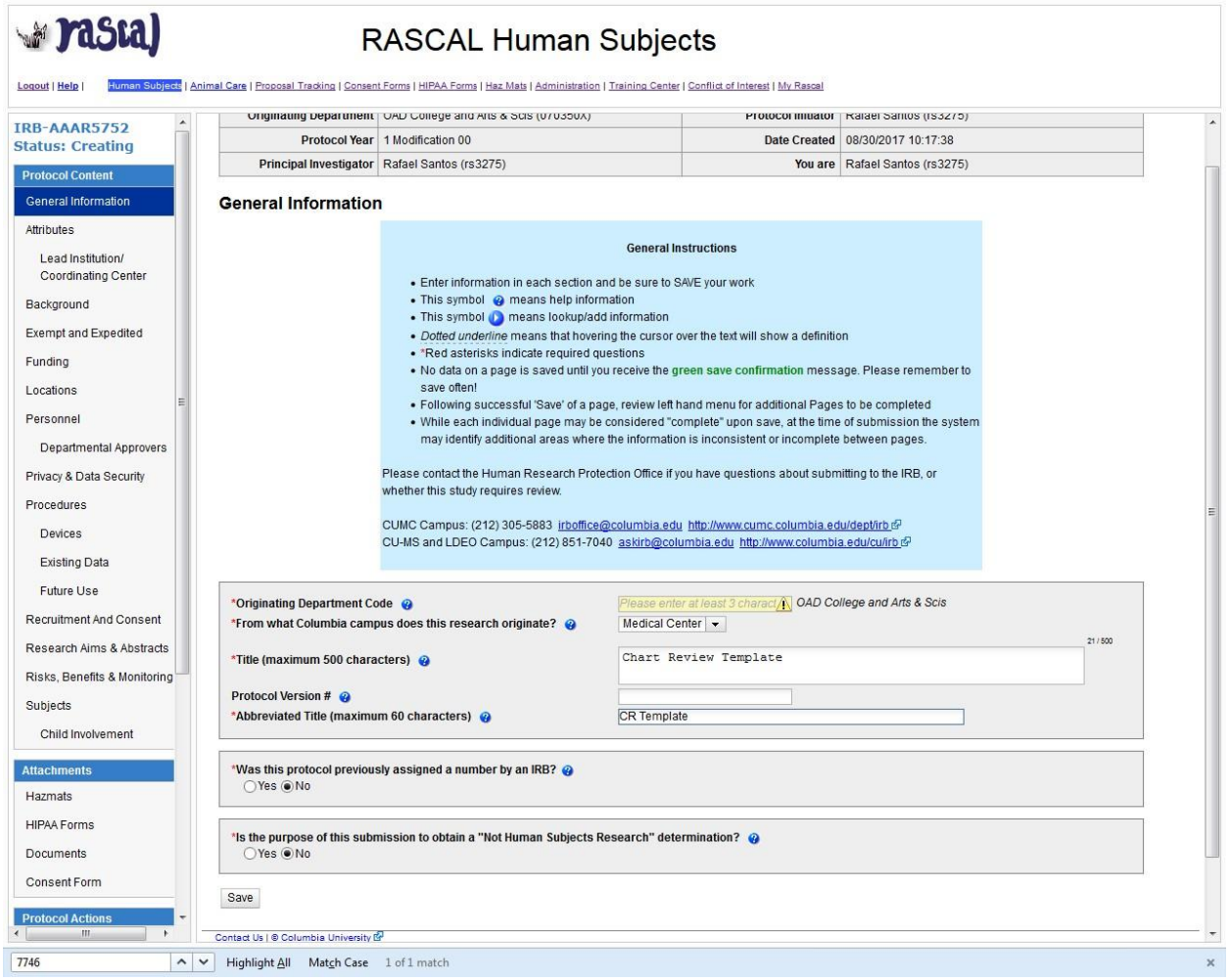
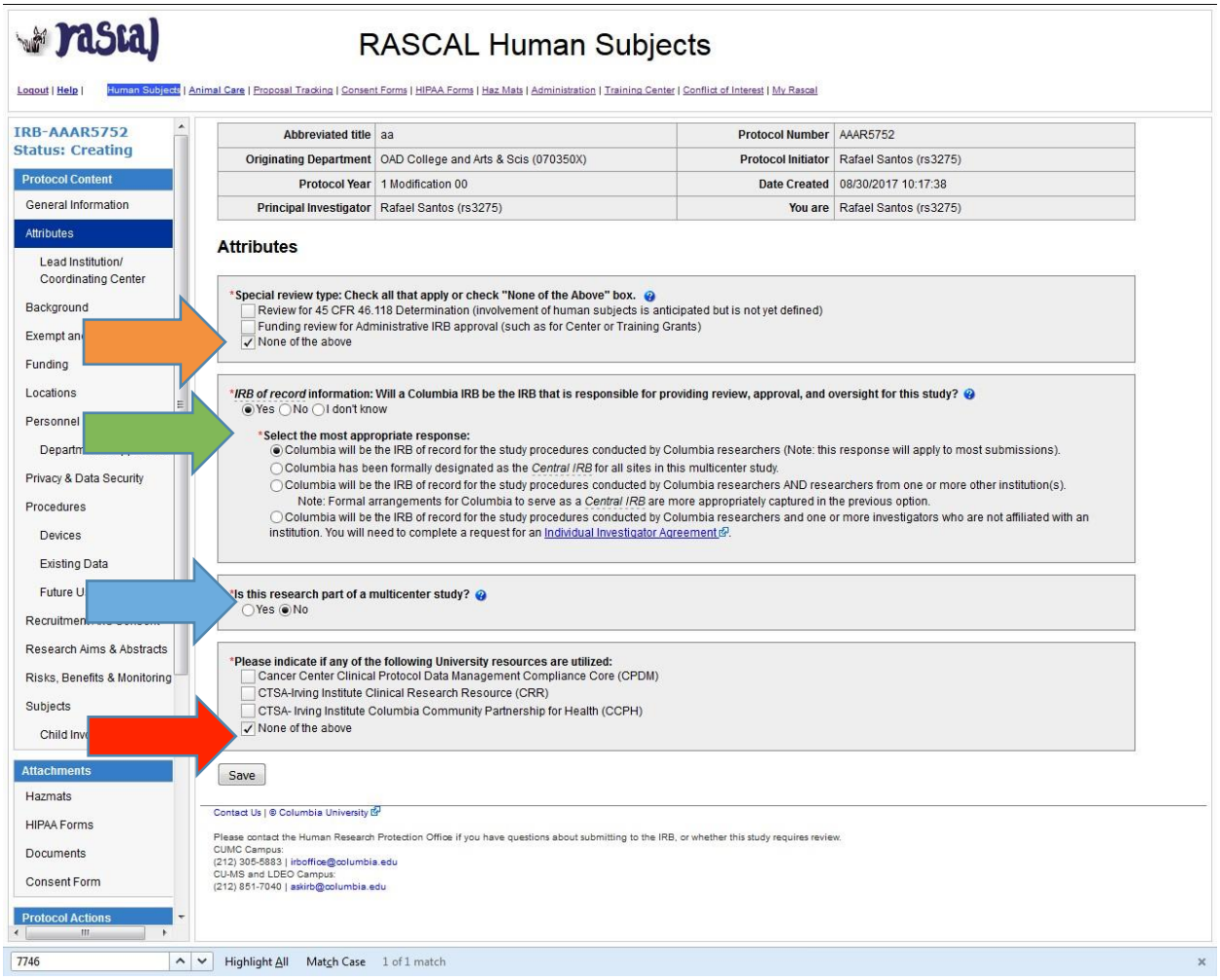


