

**University of Baltimore**

**University of Baltimore Institutional Review Board (IRB)**

**Kuali Protocols Software**

**Protocol Review Guide for UB Faculty, Staff, and Student Researchers**

**Fall 2019**

## **Introduction**

The University of Baltimore Institutional Review Board (UB IRB) is an 8-member committee responsible for the protection of human subjects in research studies that are conducted at the University. The UB IRB ensures that faculty, staff, and student researchers comply with University, University System of Maryland, and the Federal regulations set forth by the US Department of Health and Human Services (US DHHS) in 45 CFR 46 – Protection of Human Subjects. At UB there is an application, review, and approval process with regard to the use of human subjects in research studies.

The University of Baltimore has implemented Quali Protocols software to administer the application submission, review, and approval for IRB protocol applications. All UB, faculty, staff, and students have access to the Quali portal through myUB, where they can create and submit their protocol applications and review the status of pending protocol applications.

With the implementation of Quali, we have essentially converted our IRB paper application process to an entirely electronic format. This guide will help you familiarize yourself with the system, and assist you with the following tasks:

- i.* Overview of UB’s Electronic IRB Application Procedures (p. 3)**
- ii.* Accessing the Quali Protocols Software (p. 4)**
- iii.* Reviewing Information on Your Protocols Dashboard (p. 5)**
- iv.* Initiating a New Protocol Application (p. 6)**
- v.* Uploading Attachments (p. 9)**
- vi.* Submitting Your Protocol (p. 12)**
- vii.* Reviewing and Responding to IRB Questions and Comments (p. 13)**

## **i. Overview of UB's Electronic IRB Application Procedures**

The KualI Protocols software was implemented at UB: a) to improve operational efficiencies of the Institutional Review Board, and b) to serve as a centralized, electronic record keeping system. The UB IRB will continue to operate in compliance with the Federal regulations put forth in 45 CFR Part 46 – Protection of Human Subjects.

With this in mind the KualI electronic procedures will mimic what was previously done with the hard copy, paper based application:

a) Faculty, staff, and student researchers will access the KualI Protocols portal through myUB to complete their protocol application. Users can upload and label attachments to their application including their study instruments, recruitment material, and sample consent documents. Once the application is complete the users click "submit".

b) After the protocol is submitted, the OSR IRB Coordinator will receive a system generated email notification that a new application is in the queue.

c) The IRB Coordinator will login and pull up the protocol on their dashboard and complete an initial administrative review (i.e. application completeness, thoroughness in responses, all necessary attachments are included). For those protocols that qualify for an exempt or expedited review, the IRB Coordinator will assign the protocol to (2) IRB members for review. For protocols that require a full board review, the protocol will be assigned to an upcoming IRB meeting.

d) IRB members will review the protocol and insert questions or concerns within the application. The IRB Coordinator will make the pertinent reviewer questions and concerns available to the researcher.

e) The researcher will then have the opportunity to review comments and revise the application accordingly. They can also upload revised attachments (e.g. consent documents, survey instruments, etc.). The system will flag all saved changes for the IRB members to review.

