How to Submit: Initial IRB Application

Step by Step Guide for Researchers and Support Staff

Please note: there are references to "the IRB website" throughout this guidance. The site we are referring to is always www.irb.upenn.edu

When we talk about "HSERA" we are referring to the electronic submission system for human research at Penn. It is important to know that these are 2 separate Internet locations. Use of both sites is required for successfully submitting to the IRB.

*This PDF is bookmarked for quick navigation

Covered here:

- Using the IRB Website (www.irb.upenn.edu)
- Using IRB Protocol and Consent Templates
- Using HSERA

USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

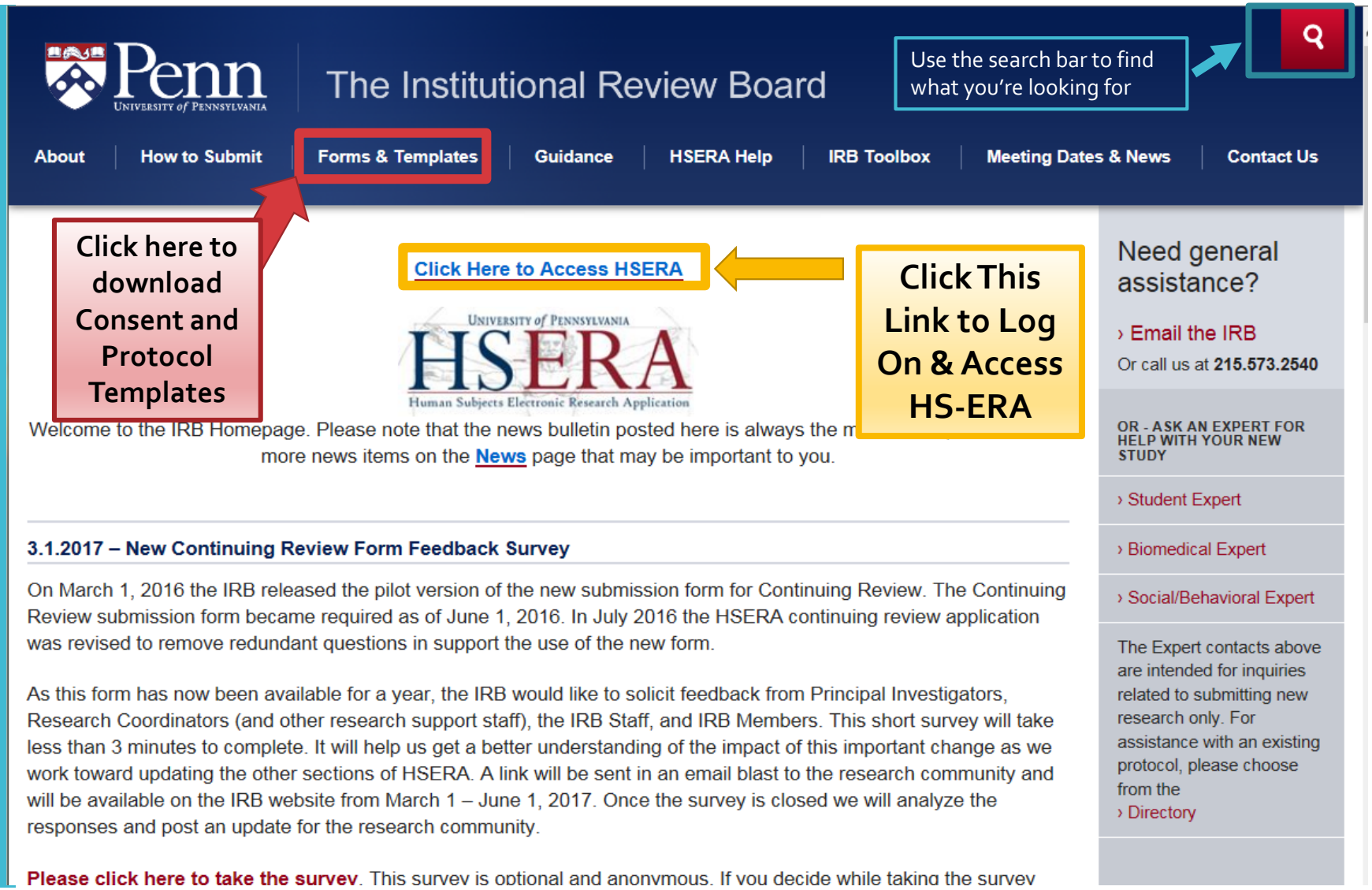
- Researchers and Research staff should reference the IRB website for instruction before logging on to HSERA to create submissions

- Go to www.irb.upenn.edu

- Use the guidance and templates provided by the IRB to build the documents for your project before you submit in HSERA

- A link to HSERA is provided on the home page for convenience

- If you work on multiple human research projects we suggest bookmarking and visiting the IRB website often to stay up to date on the latest news

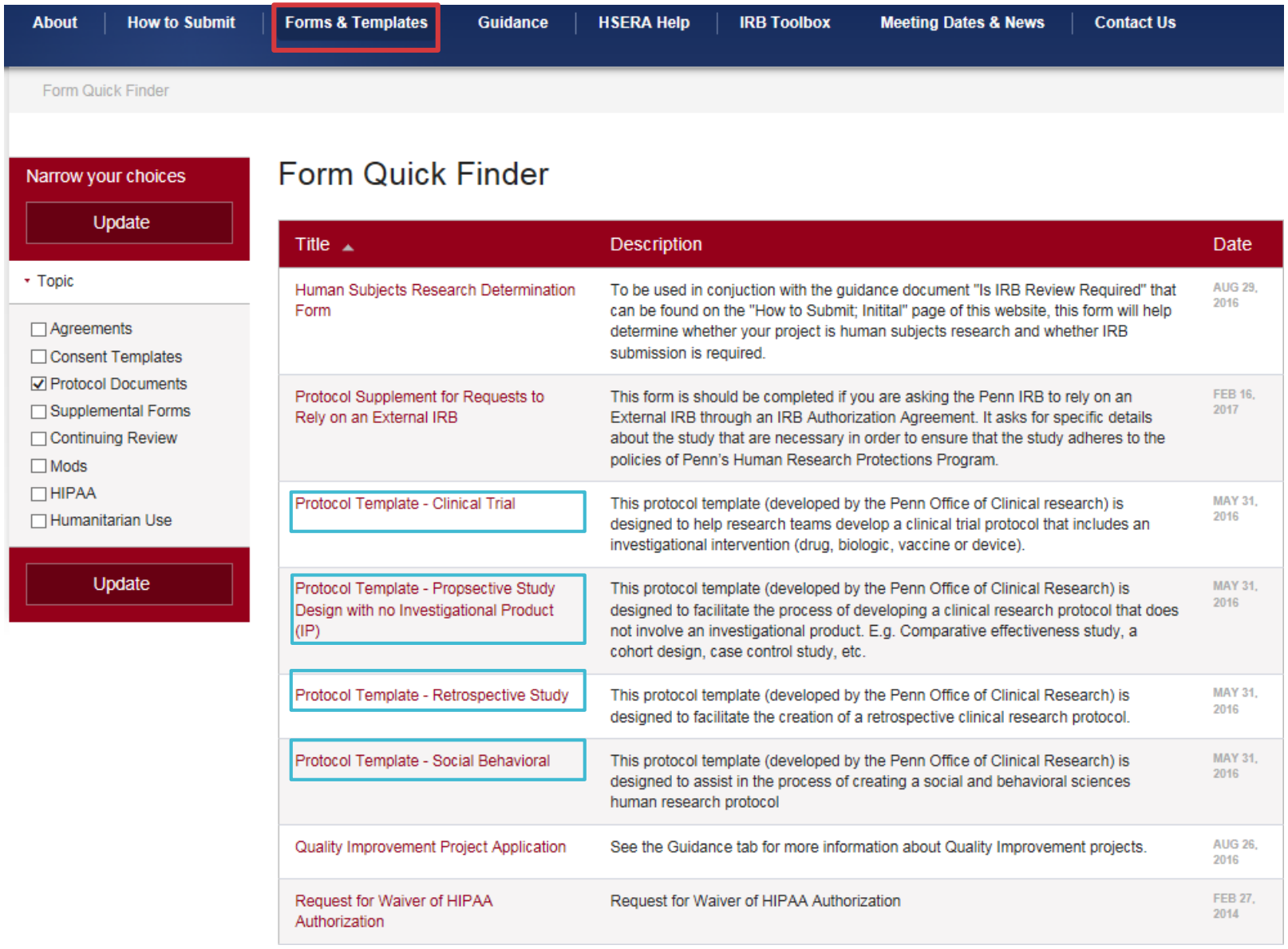


USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

- On the Forms & Templates page, filter for protocol documents

- Use the appropriate template for your type of project

- If you aren't sure if your project requires IRB review, download and complete the Human Subjects Research Determination Form and send to an IRB senior administrator via email for a consultation.



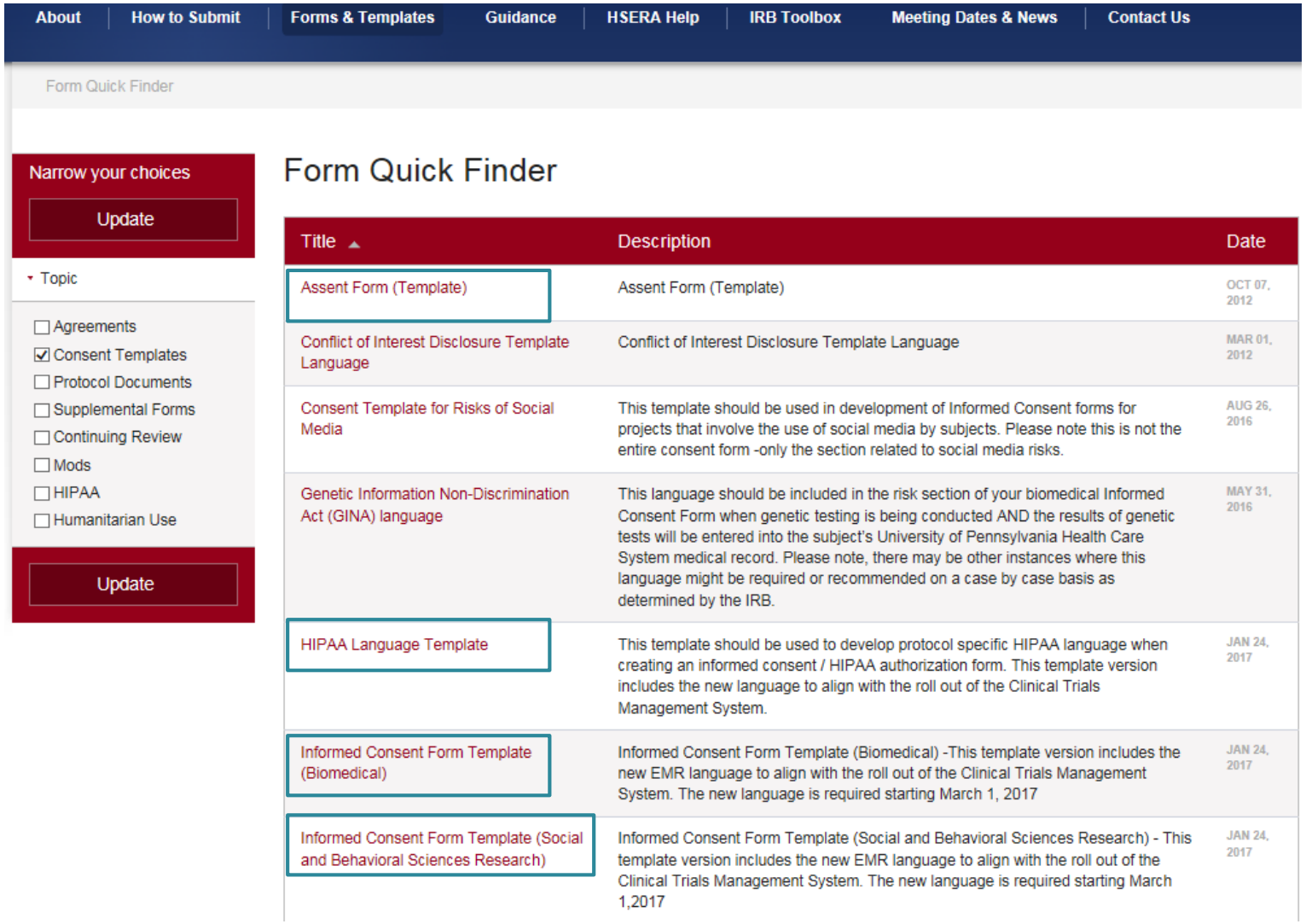
USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

- On the Forms & Templates page, filter for Consent Templates

- Download the templates that best apply to your study

- The templates have the basic required elements of consent which should be revised to describe your study.