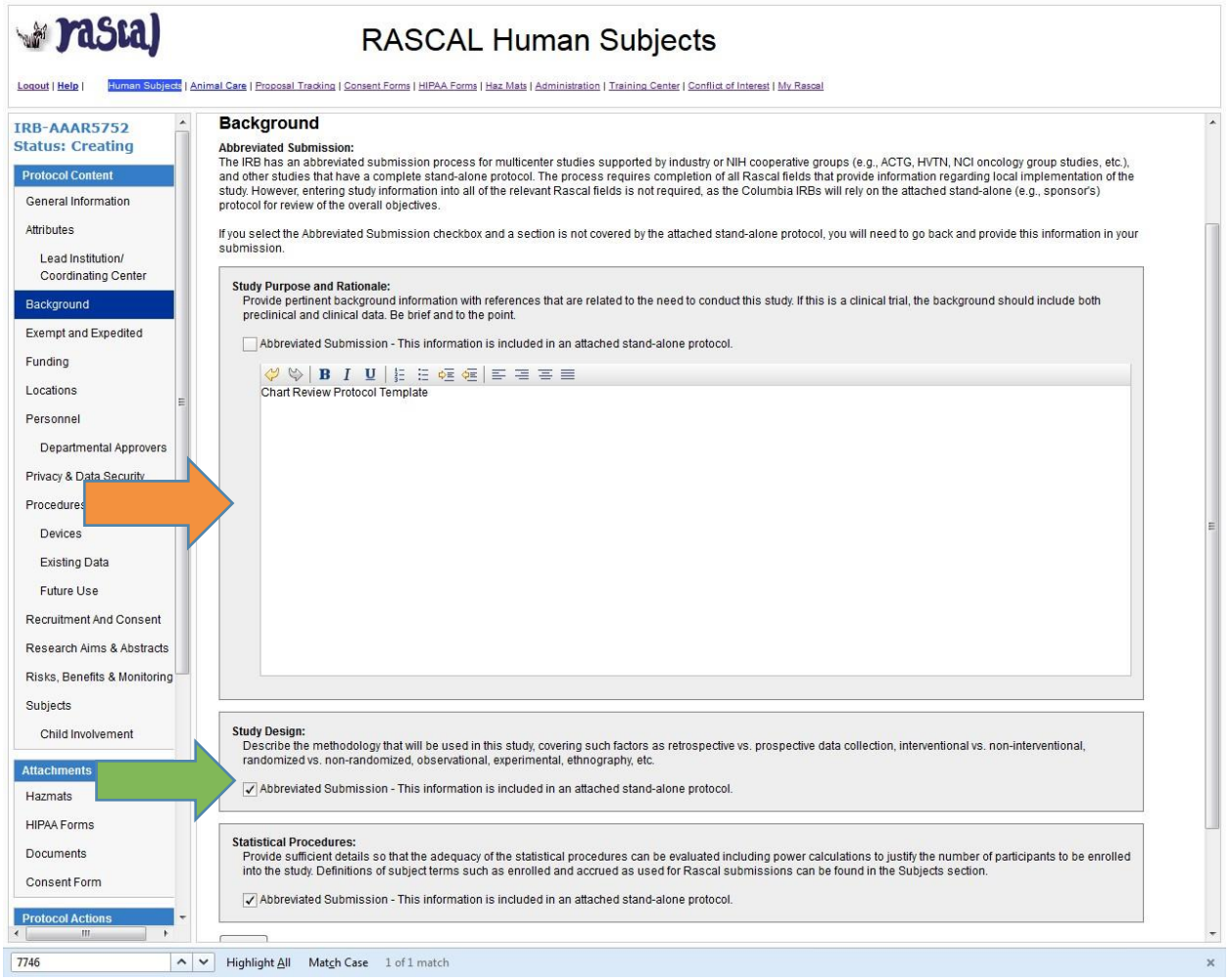
This Rascal protocol template should be utilized when conducting a study that ONLY involves a retrospective chart review of CUIMC-NYP patient records in which in-person interaction with subjects is not anticipated.

**Tips:

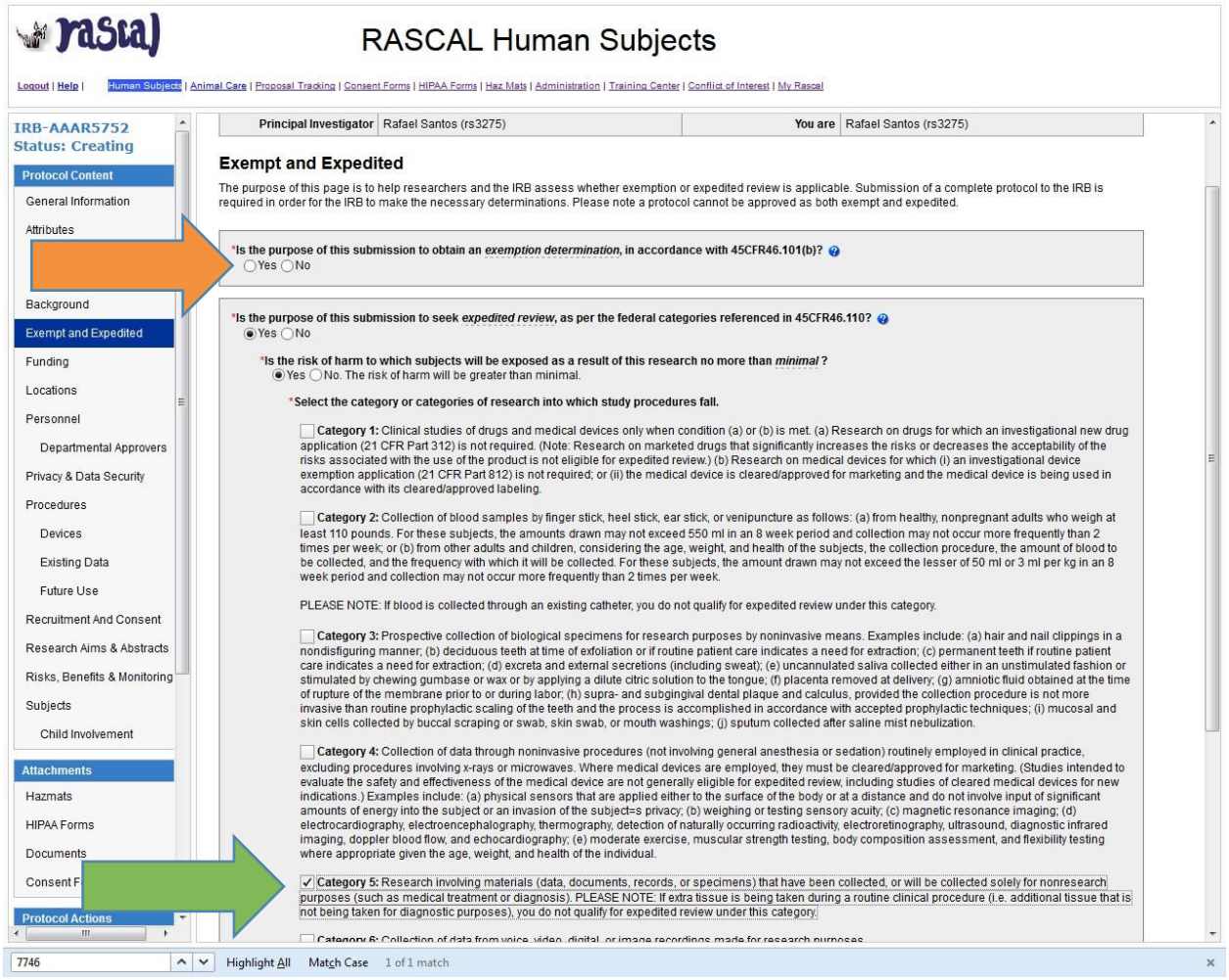
- Please select “Save” after each page.
- Selected the blue question mark icon for guidance on what is needed in each field.
- The links on the left-hand side are all pages that need to be completed prior to resubmission.
- The link of the left-hand side that is highlighted dark blue is the page that is currently accessed.