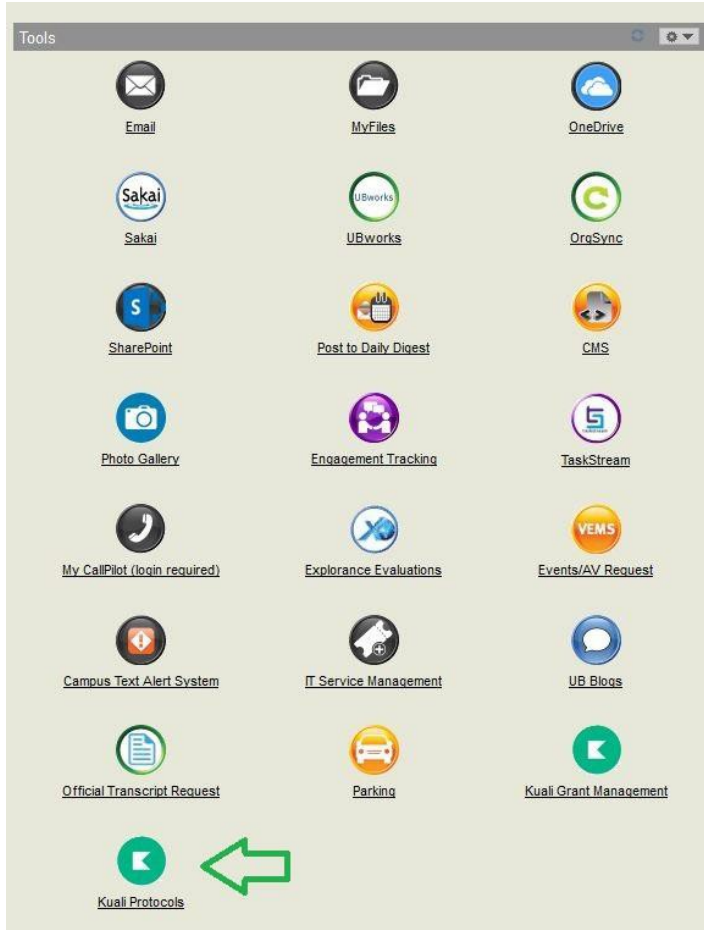
f) If/when a protocol is approved by the IRB, a formal approval letter will be issued to the researcher. *Note: For all protocol applications that are approved under expedited or full board review, there is a (1) year effective period for the approval. Those researchers must submit a renewal application after that first project year.*

g) The researcher can log into their dashboard at any time to review the status of their applications, or pull up previously submitted protocols.

## ii. Accessing the Kualii Protocols Software

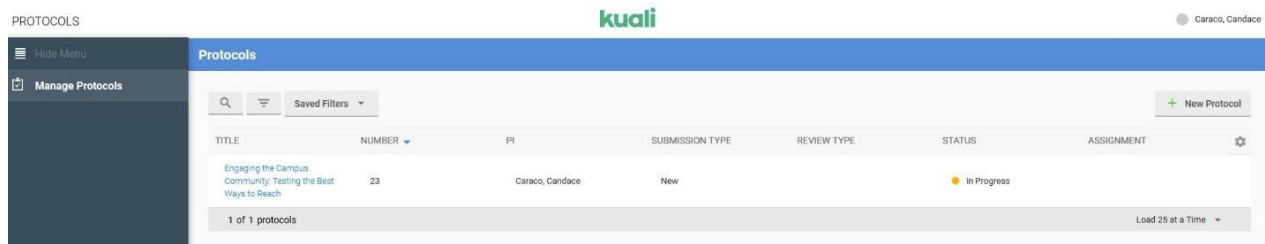
All UB faculty, staff, and student researchers have access to Kualii Protocols through the **MyUB portal**. The software utilizes a single sign on so once a user is logged into MyUB, they can navigate to the Kualii Protocols icon on the lower left hand side of the Tools menu.

After signing into myUB:



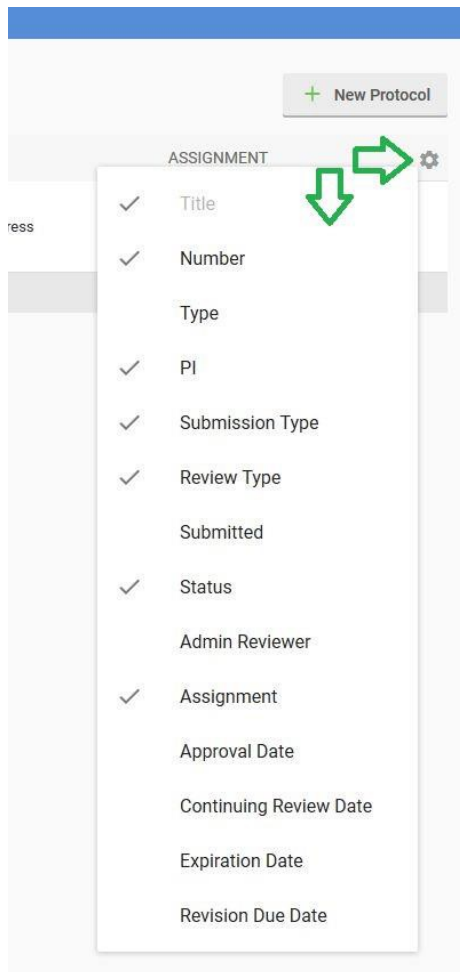
### iii. Reviewing Information on Your Protocols Dashboard