- Additional language may be required depending on your study design (e.g. use of PHI will require HIPAA language, genetic testing will require GINA language etc…)



USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- Once your basic study documents are ready, log in to HSERA to create your application

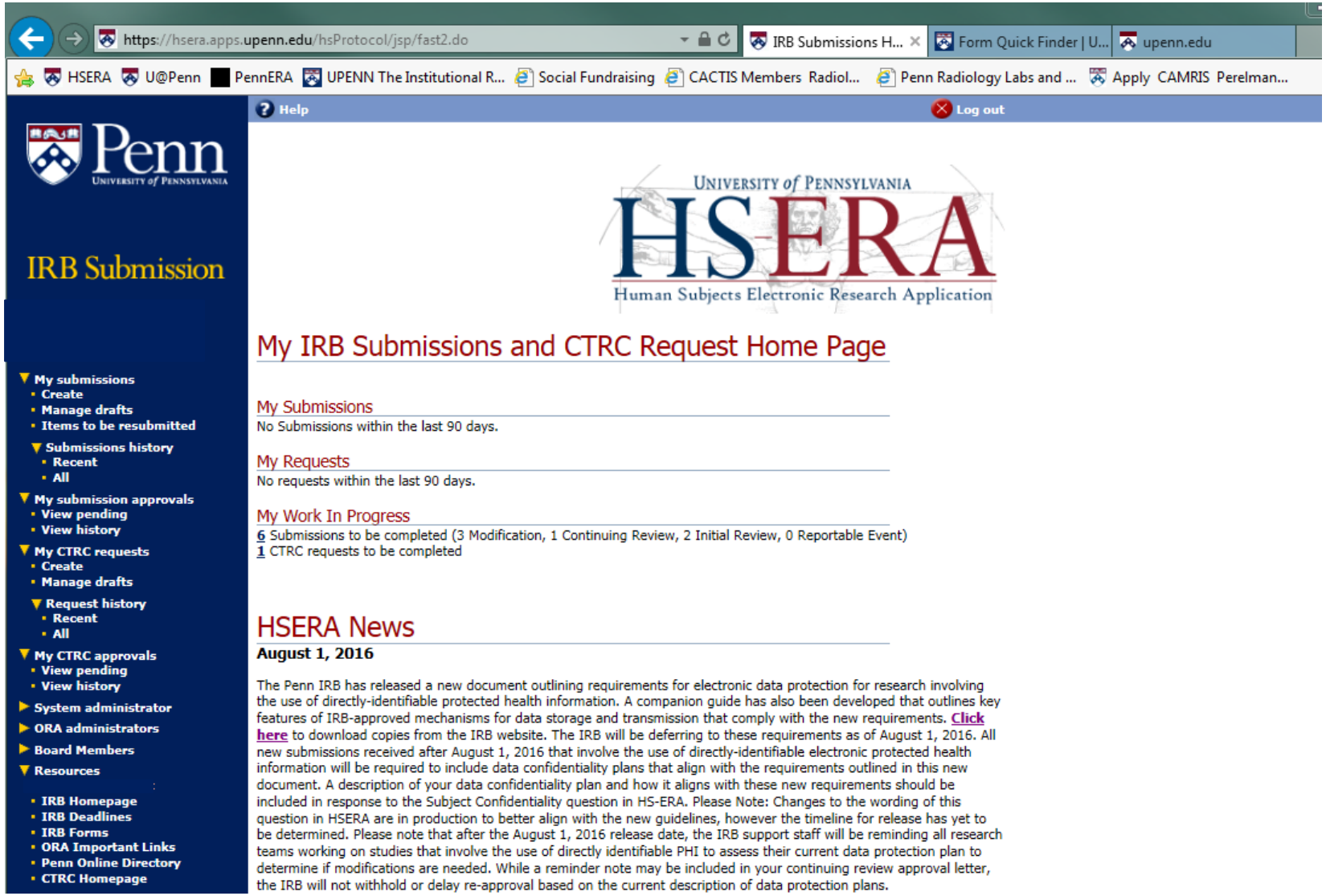
- The front page of HSERA has a menu of links along the left side for creating and managing your submissions

-The content in the center of the page shows :

"My Submissions" = your IRB submissions pending review

"My Requests" = your CTRC requests pending review

"My Work In Progress" = drafts you are working on for both IRB and CTRC

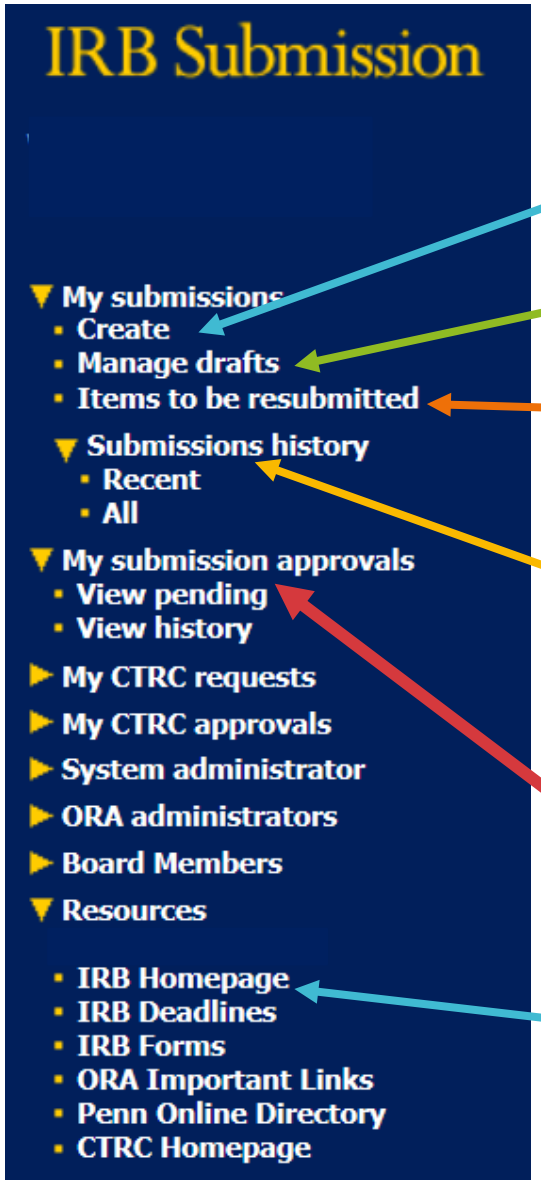


USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- To create a new study Click "Create" under "My submissions"

-Review the information on this screen shot to get an idea of how to navigate with the HSERA menu

- Please note that the IRB staff and members are provided with navigation links in the HSERA menu that may not appear for typical users. In this training we are focusing on the universal navigation links that all users have access to although the additional links may still appear in the screenshots.



Click "Create" to make something new

Click "Manage Drafts" to keep working on something you already created but did not submit. A new submission will automatically appear in manage drafts after you complete the first page.

Click "Items to be resubmitted" to work on a submission that the IRB sent back to your team after performing a review.

Both links under "Submission History" will allow you to go back and view any submission for studies you are listed as personnel. Recent shows submissions from the last 90 days. This is a view only access.

"Submission Approvals" section is for Principal Investigators and Departmental Approvers only.

Use the resources links to :
-go back to the IRB website
-view the convened board meeting schedule
-go to the forms page on the IRB website etc..

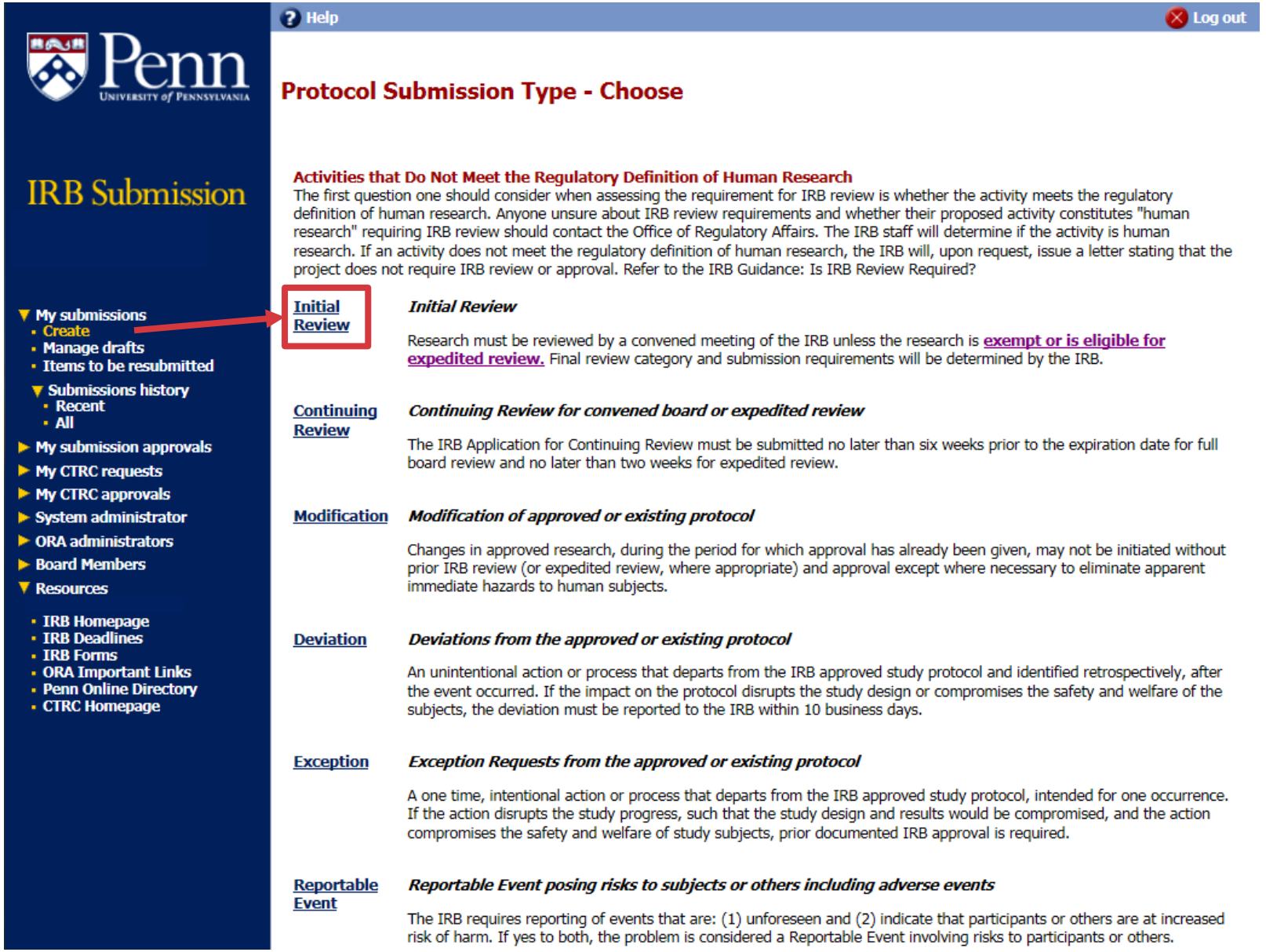
USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- After clicking "Create" you will be brought to a new menu screen. Choose "Initial Review" to begin an application for submitting a brand new study

- The other application types are also available on this page.

- After a new study receives approval, any subsequent updates must be done by creating Modification submissions.

- You can renew your protocol annually by creating a Continuing Review.



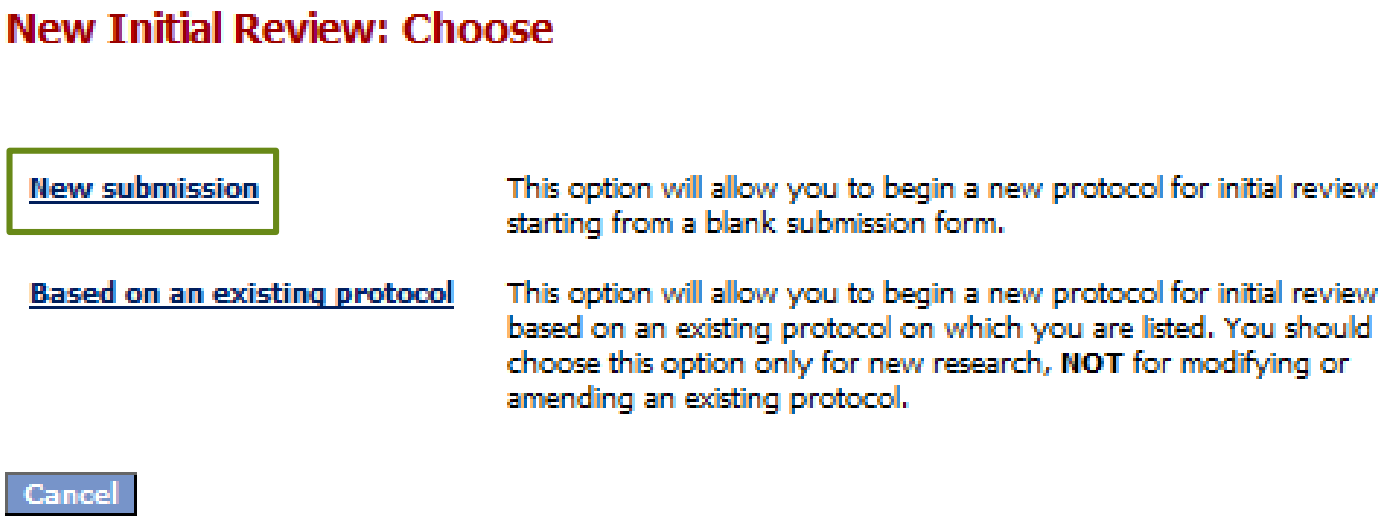
USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- After clicking "Initial Review" you will be brought to a new menu screen.

-You are given the option of opening a blank application or opening an application based on one of your existing studies

-You may only have one draft per protocol and will not be able to create a second draft for the same study.

