TIPS FOR CONDUCTING EXPEDITED REVIEW

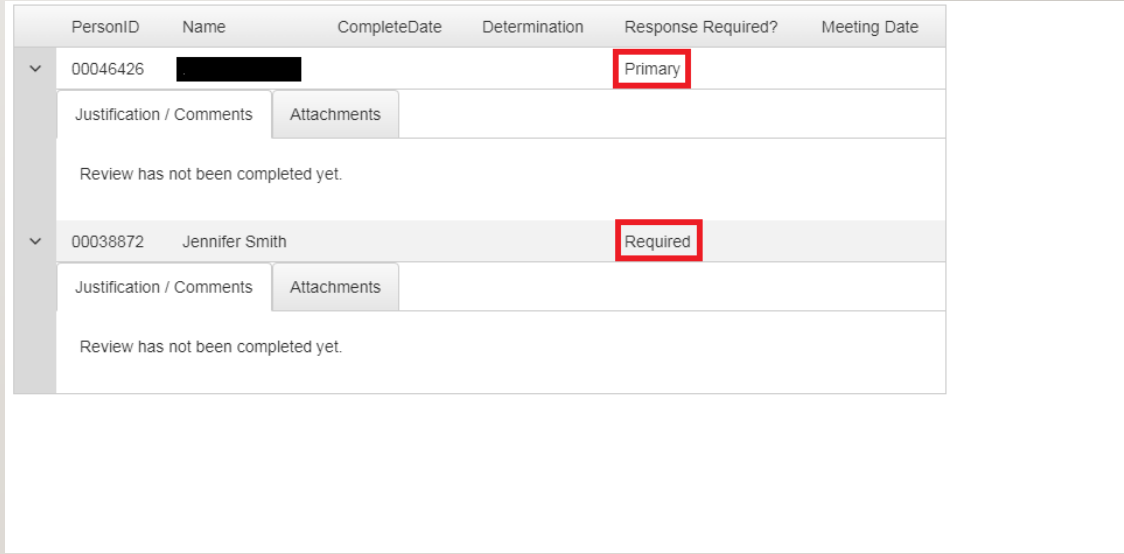
Suggestions from IRB Members and ORI Staff

DEAR EXPEDITED REVIEWERS…

THANK YOU!!

DETERMINATIONS PAGE

- Look on the determinations page to see if other reviewers have been requested (ex: HIPAA, Consultants)
- ORI suggests that the primary reviewer wait until the secondary reviewer has conducted their review so that they can take the secondary reviewers comments into consideration.



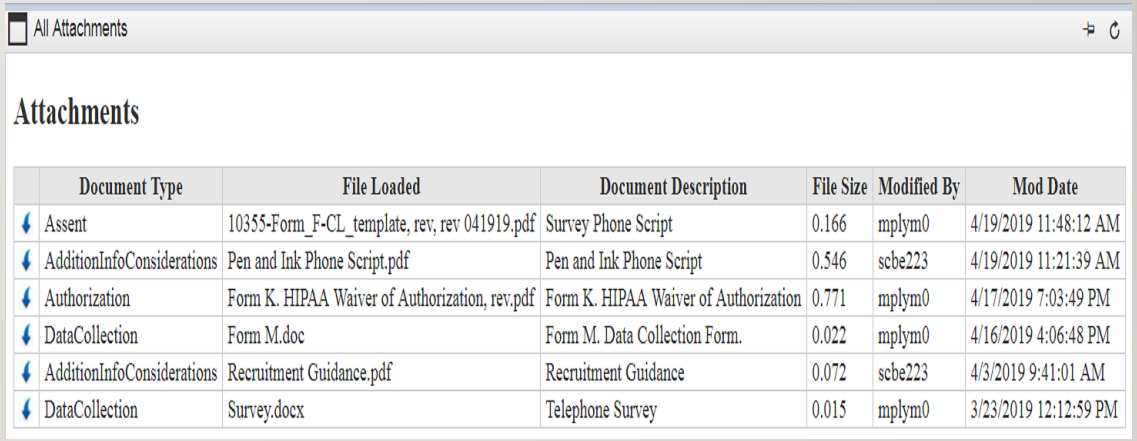
ORI COMMENTS

- Go to all comments.
- Read any comments ORI staff may have for the IRB and/or any comments that ORI made to the PI.
- Reminder: If you don't see any comments to the PI, it doesn't mean ORI didn't screen the application.