The Kuali Protocols icon will bring the user to their protocols dashboard. This dashboard will display all of the user’s own protocols that have been submitted in the system:



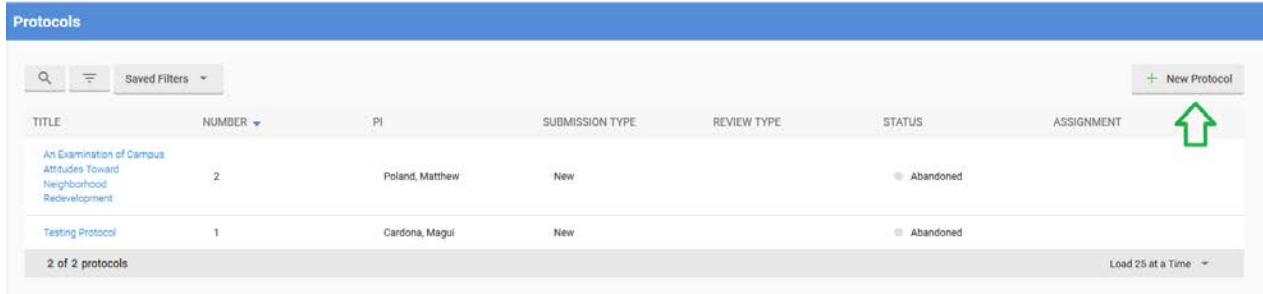
The default display settings will include the following information for each protocol: title, protocol #, PI, Submission Type, Review Type, Status, and Assignment.

By clicking on the widget on the right hand side – the user can choose to also display any of the following information:



## IV. Initiating a New Protocol Application

To initiate a new IRB protocol application, first click the “+ New Protocol” button in the upper right hand corner:



Then select “IRB”. This will bring you to the IRB General Information screen below:

The screenshot shows the "IRB - General Information" form. It has several input fields:




- Introductory Instructions Placeholder
- Principal Investigator
- Lead Unit
- Title
- Project Summary


Below the Project Summary field, there is a note: "Provide a brief, lay summary of your project and how you intend to utilize human subjects. In 3-4 sentences, please provide a lay summary of your proposed project." On the right side of the form, there are two buttons: "Cancel" and "Next" with a right-pointing arrow.

All UB Faculty, Staff, and Students should be able to search for and select their name from the pulldown menu for Principal Investigator. To search, start typing your last name and the available selections should pre-populate. *Note: If you do not see your name listed, please contact the IRB Coordinator at 410 837 6199, [irb@ubalt.edu](mailto:irb@ubalt.edu).*

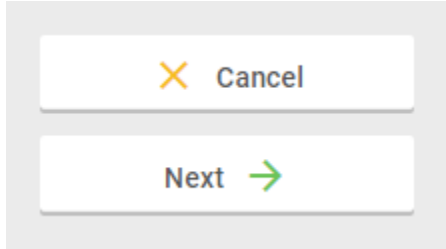
Use the pulldown menu under “Lead Unit” to select the appropriate UB unit or division. Note: If you are a **student**, select your college, If you are a **faculty or staff member** – select your department.