- This guidance document is based on choosing "New Submission"



USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

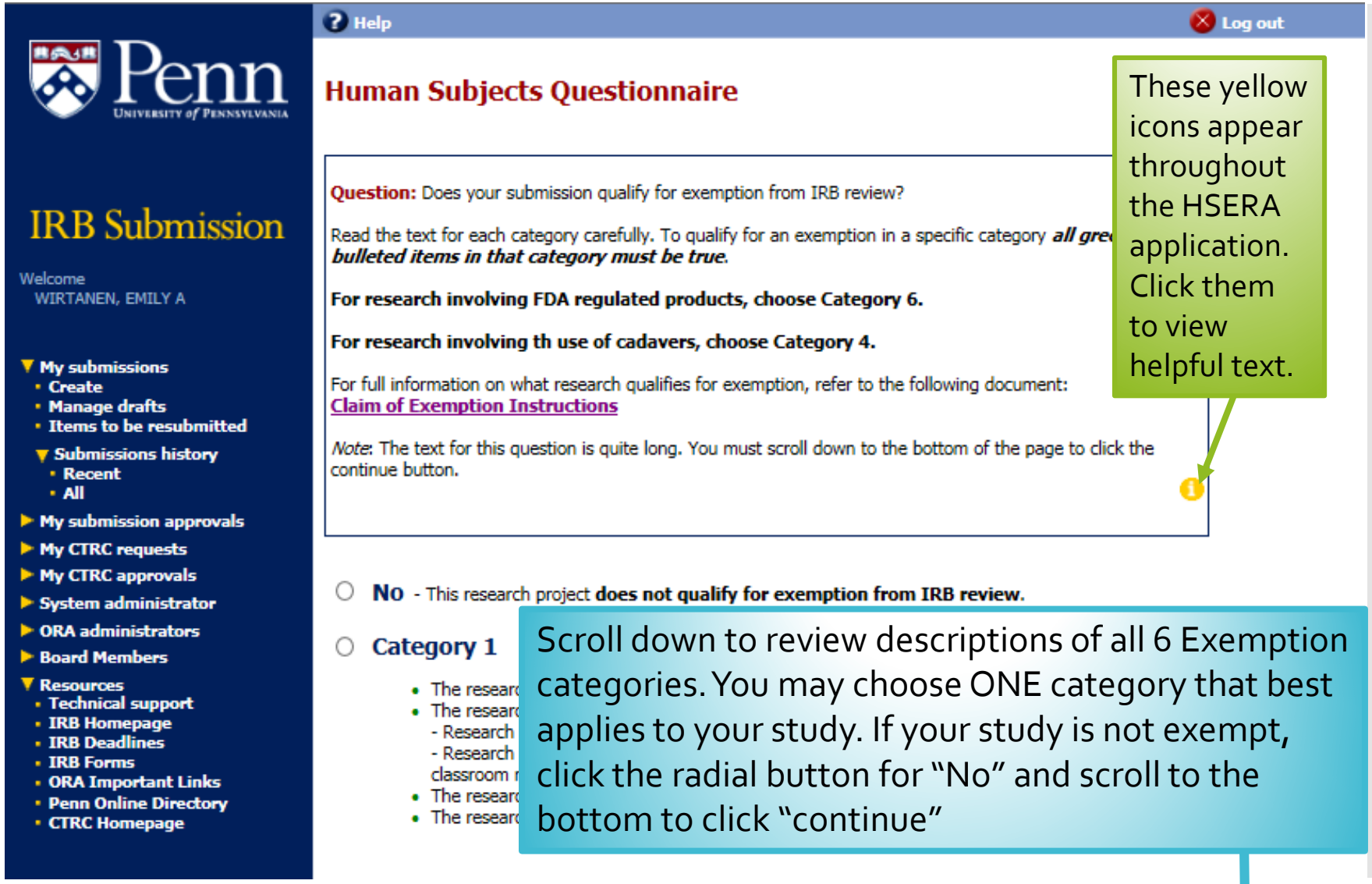
- After clicking "new submission" you are brought to the first screener page for the application

- Answering the screener questions will determine the level of specificity of your application.

- Step one is to establish if your project qualifies as "Exempt"

- Research that is exempt is minimal risk and falls into one of 6 specific categories. Once approved, Exempt research does not require any further IRB submissions throughout the life of the study.

- An Exempt application is the shortest application. If you submit an exempt application for non-exempt research you may be required to re-submit.



USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

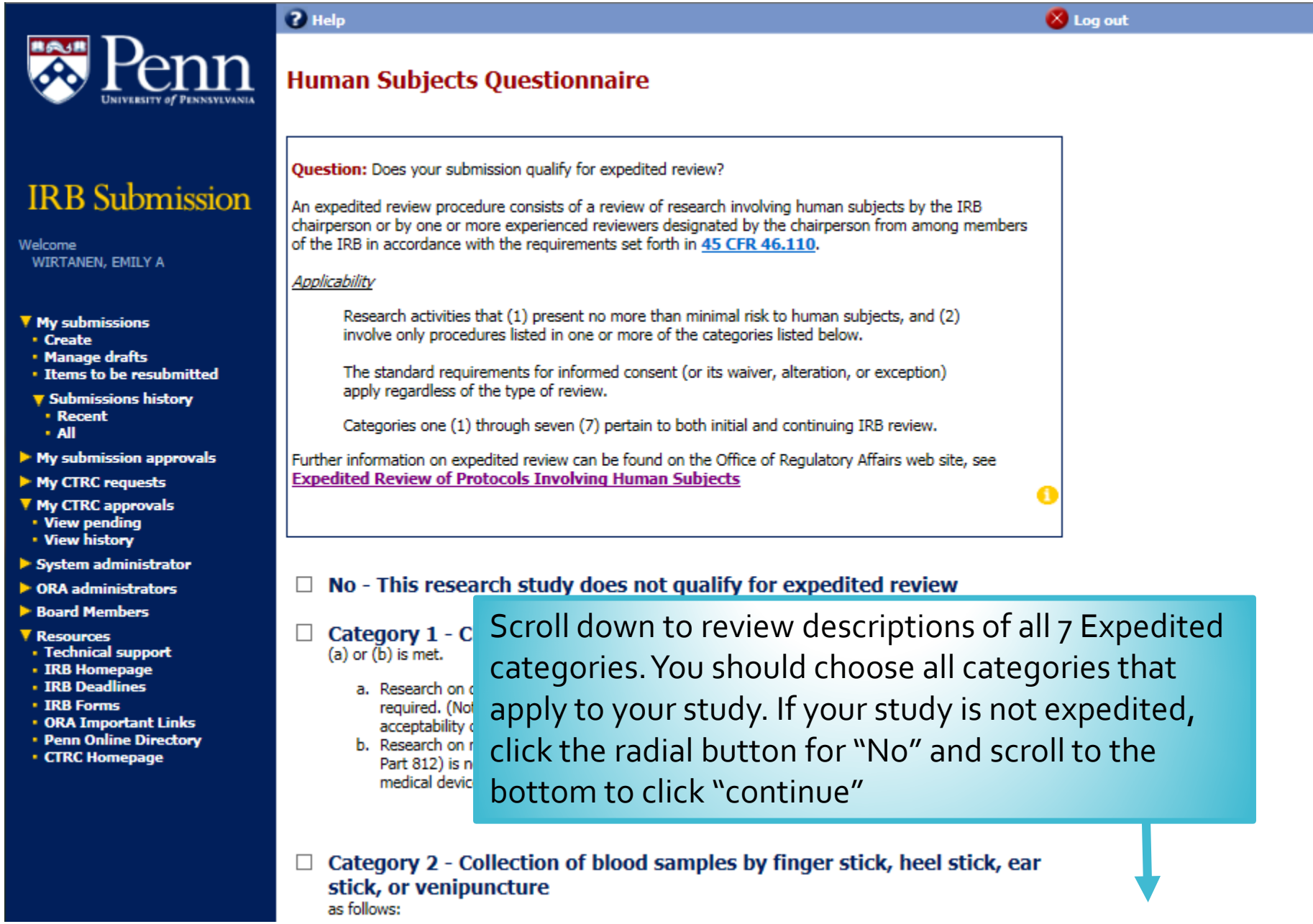
- If your study is not "Exempt", the next step is to determine if it is "Expedited"

- It is possible to submit an exempt application but the IRB may determine that your research qualifies as expedited.

- "Expedited" research is minimal risk and fits into one or more of 7 categories

- "Expedited" research requires annual continuing review to renew the application

- "Expedited" and "Exempt" research is not sent to the monthly convened board meetings for review. Instead it is screened by qualified IRB staff members and approved by one of the IRB directors



Scroll down to review descriptions of all 7 Expedited categories. You should choose all categories that apply to your study. If your study is not expedited, click the radial button for "No" and scroll to the bottom to click "continue"

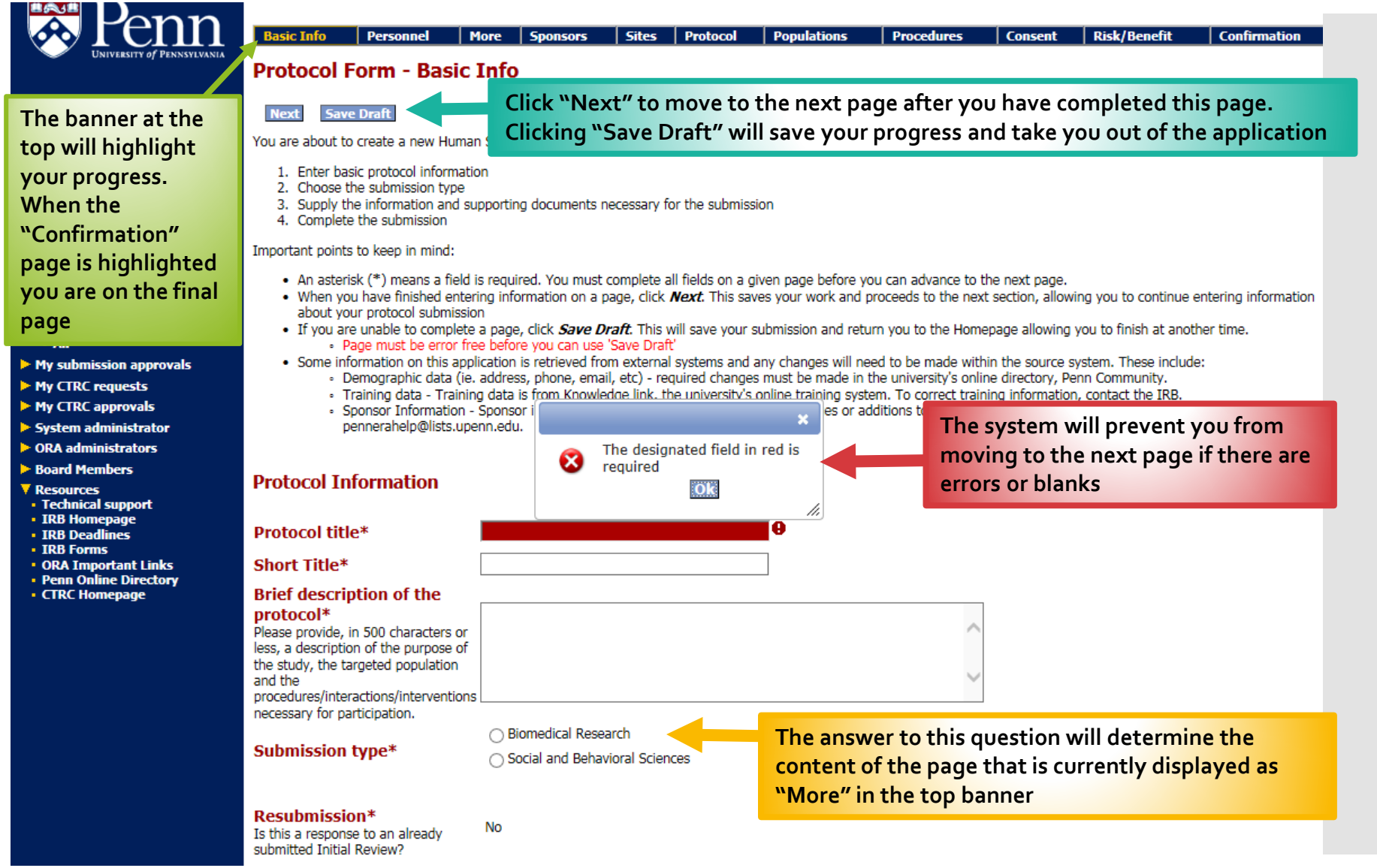
USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

--BASIC INFO--

- After completing the screening pages you will be brought to the first page of the application

- Once you start this page your draft will show in your "manage drafts" until you complete the submission by clicking "I Accept" on the "Confirmation" page