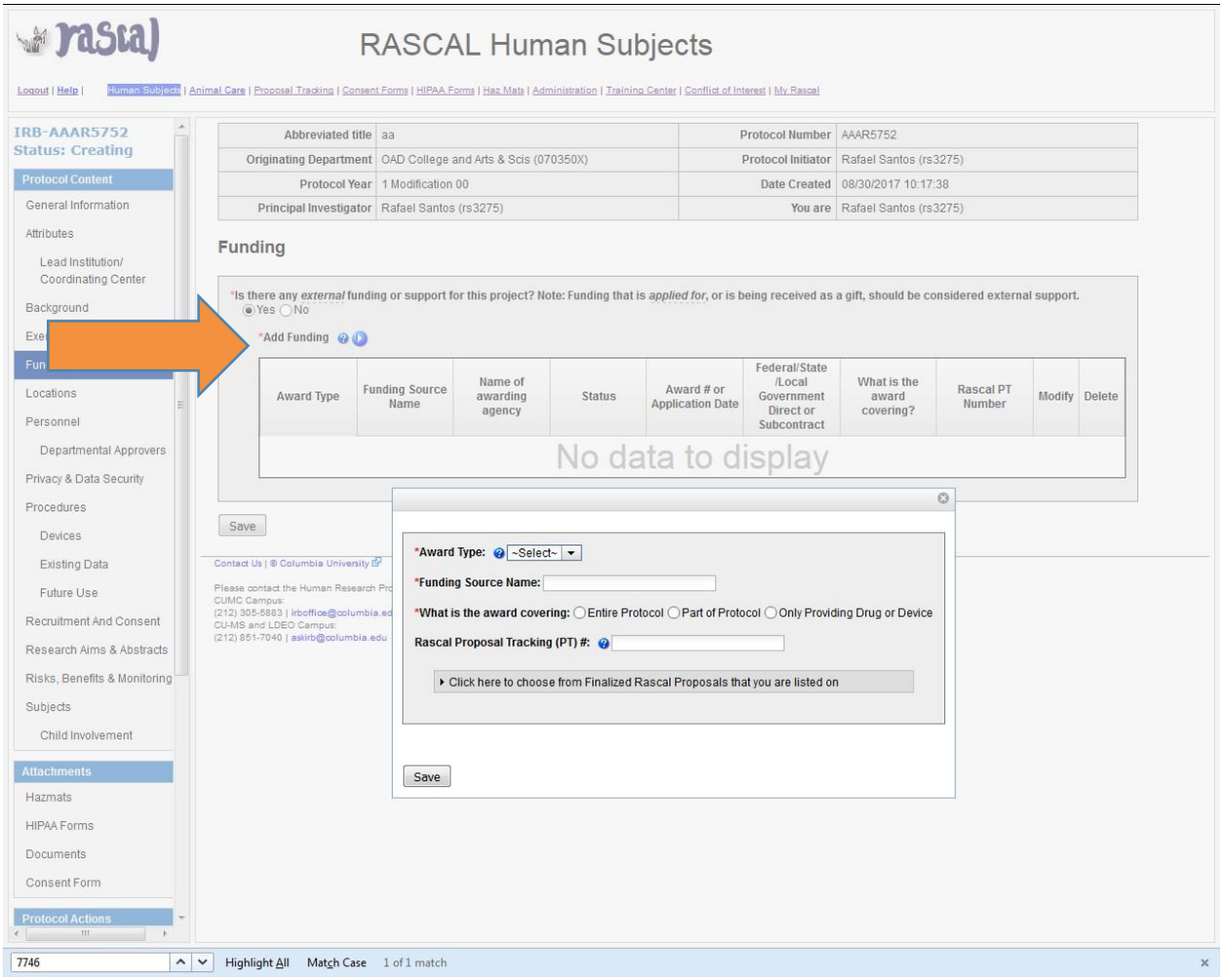
1) "[x] None of the above" should be selected
2) "[x] Yes" should be selected if the CU IRB will be providing approval for the analysis conducted by CU researchers.
3) **As this Rascal protocol template should be utilized when conducting a study that ONLY involves a retrospective chart review of CUIMC-NYP patient records, the response to this field should be 'No.'**
4) "[x] None of the above" should be selected unless utilizing any of the listed university resources.



1) Complete the text field to address the instructions found beneath each header
2) Alternatively, you may select the "[x] Abbreviated Submission" designation if a standalone protocol providing this information will be attached



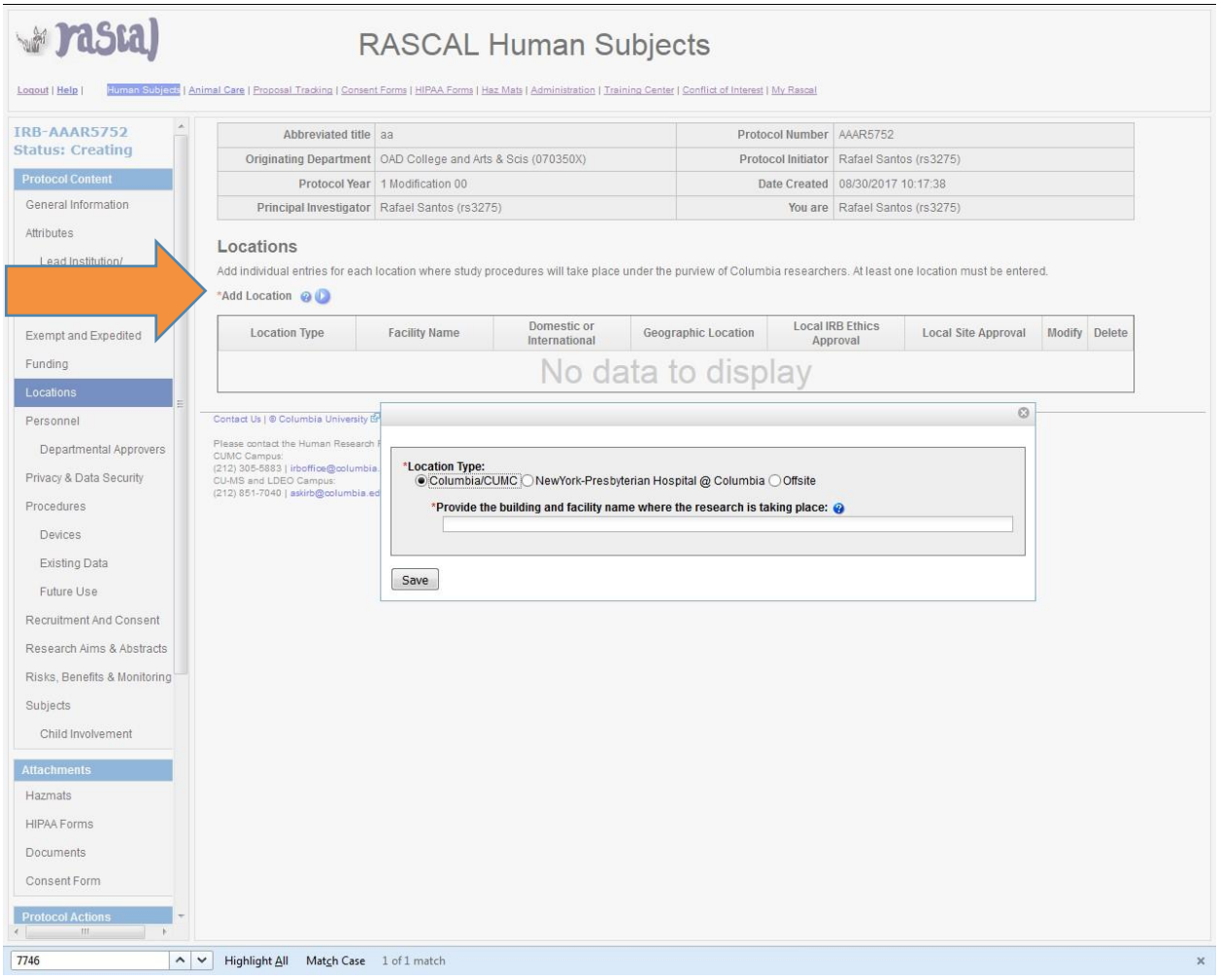
1) Studies that involve abstraction of identifiable data from patient medical records are generally not eligible for exemption. This would also be the case if any linkage between the abstracted data and the medical record exists.
2) Studies that involve analysis of existing data from the patient medical records are generally eligible for Expedited review, category 5.