*For Students (select your college):*

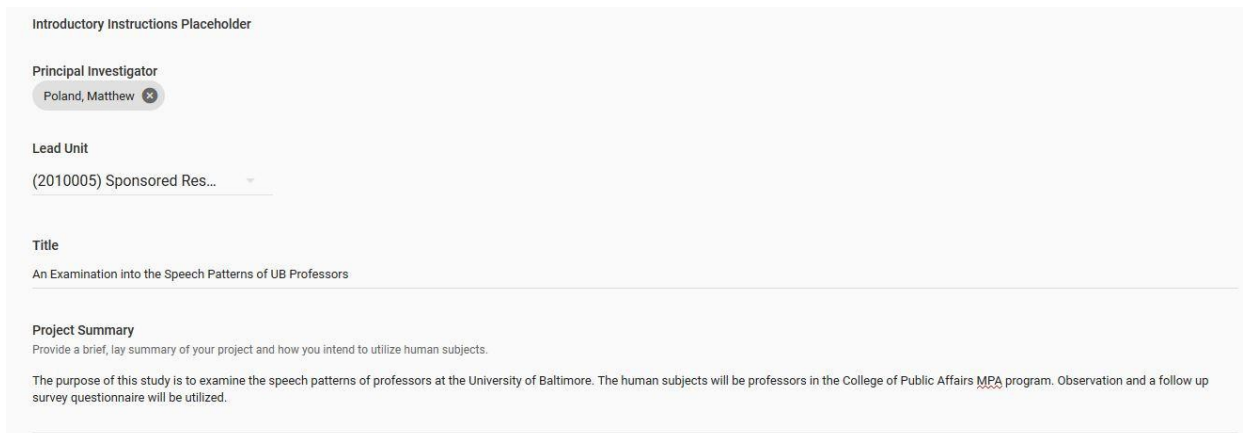
- Merrick School of Business  select “MSB Administration”
- College of Arts & Sciences  select “CAS Administration”
- College of Public Affairs  select “CPA Administration”

- UB School of Law  select “Law School Administration”

The “Next” button will guide you through what is required for the protocol to be saved. If you choose to 'Cancel' the protocol will not be saved and the system will return you to the Researcher’s dashboard.




Complete the Title and Project Summary fields, which are both open text boxes and click “Next” in the upper right hand corner to proceed to the next section of the application:

A screenshot of a web application form. It includes sections for: "Introductory Instructions Placeholder", "Principal Investigator" (Poland, Matthew), "Lead Unit" ((2010005) Sponsored Res...), "Title" (An Examination into the Speech Patterns of UB Professors), and "Project Summary" (Provide a brief, lay summary of your project and how you intend to utilize human subjects. The purpose of this study is to examine the speech patterns of professors at the University of Baltimore. The human subjects will be professors in the College of Public Affairs MPA program. Observation and a follow up survey questionnaire will be utilized.)

On the following screen, enter your estimated start and end date for running the study. *Note: IRB approval must be in place before any research activities with human subjects can commence.*

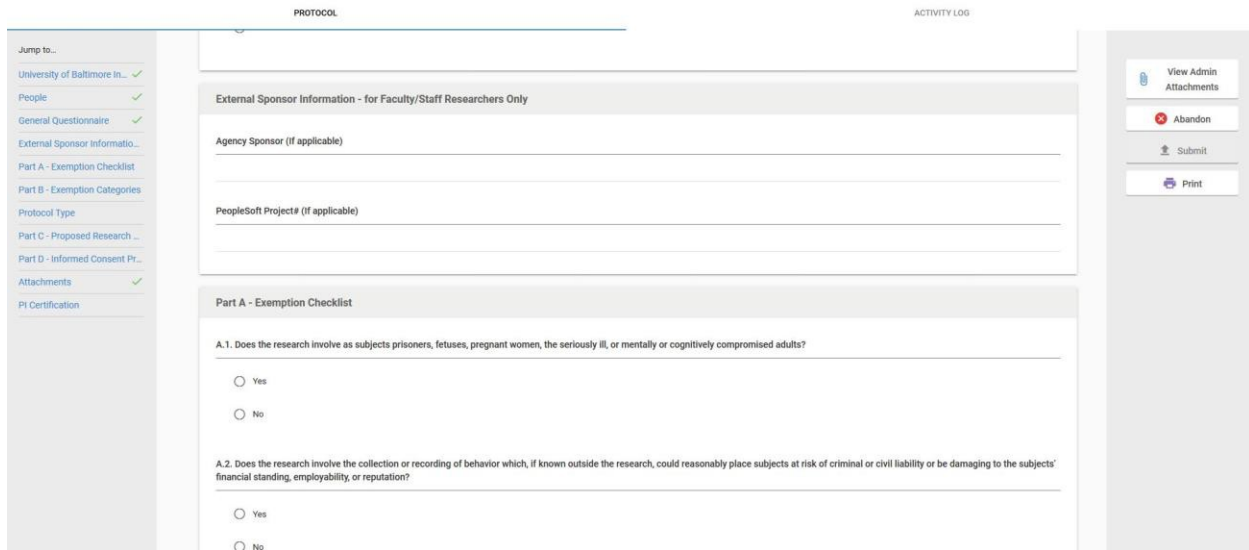
If the user is a student they must indicate that on this screen as well. For student protocol applications, the faculty advisor should be added to the personnel information in the following section.