Sections	ROLE	VC	First Name	Last Name	ModDate
All					
HIPAA	ORI	IRB/PI	Samuel	Bell	4/3/2019 10:10:49 AM
Comments: HIPAA Waiver of Authorization Comments: #2: Include demographic data you will be collecting when looking at the patient's chart. Refer back to data collection sheets if needed. Re-sign, date, and upload revised copy to E-IRB.					
Subject Demographics	PI	PI	M	[redacted]	4/16/2019 11:33:50 AM
Comments: Updated this section. thank you.					
Informed Consent	PI	PI	M	[redacted]	4/16/2019 3:33:44 PM

ATTACHMENTS

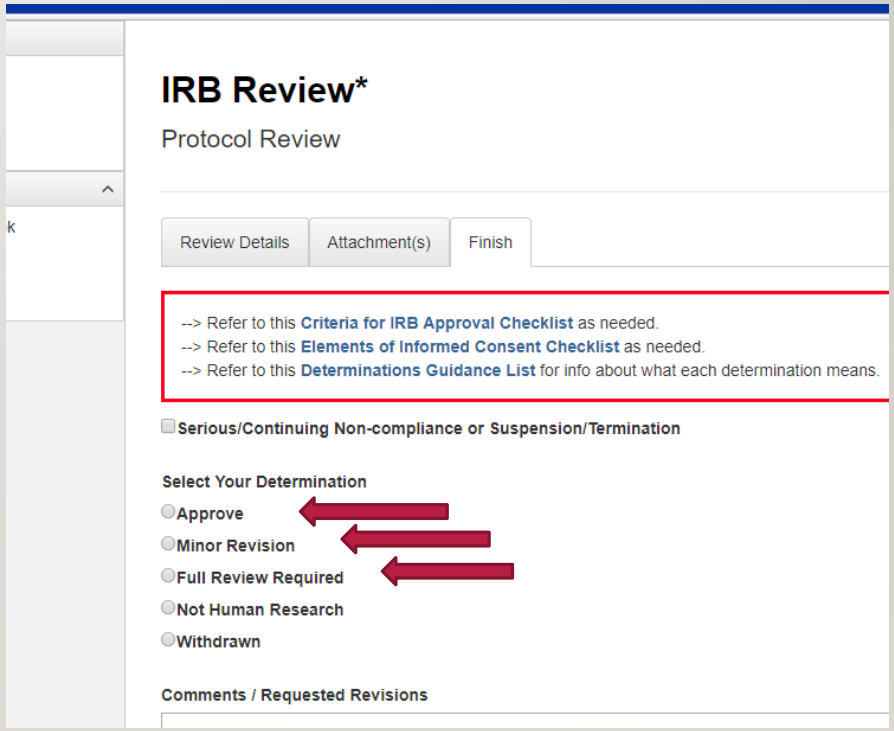
- Go to All Attachments and the corresponding sections in the application.
- Then, read the application as a whole, taking the attachments into consideration



Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
Assent	10355-Form_F-CL_template, rev, rev 041919.pdf	Survey Phone Script	0.166	mplym0	4/19/2019 11:48:12 AM
AdditionInfoConsiderations	Pen and Ink Phone Script.pdf	Pen and Ink Phone Script	0.546	scbe223	4/19/2019 11:21:39 AM
Authorization	Form K. HIPAA Waiver of Authorization, rev.pdf	Form K. HIPAA Waiver of Authorization	0.771	mplym0	4/17/2019 7:03:49 PM
DataCollection	Form M.doc	Form M. Data Collection Form.	0.022	mplym0	4/16/2019 4:06:48 PM
AdditionInfoConsiderations	Recruitment Guidance.pdf	Recruitment Guidance	0.072	scbe223	4/3/2019 9:41:01 AM
DataCollection	Survey.docx	Telephone Survey	0.015	mplym0	3/23/2019 12:12:59 PM