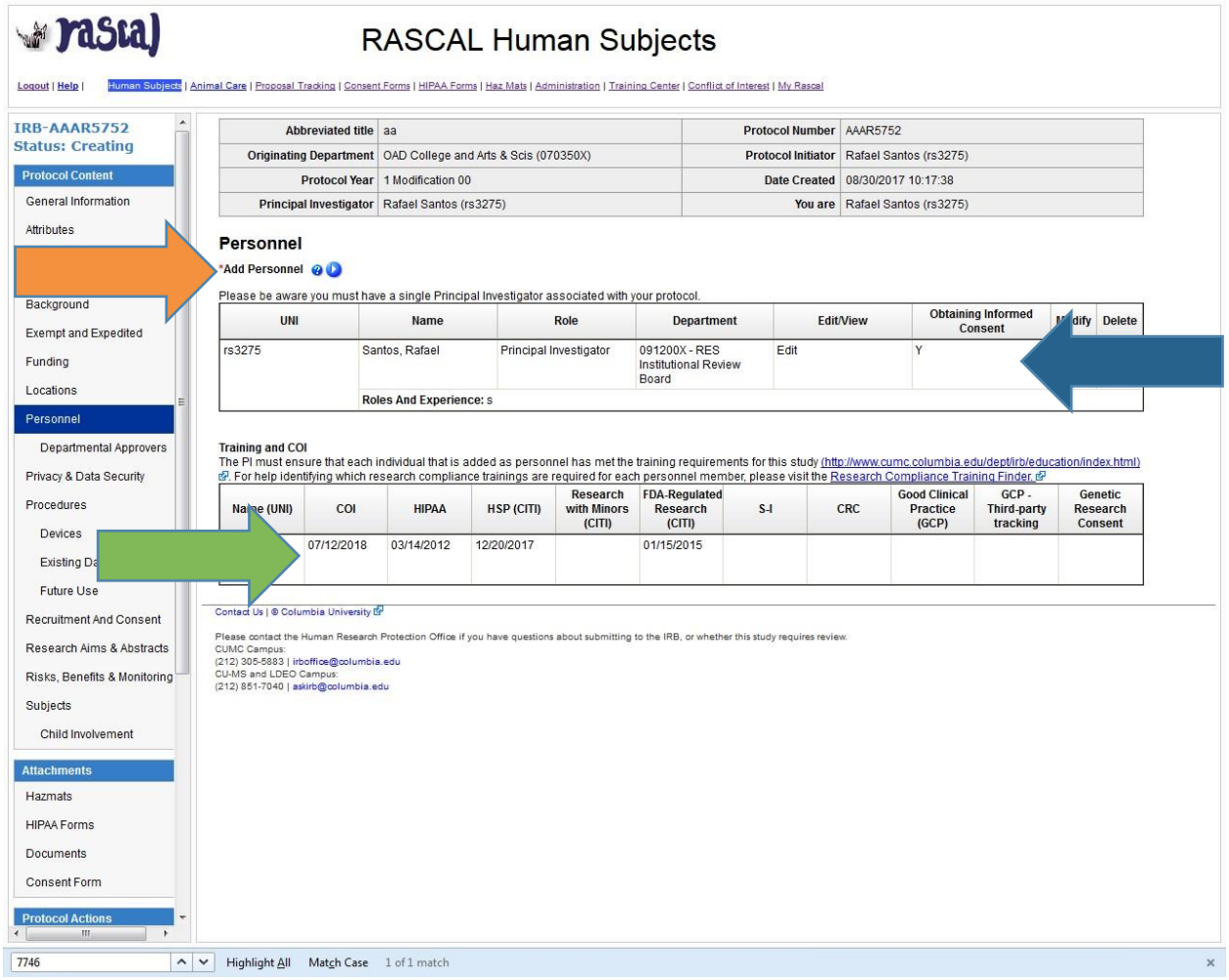
1) Describe any funding on this page.

**Tip:

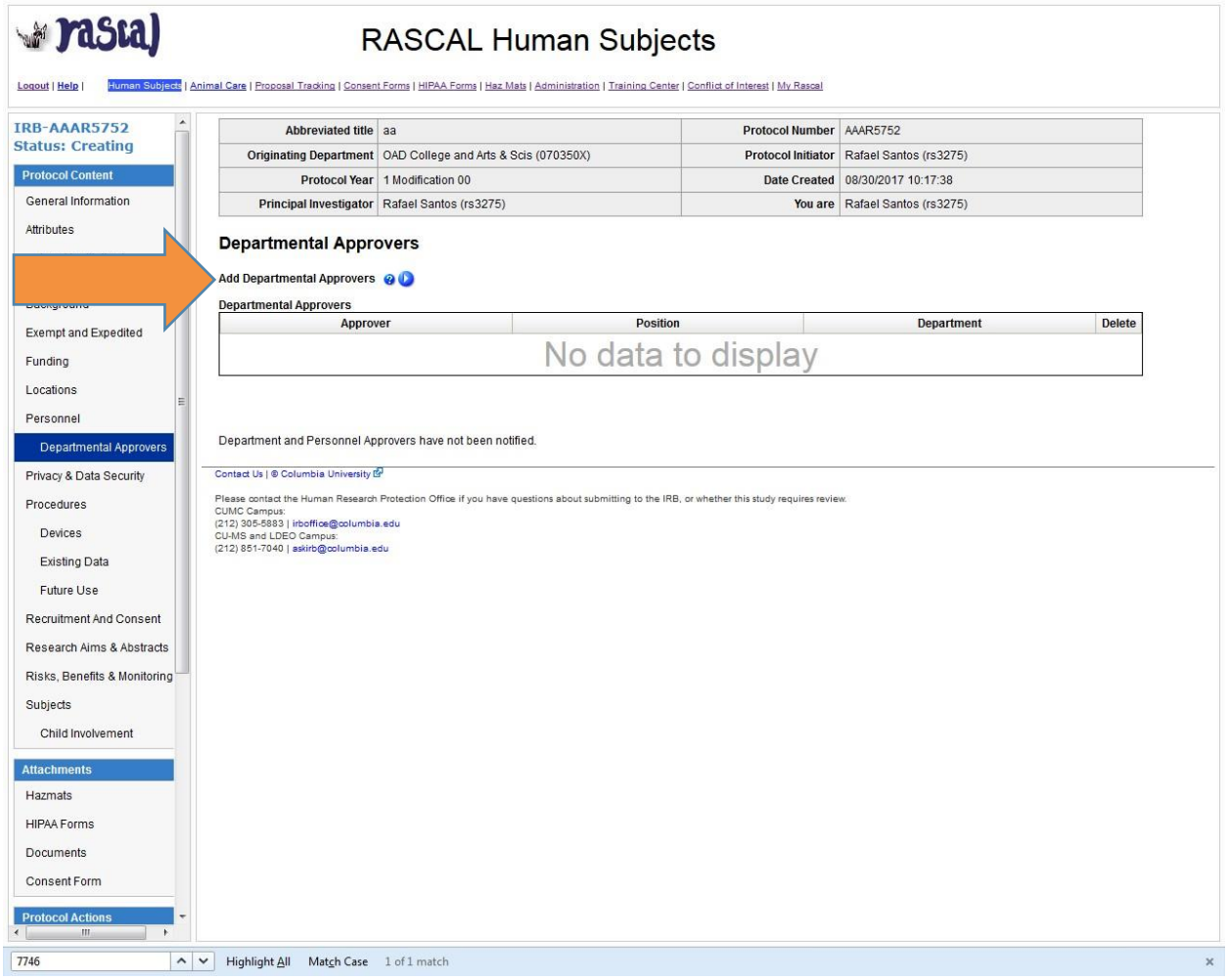
- A full funding application (face page, budget, and narrative) should be attached for all federal funding sources.
- Subcontract sites should be noted, their FWA provided, and a summary of their role described.