A screenshot of a "General Questionnaire" form. It contains three main sections: "Estimated Start Date" with a date picker set to May 1, 2018; "Estimated End Date" with a date picker set to July 31, 2018; and a question "Is the primary researcher on this protocol a student?" with radio button options for "Yes" and "No", where "No" is selected.

For Students  List “N/A” under Agency Sponsor and Peoplesoft Project # fields. These fields are for faculty researchers and have to do with externally funded sponsored research projects.

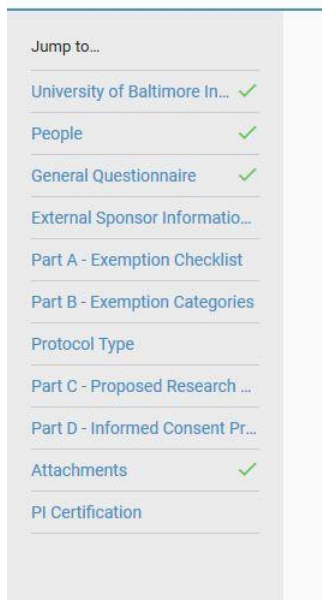
After the General Questionnaire is complete and you press the Next button the system will take you to the entire protocol view so additional information can be added and edited. All sections must be completed before the Protocol can be submitted for review.

Click “Next” to proceed to the remainder of the protocol application:



The screenshot displays a web-based protocol application interface. At the top, there are tabs for 'PROTOCOL' and 'ACTIVITY LOG'. On the left side, a vertical navigation menu lists various sections: 'Jump to...', 'University of Baltimore In...' (with a green checkmark), 'People' (with a green checkmark), 'General Questionnaire' (with a green checkmark), 'External Sponsor Informatio...', 'Part A - Exemption Checklist', 'Part B - Exemption Categories', 'Protocol Type', 'Part C - Proposed Research ...', 'Part D - Informed Consent Pr...', 'Attachments' (with a green checkmark), and 'PI Certification'. The main content area is divided into two sections. The first section is titled 'External Sponsor Information - for Faculty/Staff Researchers Only' and contains two text input fields: 'Agency Sponsor (if applicable)' and 'PeopleSoft Project# (if applicable)'. The second section is titled 'Part A - Exemption Checklist' and contains two questions, each with radio button options for 'Yes' and 'No'. Question A.1 asks: 'Does the research involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults?'. Question A.2 asks: 'Does the research involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?'. On the right side of the interface, there are three buttons: 'View Admin Attachments', 'Abandon', and 'Submit', along with a 'Print' button at the bottom.

The panel on the left hand side will indicate which sections of the application are complete with a green check mark. The user can also navigate to specific sections by clicking on each:



This is a close-up view of the left-hand navigation menu from the previous screenshot. It shows a list of sections with a 'Jump to...' header. The sections are: 'University of Baltimore In...' (with a green checkmark), 'People' (with a green checkmark), 'General Questionnaire' (with a green checkmark), 'External Sponsor Informatio...', 'Part A - Exemption Checklist', 'Part B - Exemption Categories', 'Protocol Type', 'Part C - Proposed Research ...', 'Part D - Informed Consent Pr...', 'Attachments' (with a green checkmark), and 'PI Certification'.



### *Part A – Exemption Checklist*

This section of information (along with Part B) will determine whether a protocol application can be considered “exempt” from further IRB monitoring in accordance with regulations put forth in 45 CFR 46. Included in this section are questions regarding the target population and the level of inherent risk to participants. If the researcher answers “yes” to any of the questions, they will be prompted to provide additional information.

### *Part B – Exemption Categories*

The questions in this checklist will help determine which category of exemption may be applicable for the protocol per the Federal guidelines.