- On the "Basic Info" page you will name and describe your study



USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

--PERSONNEL--

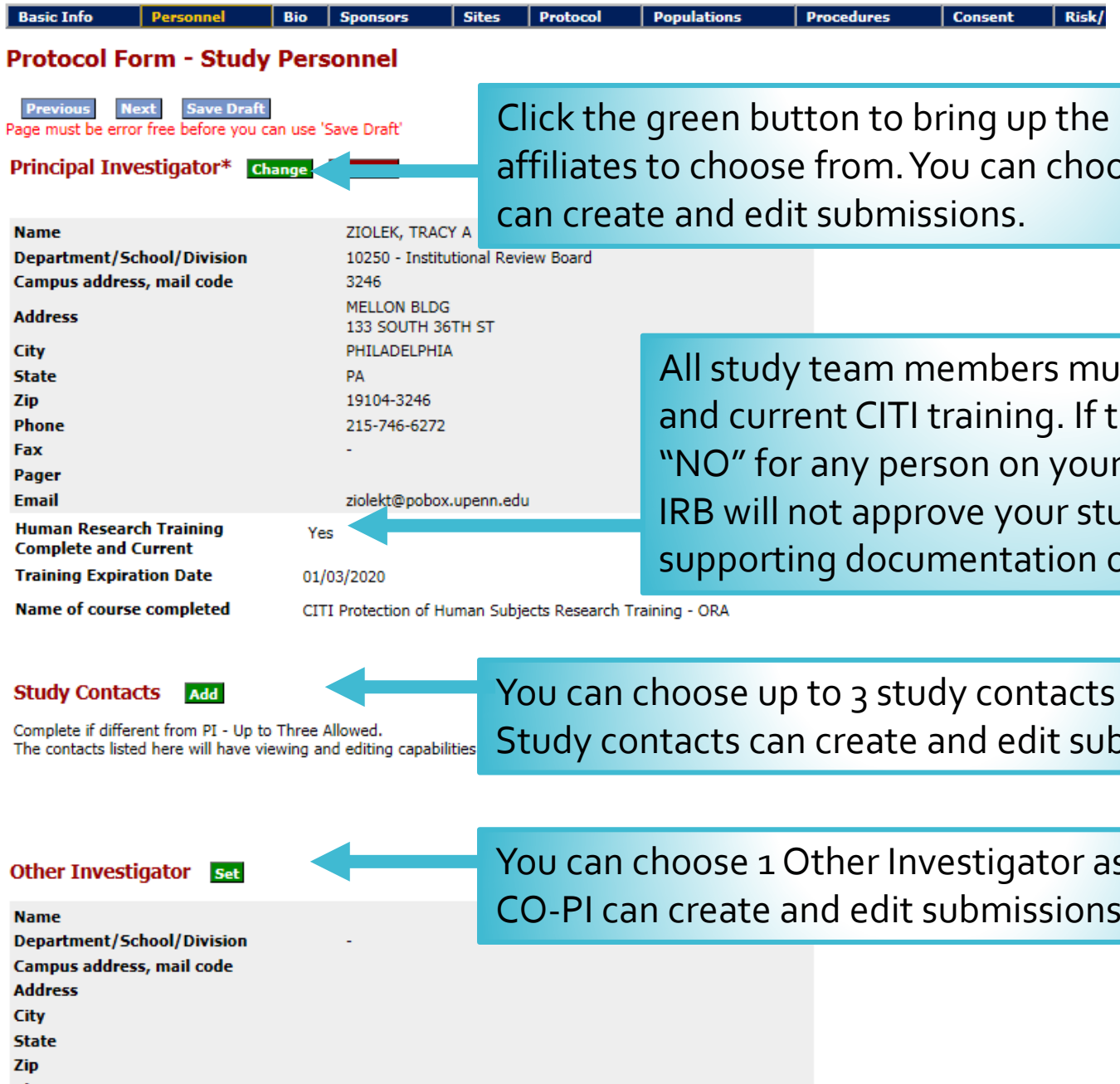
- After completing the Basic Info Page you will complete the personnel page

- The Principal Investigator (PI) must be an active Penn Faculty member who is available to review and sign off on every submission for the study

- Study contacts are study team members who can create and edit submissions to the IRB

- The "other investigator" slot is where students should name themselves on their projects since they cannot serve as PI

- It is important to keep the Personnel page up to date throughout the study



Click the green button to bring up the list of Penn affiliates to choose from. You can choose 1 PI. The PI can create and edit submissions.

All study team members must have complete and current CITI training. If this area shows "NO" for any person on your study team, the IRB will not approve your study without supporting documentation of training

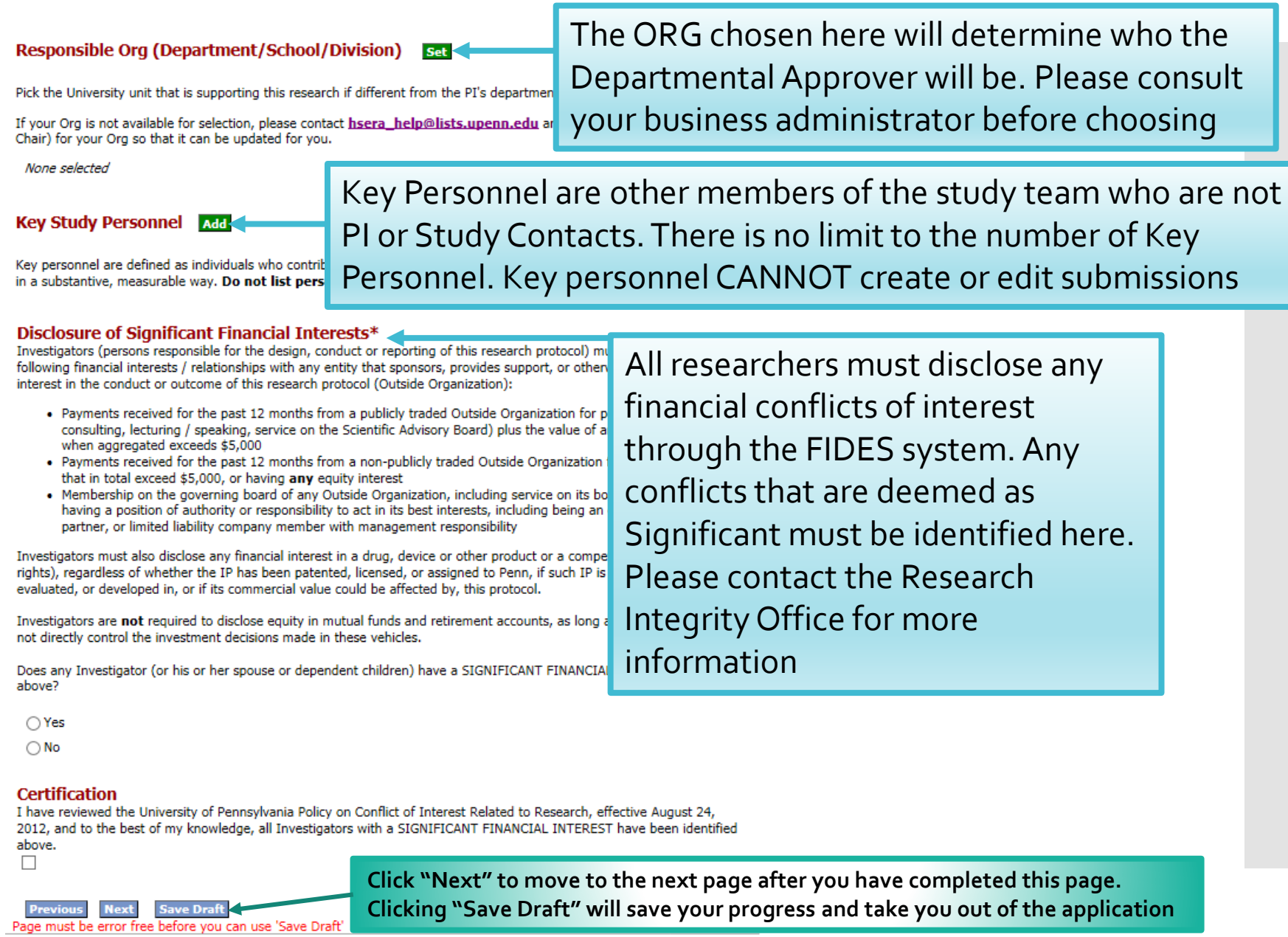
You can choose up to 3 study contacts for a study. Study contacts can create and edit submissions.

You can choose 1 Other Investigator as a CO-PI. The CO-PI can create and edit submissions.

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

Personnel Page Continued:

- The Departmental Approver assigned to your Responsible ORG must approve your initial application before the IRB receives it. Be sure to contact that person to avoid delays



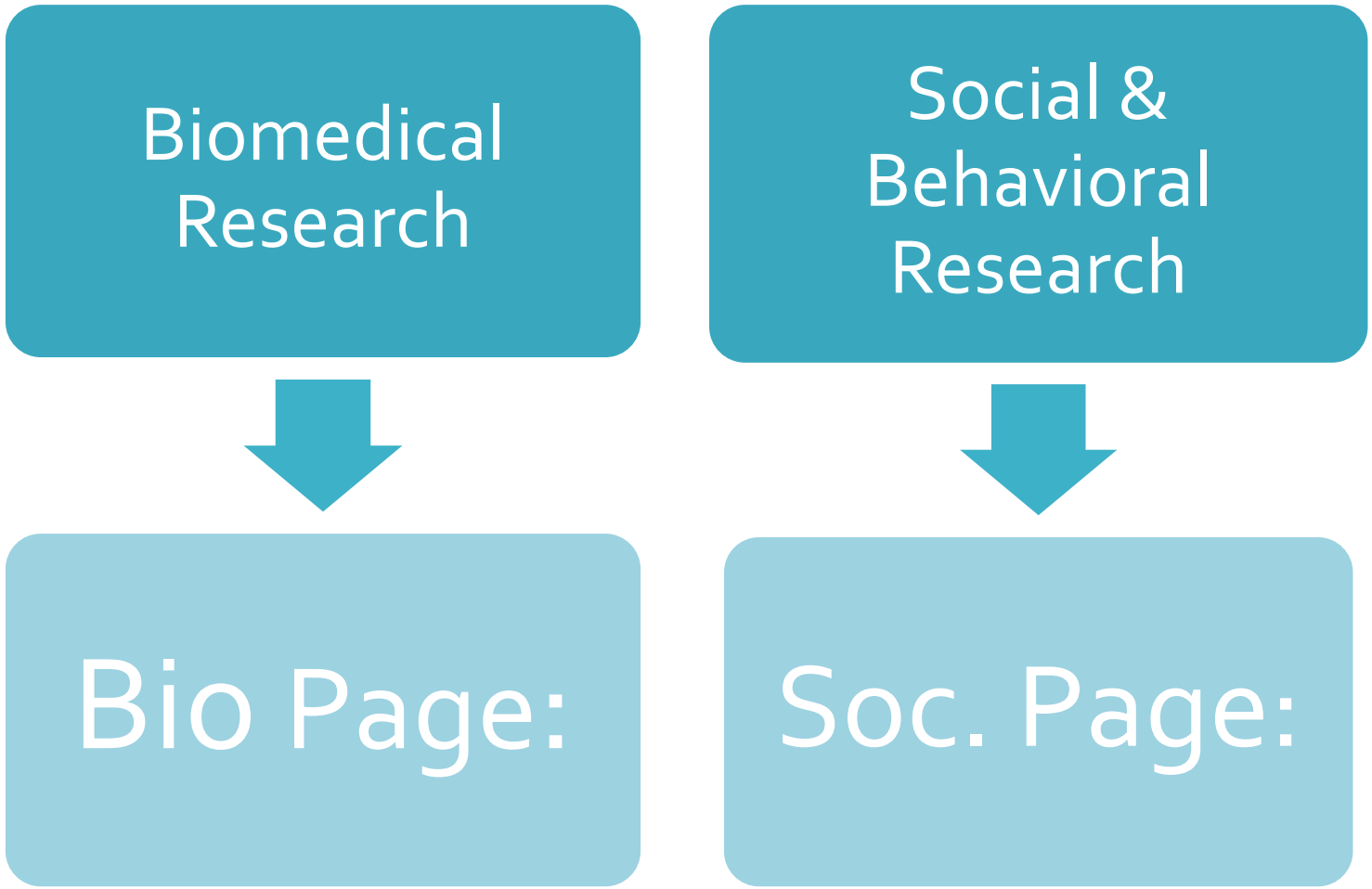
The ORG chosen here will determine who the Departmental Approver will be. Please consult your business administrator before choosing

Key Personnel are other members of the study team who are not PI or Study Contacts. There is no limit to the number of Key Personnel. Key personnel CANNOT create or edit submissions

All researchers must disclose any financial conflicts of interest through the FIDES system. Any conflicts that are deemed as Significant must be identified here. Please contact the Research Integrity Office for more information

Click "Next" to move to the next page after you have completed this page.
Clicking "Save Draft" will save your progress and take you out of the application

--BIO/SOC PAGE--
After completing the Personnel page, the next page depends on the answer provided in the first page of the application



--BIO/SOC PAGE Cont.--

The Bio/Soc page will identify any ancillary reviews that are needed for your study.

The Radial buttons chosen on this page will send pings to other Penn offices.

BIO Page

- **Questions on the BIO page include but are not limited to:**
- Drugs/Devices
- IND/IDE review
- Radiation Exposure
- Gene Transfer
- Human Source Material
- CACTIS and CT procedures
- CAMRIS and MRI procedures
- Cancer Related Research
- Medical information disclosure
- Path/lab Medicine services
- Apheresis/Transfusion
- UPHS Services

SOC Page

- **Questions on the SOC page include but are not limited to:**
- Description of survey instruments
- Description of study groups
- Methods for assigning subjects

--SPONSORS--

After completing the Bio or Soc page, you will complete a page about sponsorship and funding

All studies within the department of medicine must identify a business administrator

--SPONSORS CONT.--

In addition to Penn Budgeting information, the sponsor page requires specific information about funding for your study

Funding Sponsors

Add

Identify the agency, organization, company or person providing funds for the research study. The IRB charges fees to cover the costs associated with the review of industry sponsored investigational drug and device trials.