1) Add the location from which the data will be abstracted and the location at which your analysis will take place.

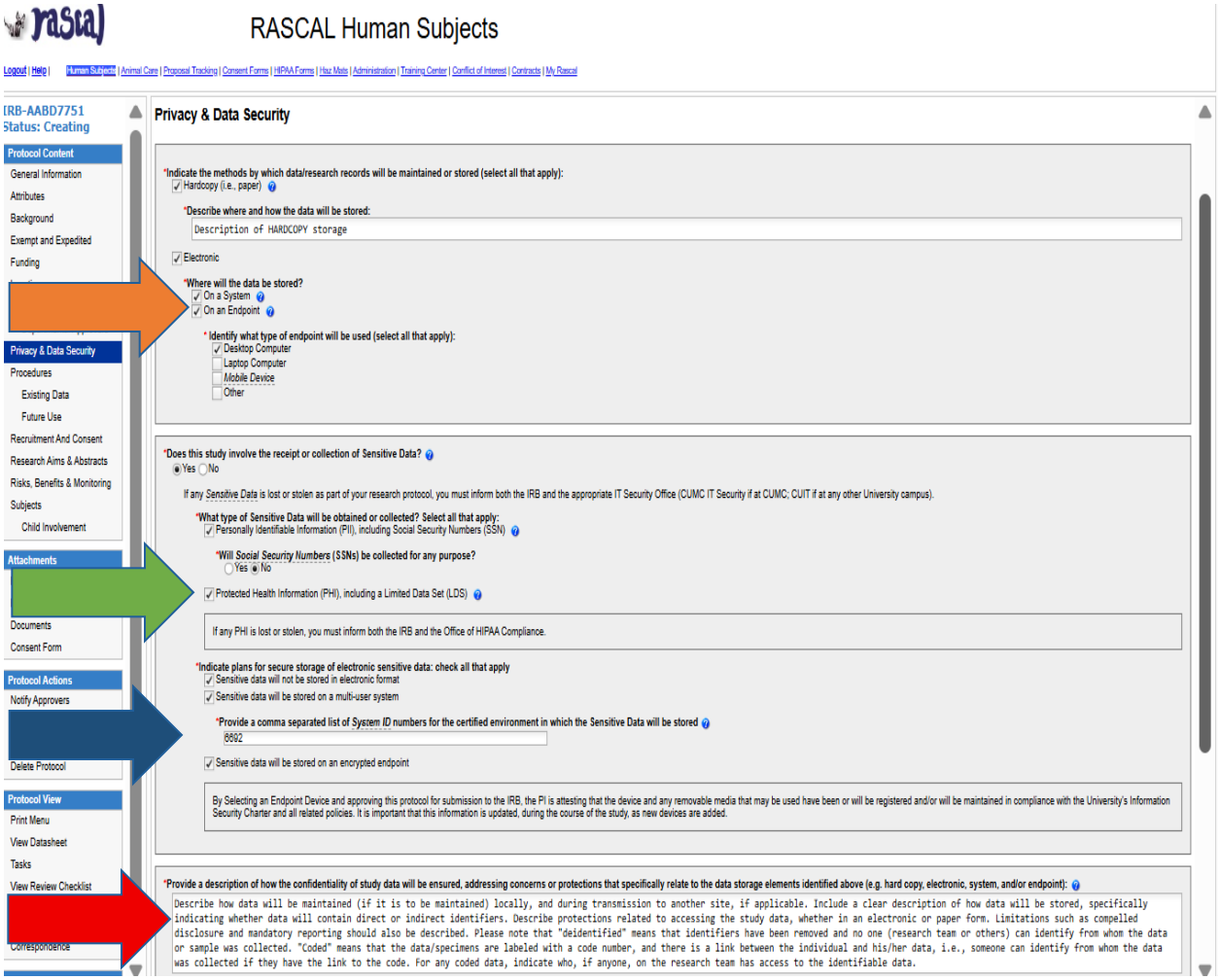


1) Add CU personnel that will be involved in the abstraction of patient data or analysis. Principal Investigators must be full-time faculty members (Professor, Associate Professor, Assistant Professor, Instructor) or full-time Officers of Research (Senior Research Scientist/Scholar, Research Scientist/Scholar).
2) Ensure that all required training has been completed. All personnel must complete the HSP TC0087 course and CUIMC researchers must also complete the HIPAA TC0019 course in order to participate in research. The elective, Research with Minors training, found within HSP TC0087 is also required if you will analyze data from children/minors. For additional guidance, visit the Training Center section of Rascal.
3) Obtaining Informed Consent column should indicate, "N" for all personnel as no interaction with subjects will take place.