### *Protocol Type*

The researcher should read this section carefully to determine which review type is best suited for the protocol application. The response here will be determined by the responses in Part A and Part B, accordingly. *Note: The IRB will make the final determination as to the protocol review type designation.*

### *Part C – Proposed Research Design*

The questions in Part C allow for the researcher to fully describe the purpose of the study, their project design, and data collection. The researcher should be as thorough as possible

### *Part D – Informed Consent Procedures & Confidentiality*

Under the Federal regulations, researchers who intend to study human subjects must obtain informed consent from potential participants. Informed consent can occur via a written document, a web based application, or a verbal exchange between the researcher and the participant. This section also includes questions on data security, confidentiality, and will ask the researcher to describe the steps they will take to protect the dataset.

### *IRB Protocol Personnel:*

All protocol personnel must be listed in the Person section. The individual listed as the Principal Investigator above, and the initiator of the protocol will both be listed. Additional individuals can be added by pressing the Add button.

People						
PERSON	HOME UNIT	RESEARCHER ROLE	CONTACT ROLES			
Poland, Matthew	Applied Behavioral Sciences	Principal Investigator	Admin			

When you press the Add button a lightbox will appear where you can enter details about the individual you are adding. The Person name, and Email address will populate automatically based on the person you select from the list in the Person field. The other fields on this screen have to be entered manually. Each individual must have a Researcher or Contact role listed. The other fields are optional. If you mark Full Access on this screen this user will be able to open and modify this protocol via the Manage Protocols screen. If you click Read-Only then this user will be able to open, but not modify this Protocol via the Manage Protocols screen.

**\*\*Student researchers must add their Faculty Sponsor on their protocol and give them full access permissions for their protocol to be reviewed. \*\***

*Other Sections:*

Below this section the rest of the IRB Protocol form will display. Be sure to read every question carefully and include all appropriate detail in the text questions.

## V. Uploading Attachments

Below the form sections you will be able to add attachments to your protocol. There are some attachments that are only required if certain answers are provided in the Protocol form. Attachment locations will populate within the form in that case. The attachments panel is for attachments that are required on all Protocols, and all optional attachments. To add a new attachment press the Add button.

Attachments						
Please attach all pertinent protocol materials including your study instrument, consent document, training certificates, and recruitment materials.						
ATTACHMENT	NAME	ATTACHMENT TYPE				
INFORMED CONSENT FORM.PDF	Informed Consent Form	Consent Document				

The lightbox that appears when you press the add button has a location where you can add your attachment, a field to Name the attachment, a dropdown list of Attachment Types, and an open text field to add comments about the attachment. Every protocol requires at least 1 attachment with the type Sample Study Instrument.

\*Note: The IRB will need to review examples of all pertinent protocol materials, including but not limited to consent documents, study instruments (i.e. surveys, questionnaires, interview scripts, focus group questions, etc), and recruitment materials. If your protocol utilizes these items, they should be attached here and labeled accordingly.

**Edit** [X]

Attachment

Informed Consent Form.pdf

View Attachment Replace

Name

Informed Consent Form

Attachment Type

Consent Document

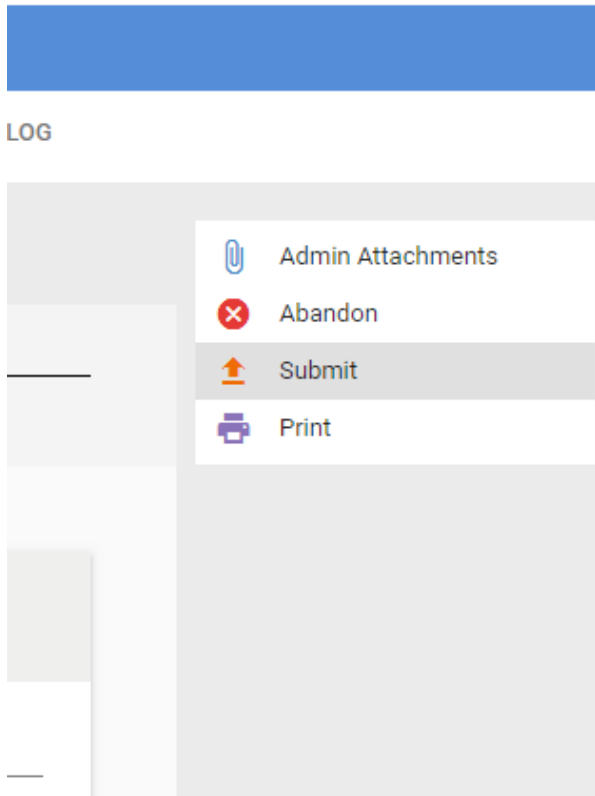
Comments

This is my consent documentation.