Name	UNIVERSITY OF PENNSYLVANIA
Type	UPENN Internal

Remove

Click the green "Add" button to choose from a list of sponsors. If your sponsor is not listed, please contact the HSERA help desk.

Funding sponsors billing address

If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/commercial, this information is not necessary to provide with your application.

Funding sponsors gift

Is this research being funded by a philanthropic gift?

- (●) Yes
- ( ) No

If the answer to this question is "yes", University Policy requires that the gift agreement signed by the donor includes a disclosure that iterates an individual gift may not fund a specific research protocol on which they or their family member wishes to participate. Please contact the Director of the IRB, Tracy Ziolek (ziolekt@upenn.edu or 215-746-6272) if you have any questions.

Please note: If the initial answer to this question is "no", but a gift is received during the conduct of this research study, the answer must be updated to "yes" upon receipt of the gift.

--SPONSORS CONT.--

For Biomedical studies using investigational drugs and devices, the Sponsor page captures the regulatory sponsor and IND holder information

Regulatory Sponsor Set

Also called the regulatory sponsor, this is the agency, organization, company or person primarily responsible for initiating and overseeing the research and ensuring the study complies with research standards and federal regulations. For clinical trials (studies involving drugs or devices) this is typically the FDA IND holder, for device studies, this is the FDA IDE holder.

- For industry-sponsored trials, typically the pharmaceutical/device/biotechnology company is the regulatory sponsor.
- For non-industry sponsored trials, the regulatory sponsor is typically the NIH or an NIH-designated entity (e.g. for the NCI, CTEP can be the regulatory sponsor if that entity holds the FDA IND or IDE).

For more information about regulatory sponsor status, INDs and IDEs, see the **Penn Manual for Clinical Research, section on Research Involving Drugs or Devices.**

Name
Type

IND Sponsor Set

This option should be selected when the Principal Investigator, or another Penn faculty member, is the Sponsor of the IND or IDE being referenced for the research.

The Perelman School of Medicine requires that sponsors meet **certain qualifications** to serve as a regulatory sponsor (IND/IDE Holder). If the person being selected does not meet these qualifications, please contact the **OCR office** for guidance on how to proceed with the application.

Name
Department/School/Division -
Phone
Fax
Pager
Email

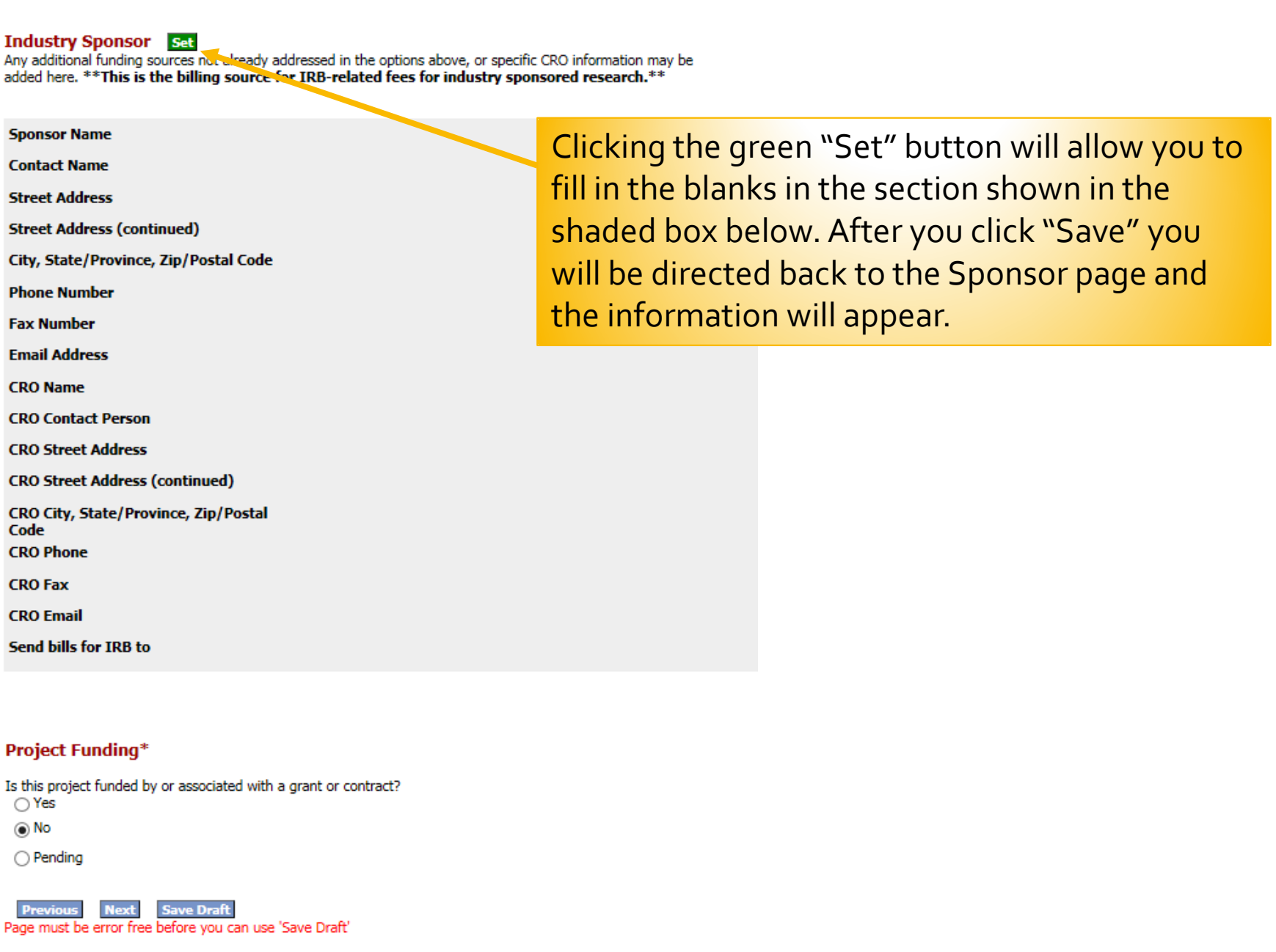
--SPONSORS CONT.—

The project funding question at the bottom of the sponsor page will expand and show additional questions based on your selection:

- If the study is funded by a grant that has a proposal linked to the PI, please select "yes" on the project funding question. Then link the proposal by clicking the "Set" button and upload the grant by clicking the "Upload Form" button. If your proposal is not available please contact the HSERA helpdesk.

- If the study is funded by a grant but the funding contract for the proposal has not yet been finalized through ORS (Office of Research Services), please select Pending for the Project Funding Question.

- If your study is being funded by an industry sponsor, please select "Yes" under the Project Funding question and select "Yes" under the Sponsor Funding question. Under Status of Contract, please select whether the contract has been completed or is pending.

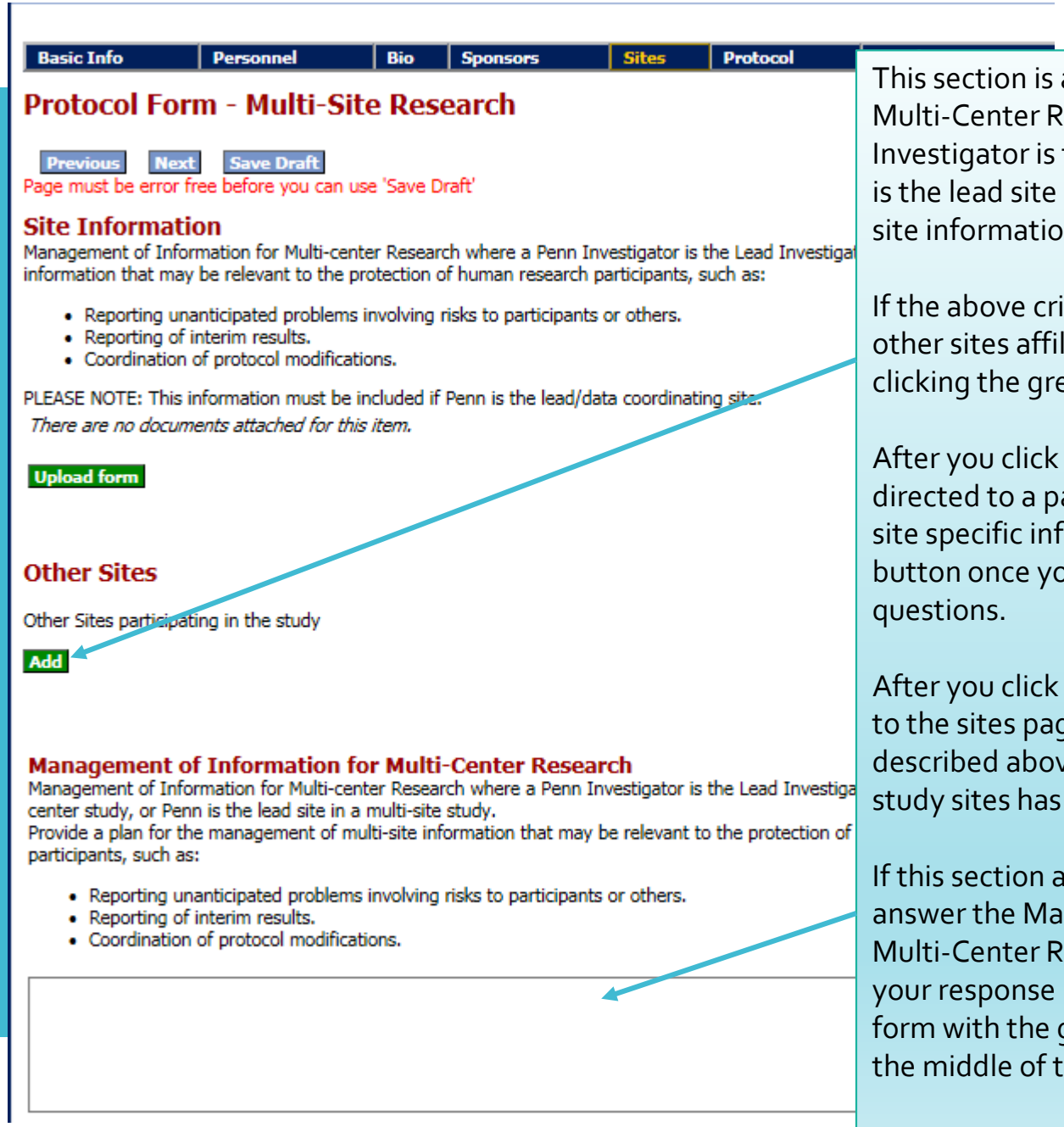


Clicking the green "Set" button will allow you to fill in the blanks in the section shown in the shaded box below. After you click "Save" you will be directed back to the Sponsor page and the information will appear.

--SITES--
After completing the sponsor page, the next page captures studies involving multiple sites

You may skip the questions on this page if :
- your study only operates at one site
-Penn researchers are not acting as the lead team or data coordinating team for the other sites involved
-the Penn IRB is not serving as the IRB of record for the other sites involved

PLEASE NOTE:
The Penn IRB oversees all research conducted at Pennsylvania Hospital, Hospital of the University of Pennsylvania (HUP) and Presbyterian Hospital (PPMC). Studies conducted solely at one or more of these locations are considered a single site study for the purposes of IRB review.



This section is applicable to studies that are Multi-Center Research and the Penn Investigator is the Lead Investigator or Penn is the lead site in the management of multi-site information(Data Coordination).

If the above criteria apply please enter the other sites affiliated with this study by clicking the green "Add" button.

After you click the "Add" button you will be directed to a page where you can enter in site specific information. Click the save button once you have answered all relevant questions.

After you click save you will be directed back to the sites page. Please repeat the steps described above until information for all the study sites has been entered.

If this section applies to your study please answer the Management of Information for Multi-Center Research question by entering your response in the text box OR attaching a form with the green upload form button in the middle of the page.

The rest of the HSERA application beyond the Sites page requires the details of your protocol objectives, design, background, population, procedures, etc.

The IRB highly recommends submission of a protocol document instead of relying on the HSERA to serve as your protocol.

If you are submitting an investigator initiated study and you have not been given a protocol by a sponsor or collaborator please see the IRB website for templates.