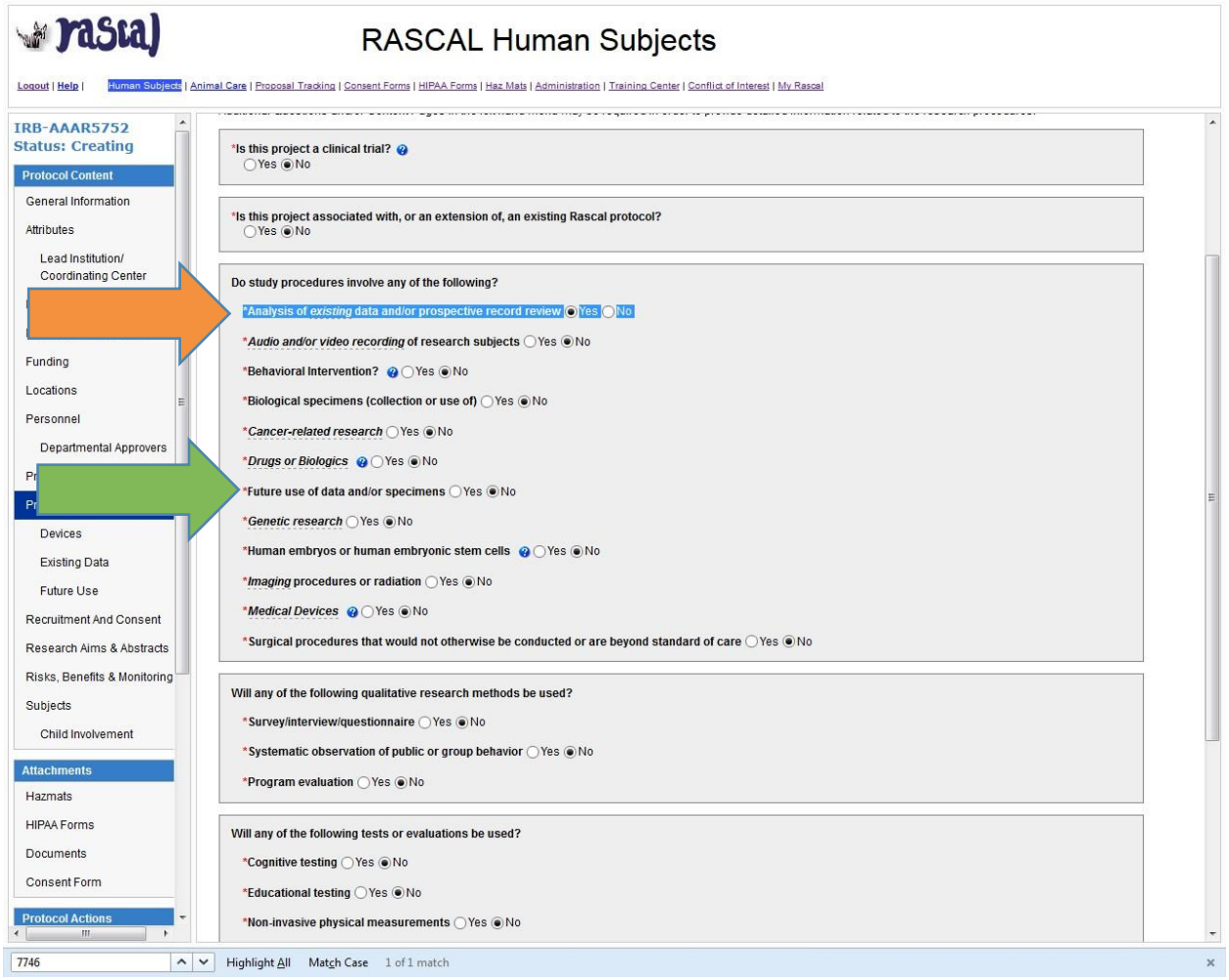


1) Add all approvers that may be required per your department.

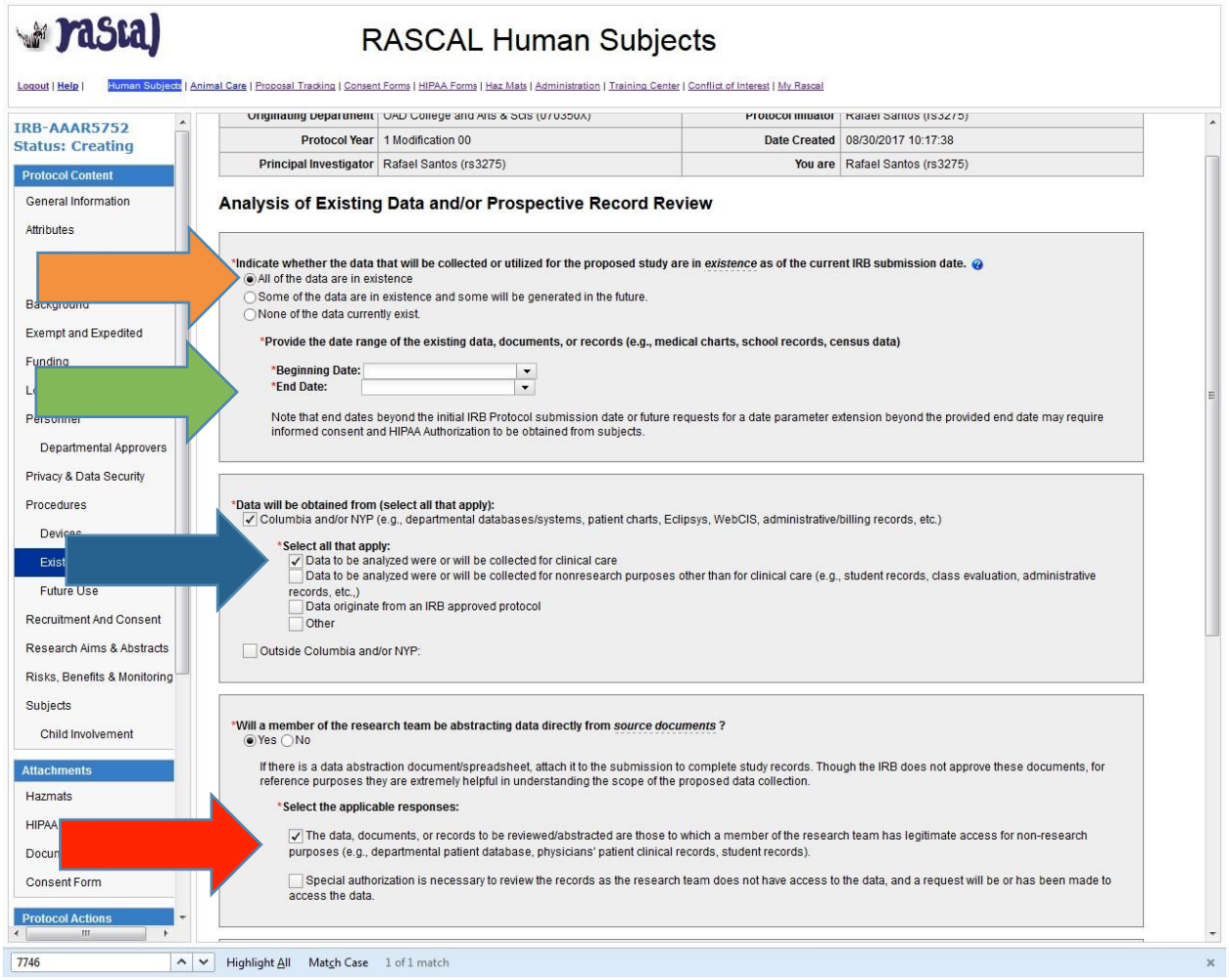
**Tip: Studies originating from a Pediatrics department must list Fiona Sanders (fs2107) as an approver.



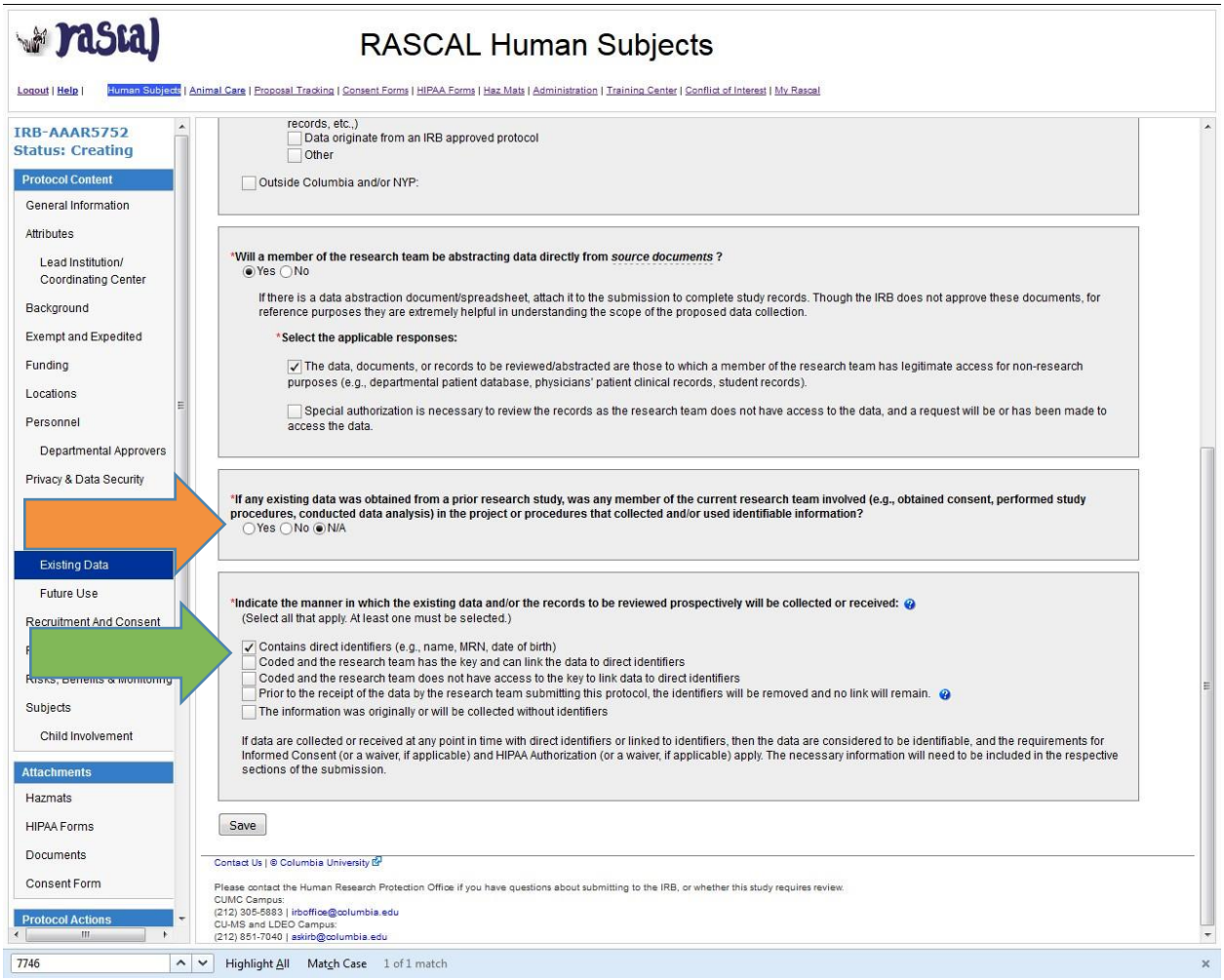
1) Please ensure that the storage selections for all electronic data are consistent with the storage requirements for electronic Sensitive Data. Any necessary explanations should be noted in the text field found on this page (e.g., nonsensitive electronic data stored on both endpoint and system, sensitive electronic data only stored on encrypted endpoint).
2) Studies that involve abstraction of data from patient medical records involve sensitive data in the form of PHI.
3) Sensitive data stored electronically must be either stored on an encrypted endpoint device or on a CUIMC IT certified multi-user system. For a list of certified multi-user systems please select the following link: https://rsam.cumc.columbia.edu/RSAM_DEFAULT.aspx
   **Please note that RSAM can only be accessed while on Columbia network or VPN.
4) Describe how data will be stored (ensure consistency with the above selections). Explain if data will be stored with direct identifiers or linked to identifiers via a code. If the latter, confirm that the key will be stored separately and explain how this key will be stored. Explain if and how data will be transferred externally and if this transfer will consist of a limited data set. If data will be used, analyzed or stored in multiple systems, all should be listed and described.