Cancel Done

## VI. Submitting Your Protocol

After all fields have been completed (your protocol saves automatically as you complete), submit your protocol by pressing the submit button at the top right of the page. If you have any errors or incomplete fields, you will be notified at this time. If not, your submission will be submitted to the IRB coordinator's dashboard. Your protocol should say submitted for review on your dashboard.



## VI. Reviewing and Responding to IRB Questions and Comments

If your protocol is missing required information and/or materials during the administrative review by the IRB coordinator, or your Board reviewers have any questions or required revisions during your protocol's Board review, your protocol will be sent back to you. You will be notified by an automated email (to your UB email) from Kualu. When you open your protocol you will see the yellow feedback bar at the top of the protocol page (seen in picture two below) with instructions on what to revise, and/or what questions to address. You will also see the date the revisions are due back by. In picture one you see an example of the comment icon. You can click the icon to review the comment(s) from your reviewer(s). You will also be able to see which sections your reviewers have left comments on by looking at the "Jump to" sections on the left hand side of the page. Once you have addressed all questions and made revisions you will resubmit your protocol.

This screenshot shows the IRB system interface for a protocol. On the left, there is a "Jump to..." sidebar with a list of sections: University of Baltimore... (1), People (✓), General Questionnaire (1), External Sponsor Informat..., Part A - Exemption Ch... (1), Part B - Exemption Cat... (✓), Protocol Type (✓), Part C - Proposed Res... (1), Part D - Informed Cons... (✓), Attachments (✓), and PI Certification (✓). The main content area shows the protocol details: Version: 2 (Resubmitted), Show Latest Changes (checkbox), Submission Type: New, Review Type: Full Board, Status: Resubmitted, and Time in Current Status: Since September 10 - a year. Below this is an "Add General Comment" button. The main title is "University of Baltimore Institutional Review Board - Application for Approval of Research and Involving Human Subjects". At the bottom, there is a "Principal Investigator" field with a "1 Comment" icon and a "Lead Unit" field with the value "(2030100) MSB Administration" and a "Comment" button.

This screenshot shows the IRB system interface for a protocol with a feedback bar. The top bar is yellow and contains the text "Feedback". Below this, there is a "Revision Due Date" field with the value "Sep 20, 2019". Below that is a "Revision Required Comment" field with the text "please make the following revisions as advised by your reviewers in the protocol." The main content area shows the protocol details: Version: 2 (Revisions Required), Show Latest Changes (checkbox), Submission Type: New, Review Type: Full Board, Status: Revisions Required, and Time in Current Status: Since September 16 - a few seconds. On the right side, there are icons for a document, a group of people, a red X, and a printer.

*General Tips for Completing Your IRB Protocol Application:*

- Start the process early, do not hesitate to contact the IRB Coordinator with any questions prior to submitting your protocol.
- The IRB is comprised of individuals with a wide variety of backgrounds, from each of the colleges on campus. Use plain language and avoid field specific acronyms or jargon. You will want to write as if your audience is not familiar with your field or academic area of study.
- Be as thorough as possible when responding to each question. The goal is to provide the IRB with a complete understanding of your project design, target population, recruitment strategies, and study instruments.
- Do not minimize risks. Put yourself in your participants' "shoes". There is an inherent amount of risk associated with all research projects involving human subjects. The goal is to show the IRB that you acknowledge those risk(s) and are taking appropriate steps to manage and mitigate those risks to participants.
- If you are utilizing existing data from an outside entity or if you wish to administer your study at your place of employment or another affiliated organization, the IRB will ask that you provide documentation from that organization that grants you permission to run the study or use the data.
- Remember the 4 C's: Consideration, Clarity, Consistency, and Completeness