For researchers who already have a prepped Protocol document:

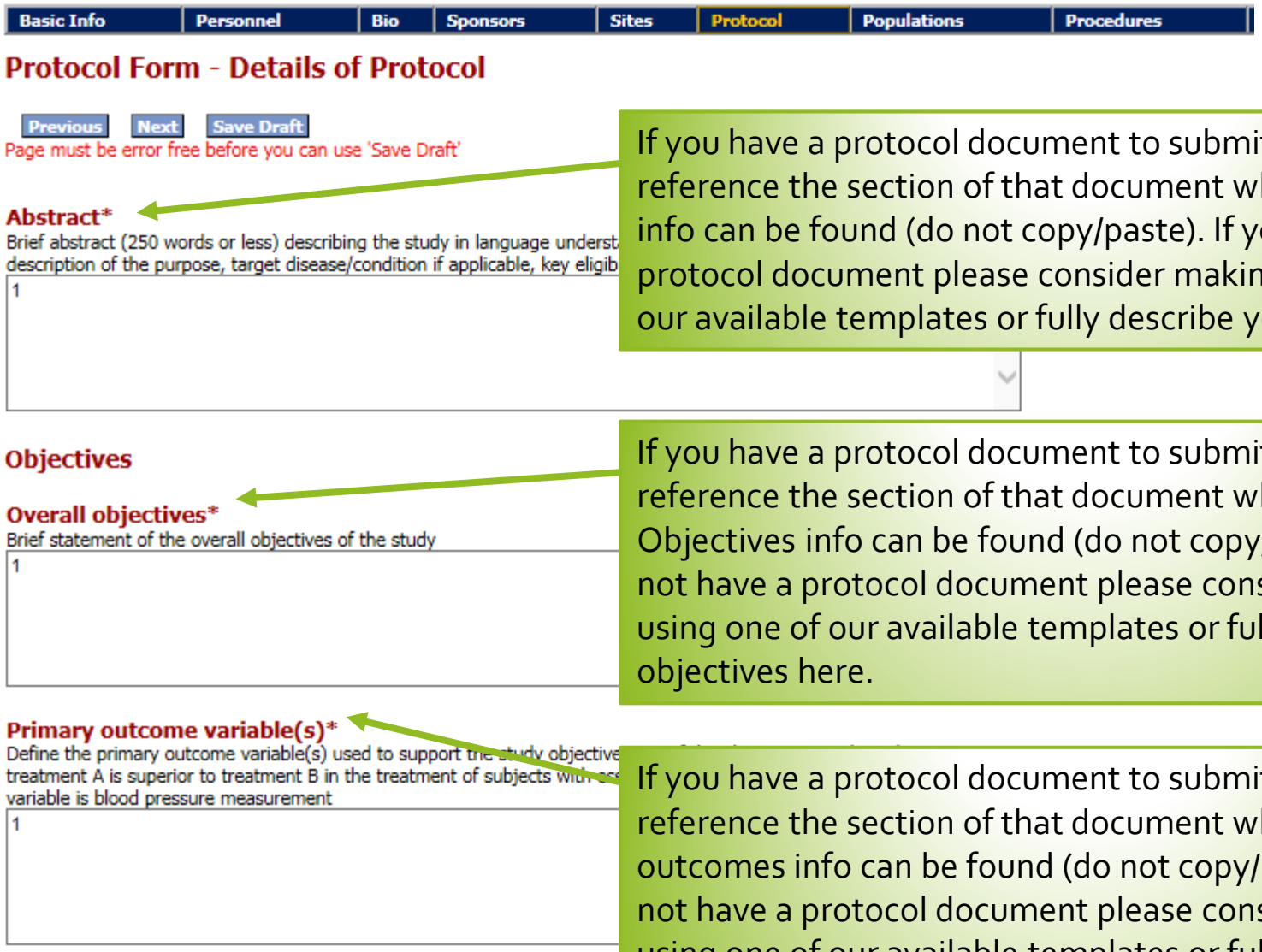
The sections that follow the Sites page can be completed by referencing the appropriate section of an attached protocol document. The IRB prefers this instead of typing out or copy/pasting sections of your protocol into the HSERA application. When making references to a protocol document in any section, please be sure to utilize the HSERA space to clearly identify any discrepancies between what the protocol document states and how the study will be conducted at Penn. For example– if the overall study includes a genetic sub study but subjects at Penn will not participate in the sub-study be sure to clearly explain that in the HSERA text field to prevent the IRB from raising unnecessary issues.

--PROTOCOL--

After completing the Sites page, the Protocol page is where specific information about the study objectives, design, duration and resources is required

The first 7 free text sections on this page should be completed with detailed protocol specific information ONLY if you are not submitting a protocol document. (Only the first 3 sections are shown in this walkthrough.)

the last section on this page about necessary resources should always be fully completed with information specific to the study at Penn regardless of the presence of a protocol document



If you have a protocol document to submit please only reference the section of that document where the abstract info can be found (do not copy/paste). If you do not have a protocol document please consider making one using one of our available templates or fully describe your abstract here.

If you have a protocol document to submit please only reference the section of that document where the Objectives info can be found (do not copy/paste). If you do not have a protocol document please consider making one using one of our available templates or fully describe your objectives here.

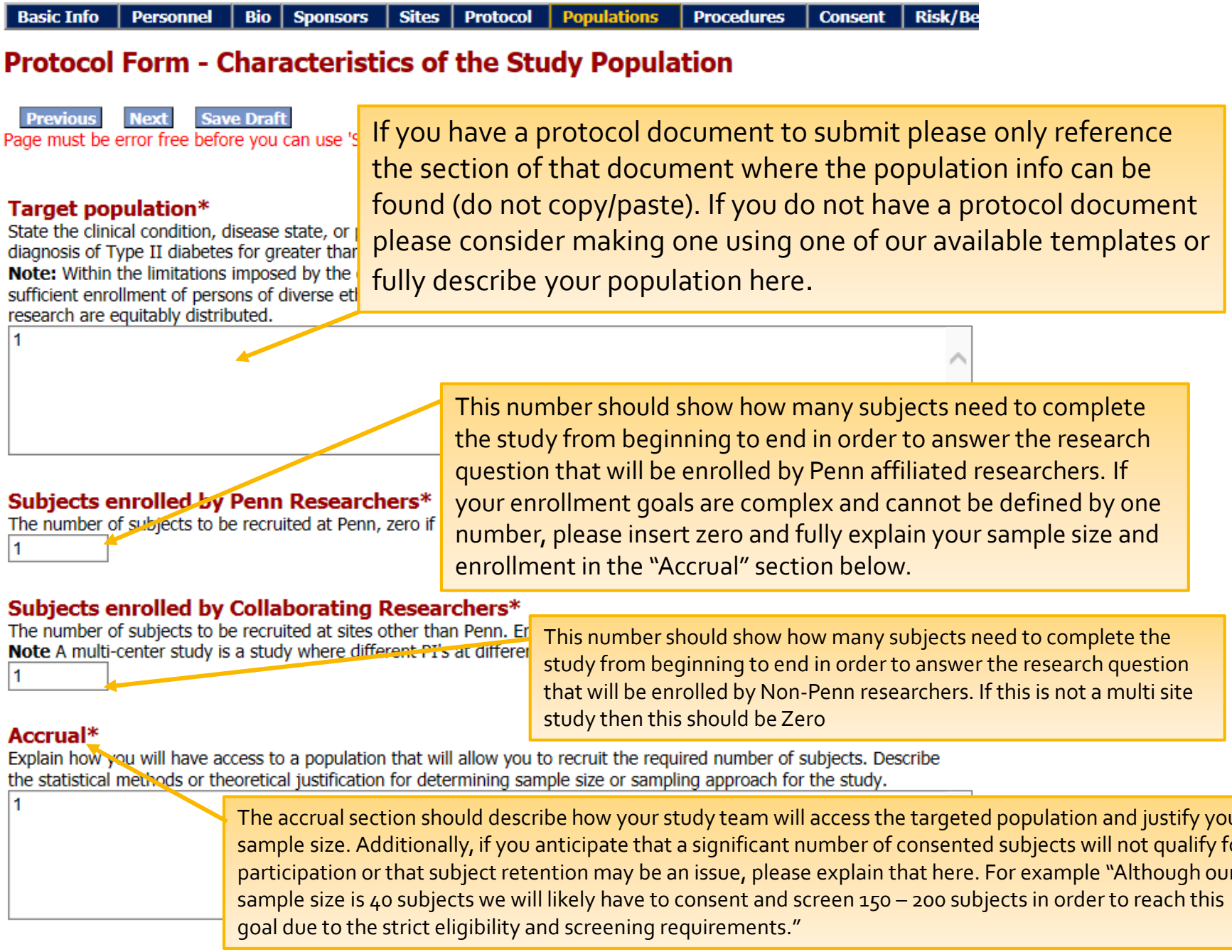
If you have a protocol document to submit please only reference the section of that document where the primary outcomes info can be found (do not copy/paste). If you do not have a protocol document please consider making one using one of our available templates or fully describe your primary outcomes here.

--POPULATIONS --

The next page of the application is related to your targeted populations.

The Populations page has been divided into 4 slides to capture all of the questions

Part 1: Target population and sample size



--POPULATIONS --

Part 2: Inclusion and Exclusion + vulnerable populations by regulatory definitions

Key inclusion criteria*

List key inclusion criteria including age ran

1

If you have a protocol document to submit please only reference the section of that document where the inclusion criteria info can be found (do not copy/paste). If you do not have a protocol document please consider making one using one of our available templates or fully describe your inclusion criteria here.

Key exclusion criteria*

List key exclusion criteria. If subjects are e
justification for exclusion.

1

If you have a protocol document to submit please only reference the section of that document where the exclusion criteria info can be found (do not copy/paste). If you do not have a protocol document please consider making one using one of our available templates or fully describe your exclusion criteria here.

Vulnerable Populations*

Specify if the study intentionally includes any of the following populations:
Note: Include the appropriate supplemental form for each vulnerable population included in the study.
Note: Subjects who become imprisoned or are court-ordered to attend residential alcohol or other drug treatment facilities will be considered prisoners under Subpart C of the federal regulations 45CFR46. Such subjects cannot be continued in the research unless an amendment to the protocol is submitted and approved by the IRB and certification to the federal Office of Human Research Protections if the research is supported by the Department of Health and Human services.

- ☐ Children Form
- ☐ Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
- ☐ Fetuses and/or Neonates Form
- ☐ Prisoners Form
- ☐ Other
- ☑ None of the above populations are included i

There are no documents attached for this item.

Upload form

Certain populations are designated as "vulnerable" by the human research protections regulations. If your study involves the participation of these populations , your study will require additional IRB consideration. Please identify them by checking the appropriate boxes and attach a completed copy of the related supplemental form that is required for each population.

-- POPULATIONS --

Part 3: Other Vulnerable Populations and Recruitment

Populations vulnerable to undue influence or coercion*

When some or all of the participants were likely to be vulnerable to coercion or undue influence or influence such as mentally disabled persons, or economically disadvantaged persons, employees or students of Penn describe the additional safeguards have been included in the study to protect the rights and welfare of these subjects from coercion or undue influence.

Note: This section is intended to elicit information regarding additional protections when specific populations are included in a research study. It is not intended to trigger an exclusion of these populations.

1

Please read these instructions carefully before responding. This question is required for approval and your answer may dictate additional language for your consent process. Please be sure to note that any Penn affiliates will be told that their decision will not affect their standing with the University. Also, you don't need to reiterate any groups from the vulnerable populations section.

Subject recruitment*

Overview the approach to subject identification and recruitment, including referrals from physician offices, clinics ...

1

All recruitment materials must be IRB approved prior to use. If your protocol document fully outlines the recruitment methods that will be utilized at Penn, please only insert a reference to that section of the protocol. Otherwise please fully outline the plan here including : Flyers, television or radio ads, posters, physician referral, patient referral etc..

Use the following button to upload sample ***recruitment materials*** (i.e. radio/video scripts, flyers, internet postings, etc.)
For guidance regarding recruitment materials, please see the following link:
http://www.upenn.edu/regulatoryaffairs/Documents/irbgui-4.pdf

There are no docume

Upload form

Click the "upload form" button to attach your flyers, posters, scripts, and other recruitment materials.

-- POPULATIONS --
Part 4: Internet recruitment and subject compensation

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?*

(•) Yes
( ) No

Please indicate whether social media or the internet will be used to recruit subjects. Guidance about use of social media in research is available on the IRB website.

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.*

1

If the plan for online recruitment is fully outlined in your protocol document please only include a reference to the applicable section. Otherwise, please detail your plan for the online recruitment strategies including; the names of sites, the plan for publishing and managing online content, confidentiality etc.

Subject compensation*

Will subjects be financially compensated for their participation?

(•) Yes
( ) No

Please indicate whether subjects will be compensated in any way for participation.

Summarize any financial compensation that will be offered to subjects, e.g. cash payments, gift card, reimbursement for travel. The amount of compensation may not constitute an undue inducement to participate in the research. A prorated system of financial compensation is required in most circumstances. Provide the schedule for compensation per study visit or session and total amount for entire participation.

1

If the plan for compensation is fully outlined in your protocol document please only include a reference to the applicable section here. Otherwise please fully detail the compensation plan including; total amount a subject may receive, amounts received per study interaction, form of compensation. Compensation must also be fully outlined during the consent process.

There are no docume

Upload form

-- PROCEDURES--

After completing the Populations page, on the next page you will detail the procedures, statistical analysis, and data security methods for your study.

The procedures page is the longest part of the application therefore screenshots have not been included

Sections included on the Procedures Page

- Suicidal Ideation / Use of a test article that may effect the Central Nervous System
- Full description of procedures
- Use of deception
- Analysis Plan
- Confidentiality
- Sensitive Research Information
- Subject Privacy
- Data Disclosure
- Protected Health Information
- Waiver requests
- Tissue/Specimens information
- Genetic Testing

Tips for completion

- As you complete the questions on this page, additional questions may populate depending on your response to the trigger questions.
- Any section on this page that is a free text box can be completed with a reference to the appropriate section of your protocol document. If you do not have a protocol document please fully explain each response in the space provided
- When making references to your attached protocol, please be sure to clarify any information in the protocol that may be different for the Penn site (for example if subjects at Penn will not have a particular MRI scan, or sub study blood draw please clearly state that in the HSERA text box)
- Any checkboxes or radial buttons must be completed accurately regardless of whether the information is included in an attached protocol

Regarding Privacy, Confidentiality and Data Protection:

The procedures page requires information about ensuring subject privacy, protecting confidentiality and protecting identifiable data

Privacy VS. Confidentiality

- Your Privacy plan should outline how you will make each face to face,telephone, or online interaction with subjects as private as possible
- Your Confidentiality plan should outline how you will keep subject information confidential after it has been documented or recorded. This relates to storage and sharing of PHI.