1) Select “Yes” to the Analysis of Existing Data and/or Prospective Record Review” field.
2) Select “Yes” to the Future Use of Data and/or Specimens field if you anticipate utilizing the data in future research or if you will transfer the data to an external site and the recipient may utilize the data in future research. All data transfers require an appropriate data use/transfer agreement.

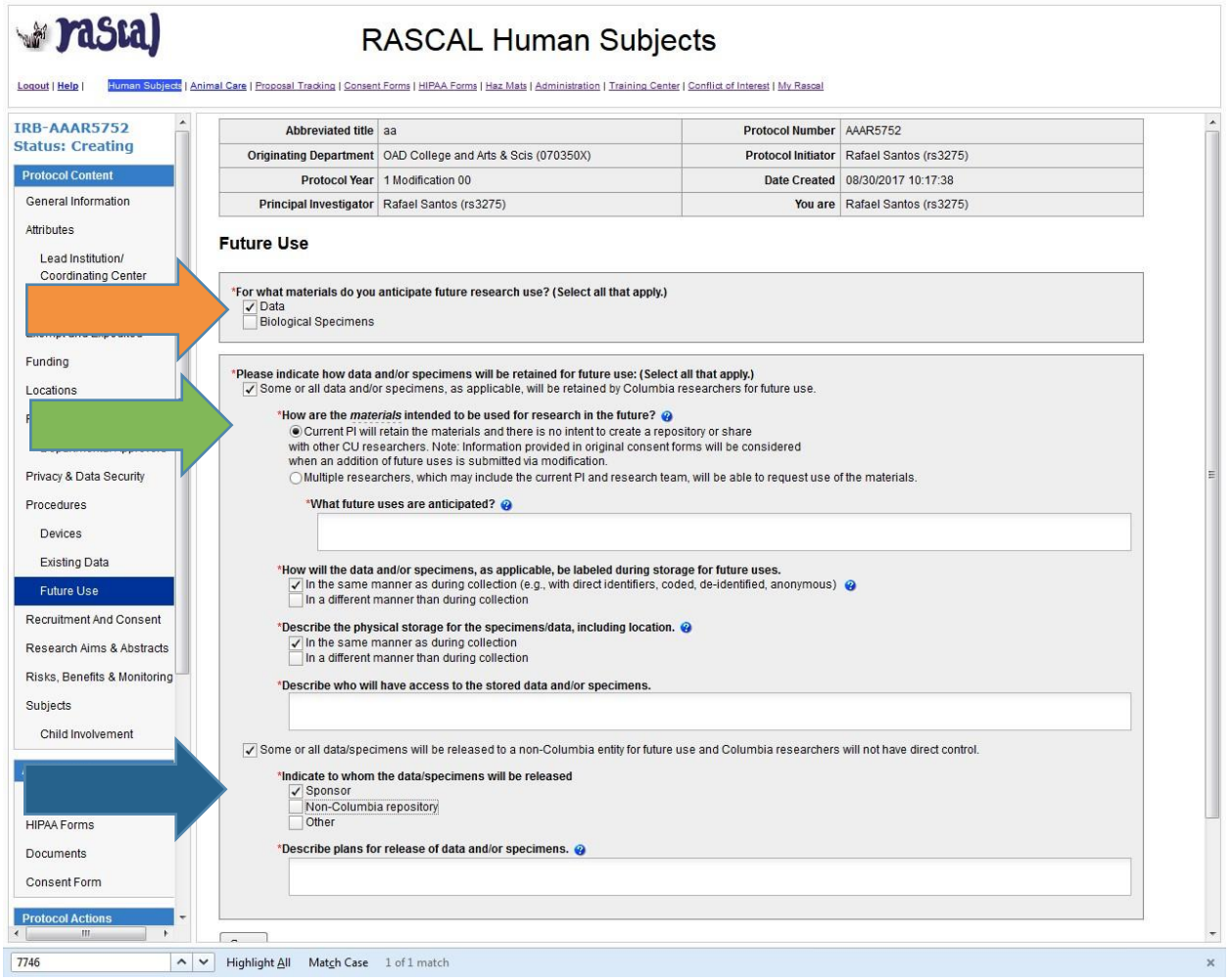


1) The data are only considered retrospective if "[ ] All of the data are in existence" at the time of the protocol submission.
2) Include the beginning date and end date of the data to be analyzed. Note that the end date should not surpass the date of the protocol submission in order for the study to be considered retrospective. Note that if a modification is submitted to include dates beyond the initial IRB Protocol submission date, informed consent and HIPAA Authorization from the subjects may be required.
3) Select "[ ] Columbia and/or NYP and "[ ] Data to be analyzed were or will be collected for clinical care" if all data come from CU/NYP medical records.
4) Select "Yes" to the field that asks if a member of the research team will be abstracting data directly from source documents. Complete the subsequently generated field that asks if you normally have access to the data as part of clinical care or if special authorization is needed. If special authorization is needed, please explain what approval will need to be sought or attach this approval to the protocol. Select "No" if data will be provided in report form as the result of a TRAC request.



