on the website and difficult to know where to go on the website for the information.

difficult to navigate

very crowded website

very poor system; need to be rethought out and time of faculty needs to be considered, (essentially 'budgeted' )

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