PHI and Data Protection

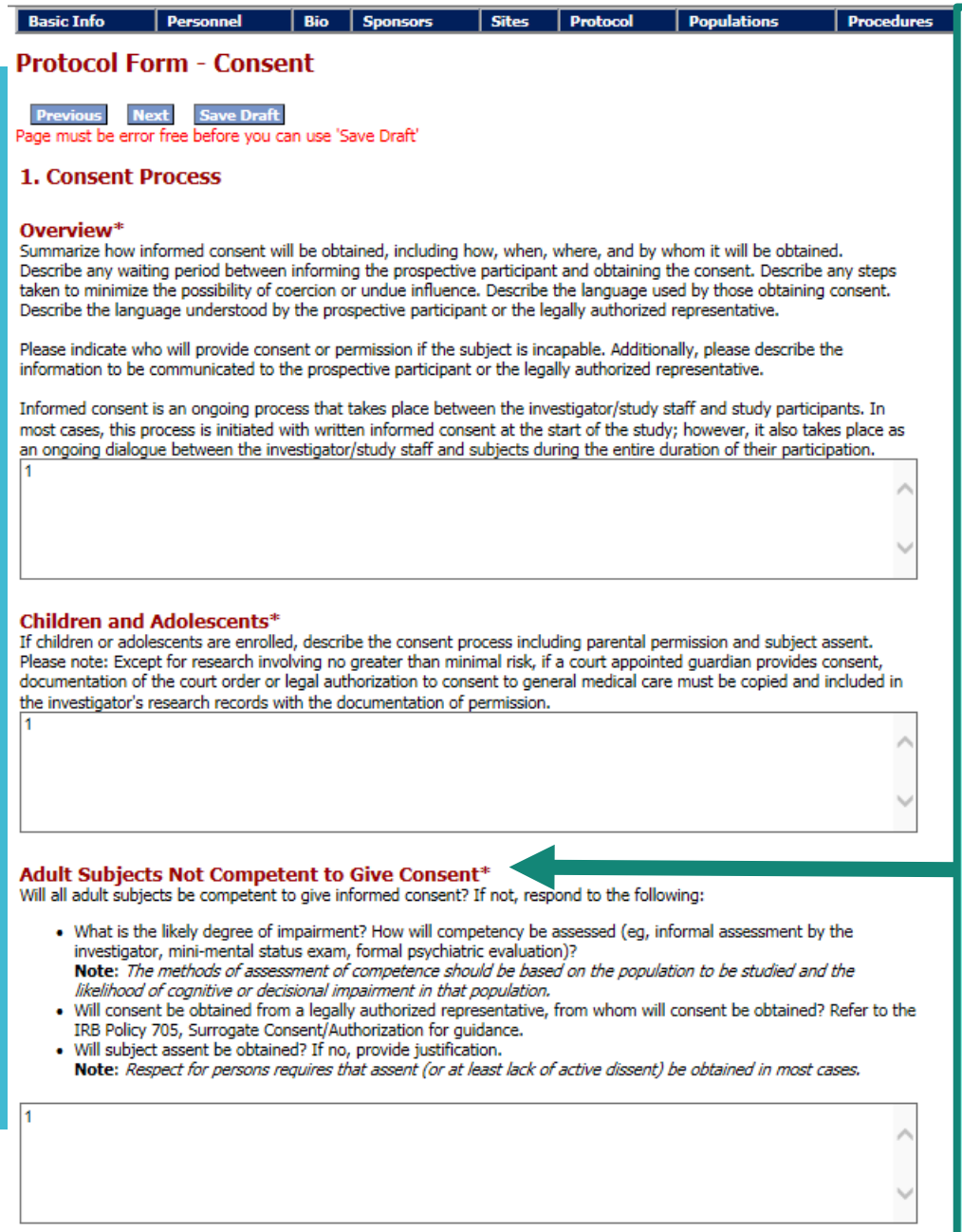
- PHI is Protected Health Information. Most PHI and study data is recorded electronically. Implementation of a University vetted plan to protect electronic research data (storage, and sharing) became required in August 2016.
- There are 2 documents available on the IRB website to assist investigators in developing an appropriate electronic PHI / Data protection plan in collaboration with local IT support providers.

--CONSENT--

After completing sections about procedures, you must described the consent process. If this information is fully detailed in your protocol please only include references to the applicable sections.

When making references to the protocol document please be sure to clarify any differences for how consent will be obtained at the Penn site.

For example if the protocol includes an assent and parental permission section but Children will not be on the study at Penn, the children and adolescent section should state "Children will not be enrolled at Penn"



Basic Info | Personnel | Bio | Sponsors | Sites | Protocol | Populations | Procedures

Protocol Form - Consent

Previous Next Save Draft

Page must be error free before you can use 'Save Draft'

1. Consent Process

Overview*

Summarize how informed consent will be obtained, including how, when, where, and by whom it will be obtained. Describe any waiting period between informing the prospective participant and obtaining the consent. Describe any steps taken to minimize the possibility of coercion or undue influence. Describe the language used by those obtaining consent. Describe the language understood by the prospective participant or the legally authorized representative.

Please indicate who will provide consent or permission if the subject is incapable. Additionally, please describe the information to be communicated to the prospective participant or the legally authorized representative.

Informed consent is an ongoing process that takes place between the investigator/study staff and study participants. In most cases, this process is initiated with written informed consent at the start of the study; however, it also takes place as an ongoing dialogue between the investigator/study staff and subjects during the entire duration of their participation.

1

Children and Adolescents*

If children or adolescents are enrolled, describe the consent process including parental permission and subject assent. Please note: Except for research involving no greater than minimal risk, if a court appointed guardian provides consent, documentation of the court order or legal authorization to consent to general medical care must be copied and included in the investigator's research records with the documentation of permission.

1

Adult Subjects Not Competent to Give Consent*

Will all adult subjects be competent to give informed consent? If not, respond to the following:

- What is the likely degree of impairment? How will competency be assessed (eg, informal assessment by the investigator, mini-mental status exam, formal psychiatric evaluation)?
  Note: *The methods of assessment of competence should be based on the population to be studied and the likelihood of cognitive or decisional impairment in that population.*
- Will consent be obtained from a legally authorized representative, from whom will consent be obtained? Refer to the IRB Policy 705, Surrogate Consent/Authorization for guidance.
- Will subject assent be obtained? If no, provide justification.
  Note: *Respect for persons requires that assent (or at least lack of active dissent) be obtained in most cases.*

1

This section should detail any specialized consent procedures or resources in place for subjects who may participate but are unable to complete a traditional consent process noted in the overview section. Such as:

- Blindness or other visual impairment
- Deafness or other hearing impairment
- Short term or permanent cognitive impairment
- Short term or permanent physical limitations

Please note that predicting all possible scenarios is not required. If necessity for a specialized consent process is identified in the future, the IRB may approve the plan via submission of an exception request

--CONSENT--

The final question on the Consent page is related to waivers of consent.

If you indicate on this page that you are requesting any type of waiver, additional required questions will populate.

If you are not requesting a waiver of consent, please select "No Waiver Requested"

Waiver or alteration of required elements of consent

- Requesting this type of waiver means you do not intend to ask subjects to be part of your protocol.
- Typically this is related to retrospective review of existing medical records or publicly available data
- If you plan to waive consent altogether, you may also need to include a request for waiver of HIPAA authorization for use of health information if applicable. The HIPAA waiver request form is available on the IRB website

Waiver of documentation of consent

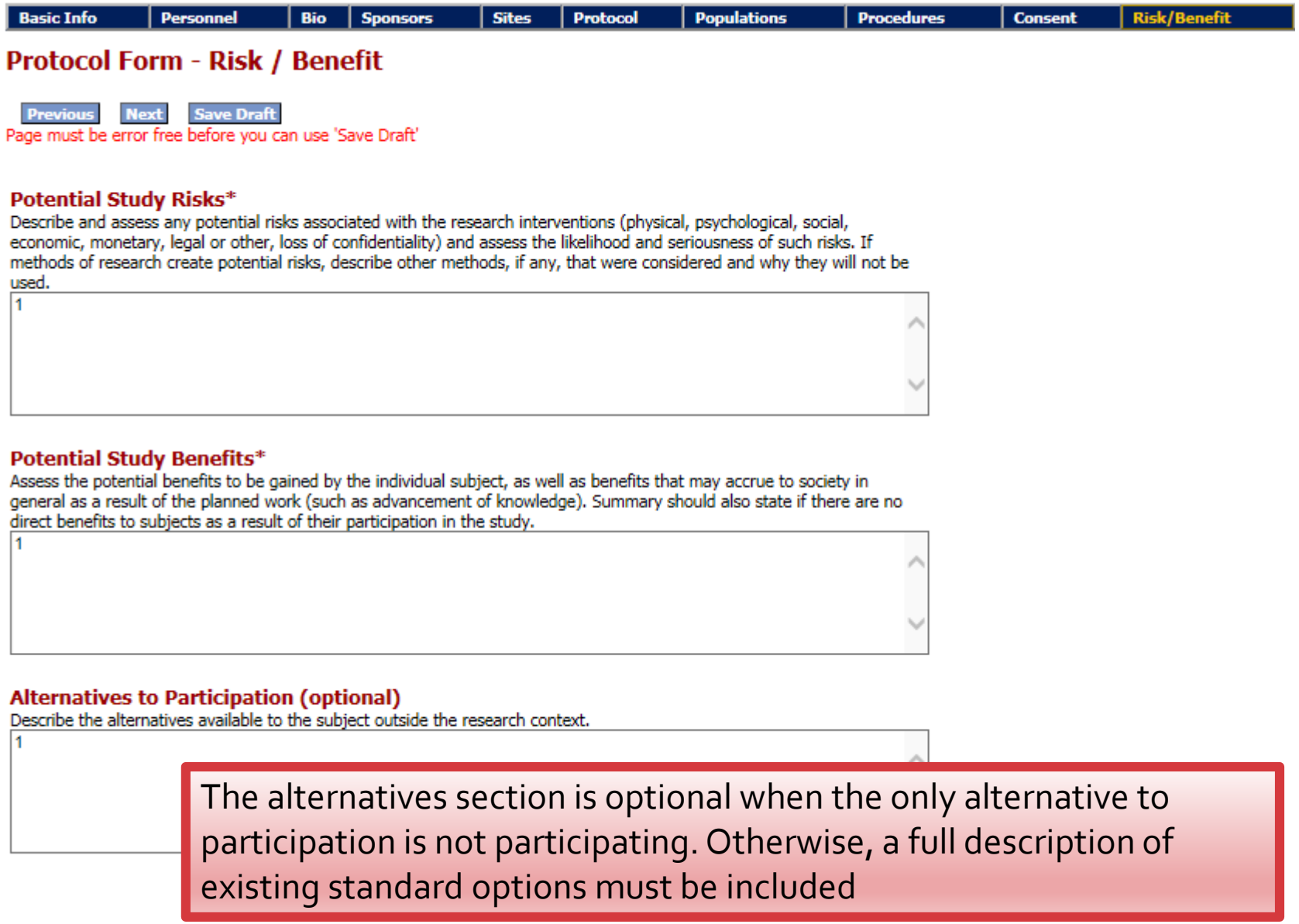
- Requesting this type of waiver means you WILL ask subjects to be part of your study but they will not physically sign their name to a document
- Typically this is related to online surveys where subjects click "I agree to participate" OR for telephone surveys where verbal consent is obtained.
- Occasionally subjects would only be identified by their signature on a form which may increase risk to the subject

--Risk/Benefit –

After describing the consent process, the application requires an assessment of risk to subjects and potential benefits of participation.