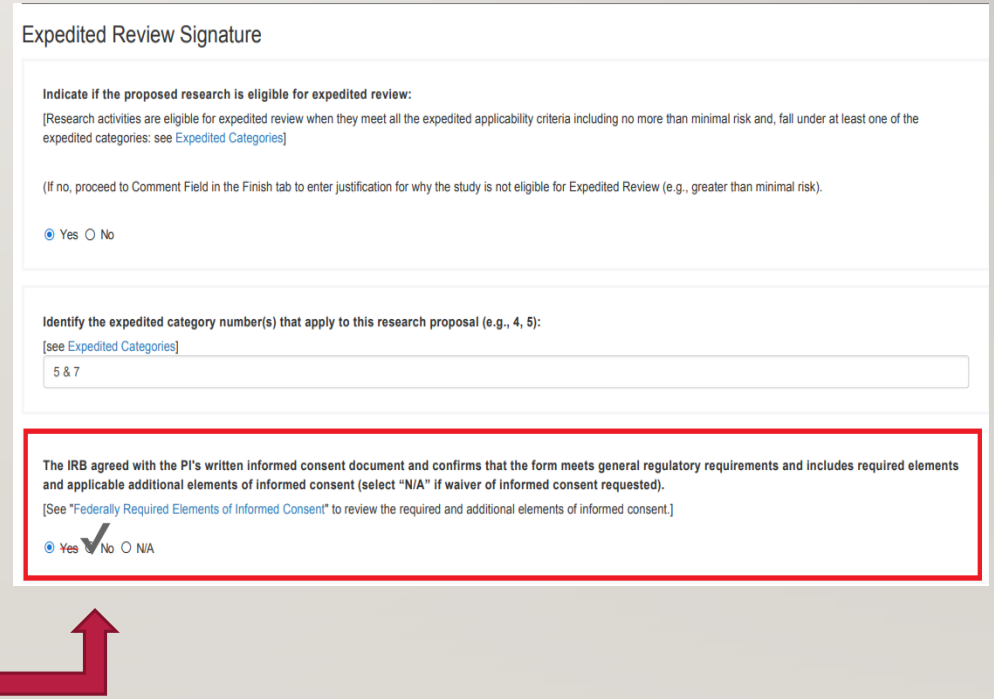
EXPEDITED REVIEWER OPTIONS

- As an Expedited Reviewer, you have three primary options when completing your review. You can…
  - Approve the Application
  - Request Minor Revisions
  - Request that the application be reviewed by the full board at an upcoming meeting



REQUESTING REVISIONS

- If you are requesting revisions to the protocol, you should mark "No" for the relevant section on the IRB reviewer form.
- For the sample review, the reviewer should have chosen "No" for the informed consent compliance question, because her comments indicated she did not agree w/PI on waiving informed consent.



ODDS AND ENDS

- When completing your review, go back into the application and double check the categories that appear on the reviewer sheet. These include:
  - Making sure the expedited category the PI chose is appropriate
  - Checking to see if there is an attached consent document (or cover letter for survey research)
  - If no consent document, check to see whether the PI is requesting a waiver of informed consent/waiver of documentation of informed consent
  - Check whether the study will involve a vulnerable population (on subject demographics page)
  - Check whether the study involves a drug or device, and whether the PI has submitted appropriate documentation

ADDITIONAL INFO

- Don't forget, ORI has a video and quiz tailored towards qualifying individuals to serve as expedited reviewers. This video/quiz can also be used as a refresher for current expedited reviewers. These resources can be found on the ORI website, or by following this link: https://www.research.uky.edu/office-research-integrity/expedited-initial-review-training
- Finally, ORI is happy to offer personalized training sessions for conducting expedited reviews. One of our expedited review staff can meet you at your office and walk you through the expedited process in ~ 30 minutes or less. If you're interested, feel free to contact

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