If your protocol document fully discusses the topics on this page please make references to the applicable sections (do not copy/paste)

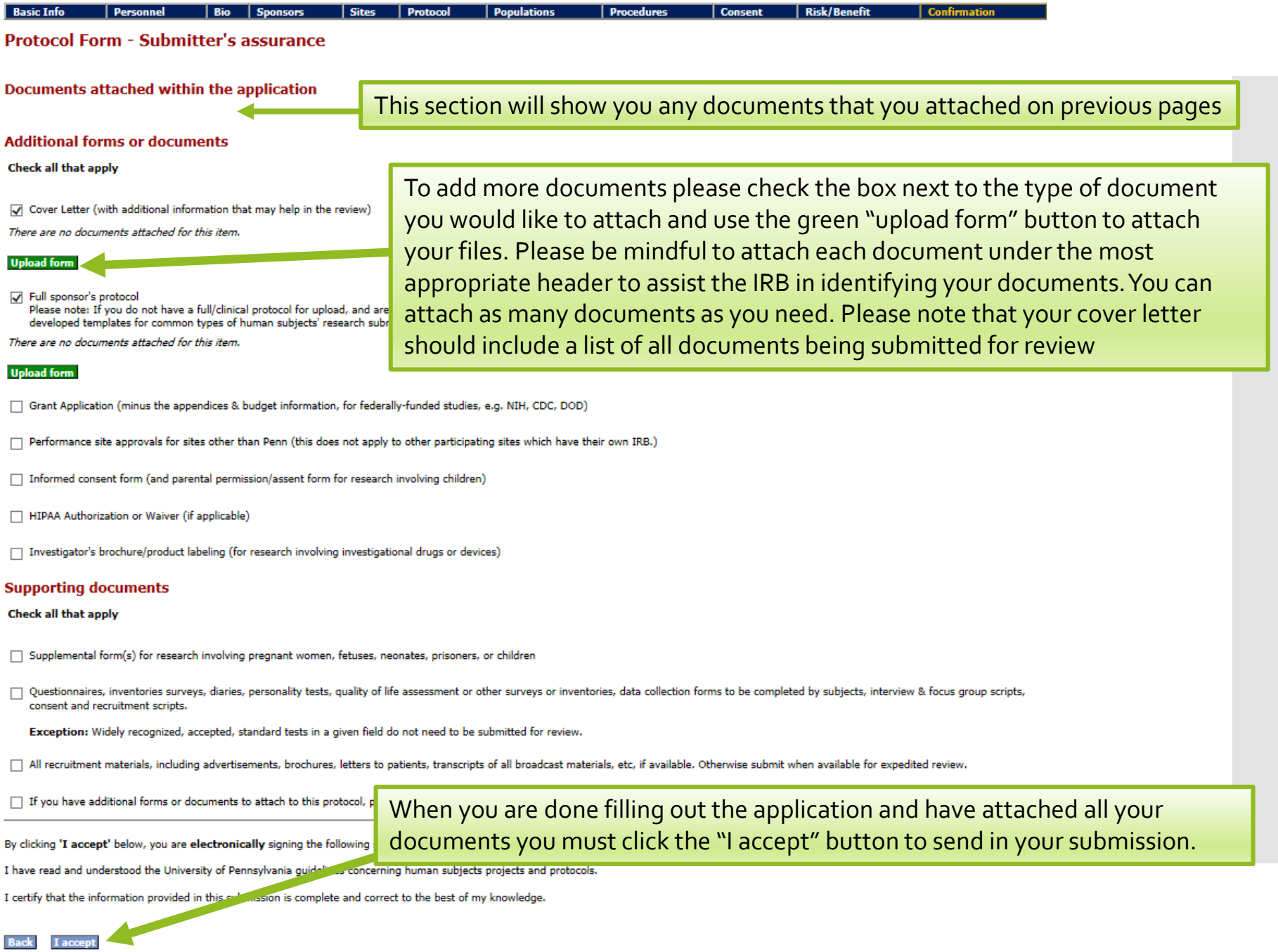
This page also requires description of the Data and Safety monitoring plan. This plan will be referenced during annual continuing review (if applicable) to ensure adherence to the plan throughout the life of the study.



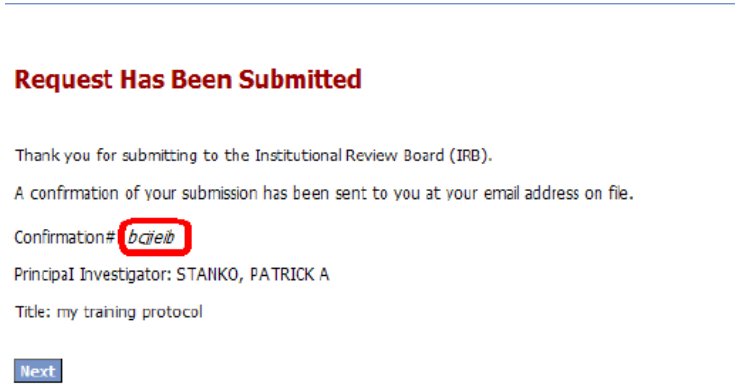
The alternatives section is optional when the only alternative to participation is not participating. Otherwise, a full description of existing standard options must be included

--CONFIRMATION –
The confirmation page is the final page of the application where you will attach any necessary documents that you have not already attached.

-Note: All initial submissions should always provide a cover letter that includes a complete list of documents you are submitting for approval (document name,version,date)



What happens after you click "I Accept"..?



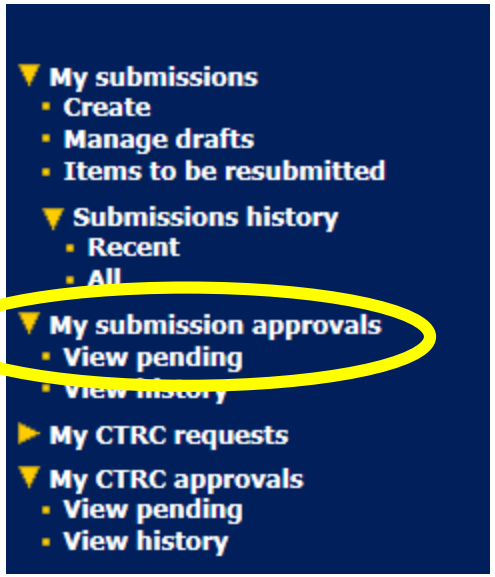
Immediately after clicking "I Accept" you will be shown a screen that provides a confirmation code. You should save the confirmation codes for every submission you create in the system

- The IRB will rely on this code to find your submission in the system. Please include it in all email correspondence or have it ready before you call on the telephone
- You will need the code to locate your decision letter in the system once it is uploaded by the IRB staff. The code associated with each submission is included in the IRB determination letter for that submission
- If you ever need to refer back to your original application in the future, you will need the code to locate it in your "Submission History"

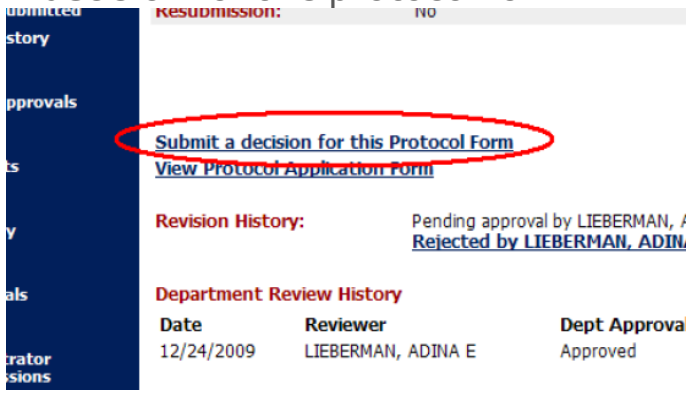
What happens after you click "I Accept"..?

Clicking "I Accept" on an initial submission does not mean the IRB can begin its review.

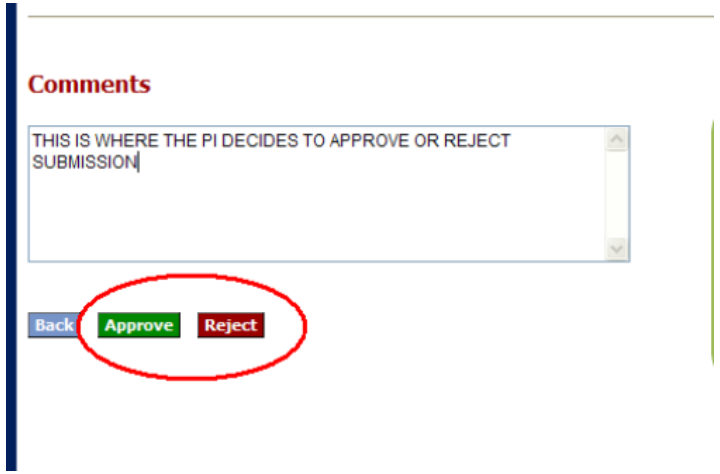
- If the submitter of the initial application is not the PI, the submission then requires PI approval. The PI will receive an automated email alerting them of the pending submission. The PI can access the application by clicking "View Pending" under "My Submission Approvals" on the blue left side menu in HSERA



- Once the submission is identified and chosen in the "view pending" list, the PI must click "submit a decision for this protocol form"

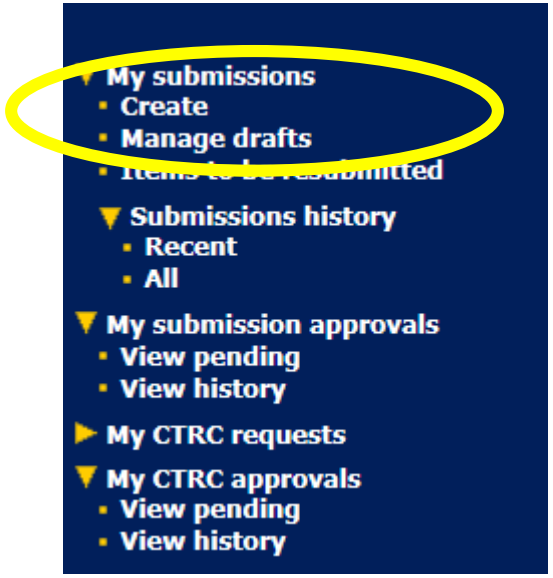


and on the last page of the application, choose to either approve or reject it



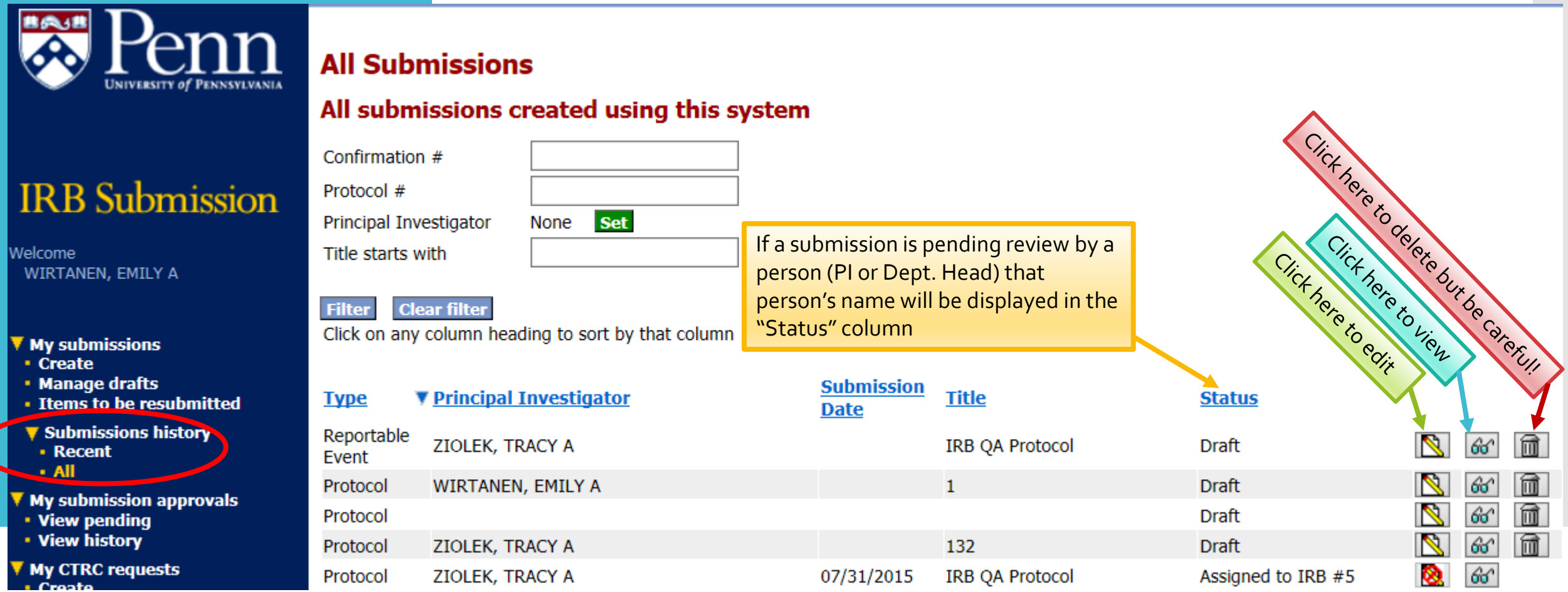
What happens after the PI approves it?

- If the PI identified any issues with the application and decides to reject it, the submission will be available to the study team in the "manage drafts" . Searching on this page by confirmation code is the fastest way to find the submission.



- Once the PI approves the submission it then requires approval by the department head. The department head who is charged with approving the submission is determined by the "ORG code" that was chosen on the Personnel page
- The department head follows the same steps as the PI to approve the submission and may also reject the submission for any reason
- After the department head approves the submission, the IRB receives it in the system to begin its review.
- Departmental approval is only required for submission of the first draft of an Initial submission. All future submissions require only PI approval

Members of the study team can check the status of any submission by looking in "Submission History" and sorting by the available search fields



Summary of submission process

If you have begun the process and have questions that cannot be answered by this walkthrough, please send a detailed email to an IRB staff member.

Various contacts are available on the IRB website

- **Step 1:Submission is drafted.**
- **Step 2: PI reviews and approves the study. (submission may be returned for revision)**
- **Step 3: Department Chair reviews and approves the study. (submission may be returned for revision)**
- **Step 4: IRB pre-screen for initial review. (submission may be returned for revision)**
- **Step 5: IRB Review is scheduled. Protocol number and IRB Board number assigned.**
- **Step 6: IRB Review. Submissions requiring full board review will likely be returned for revisions prior to receiving full approval.**
- **Step 7: Resubmission of protocol to meet IRB stipulations.**
- **Step 8: Final IRB Review and approval.**