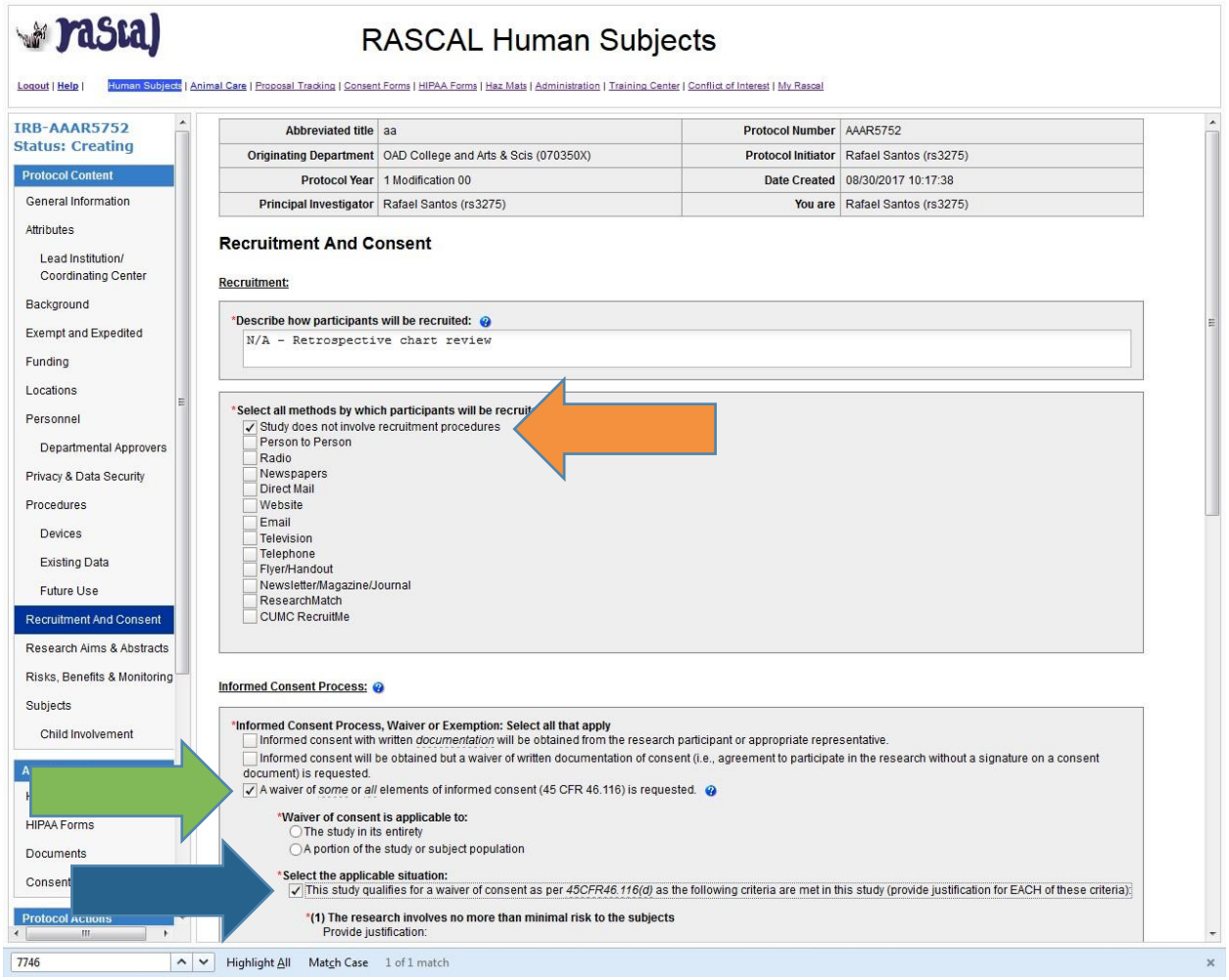
1) As data are abstracted from medical records only, please update this field to indicate "N/A:, No data will come from a prior research study."
2) This section refers to the manner in which data is received/accessed. As patient medical records contain direct identifiers, please update this field to select, "[x] Contains direct identifiers".

**Tip: Studies involving access to patient billing information will require approval from the CU Billing Compliance Office. They can be reached at billingcompliance@cumc.columbia.edu.

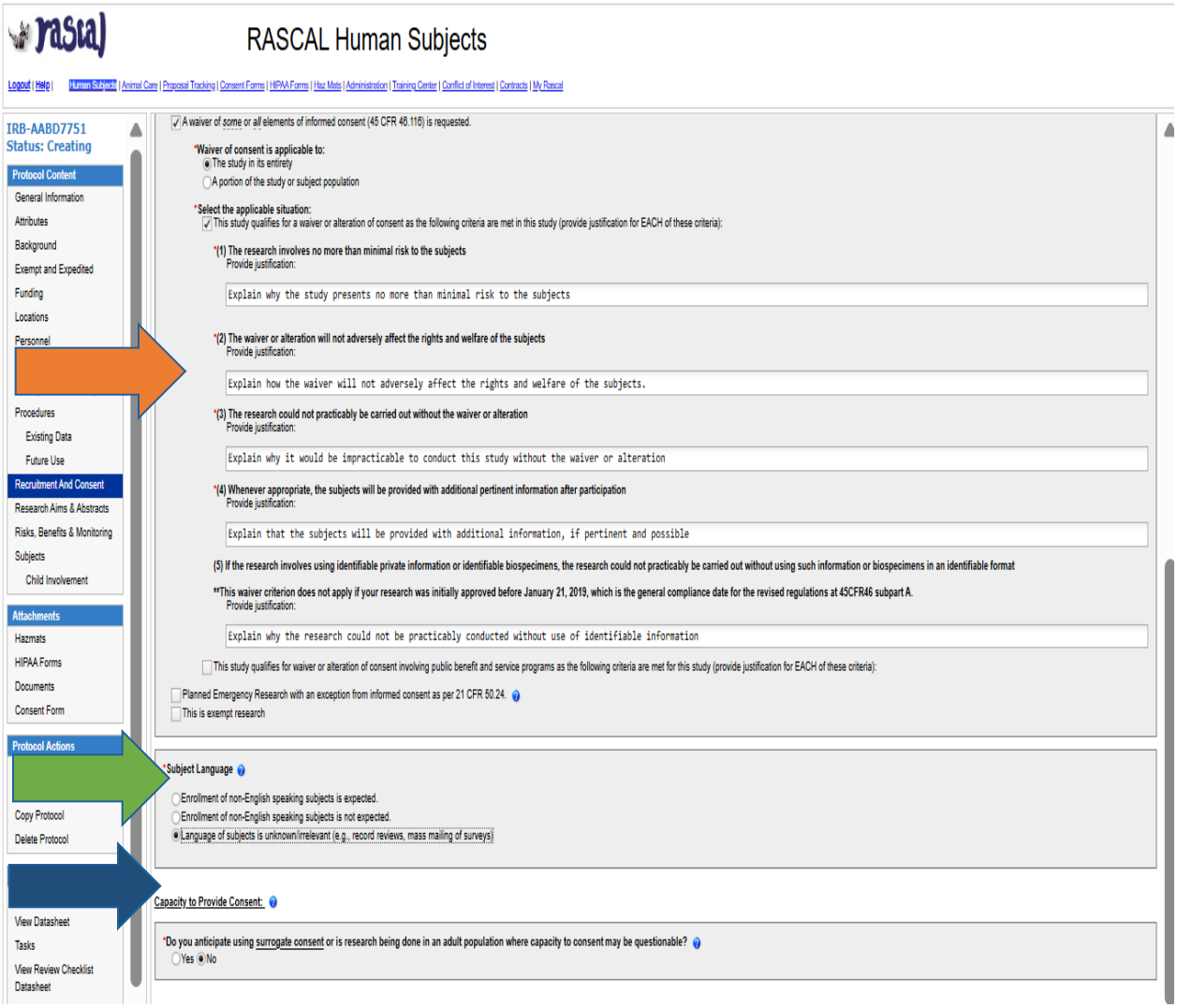


1) If you previously indicated, "Yes" to the future use of data on the Procedures page, the page above will be subsequently generated. Please select, "[ ] Data".
2) If you will retain the data at CUIMC, please select "[ ] Some or all data and/or specimens will be retained by Columbia researchers for future use" and complete the subsequently generated fields.
3) If data will be released externally, please select, "[ ] Some or all data/specimens will be released to a non-Columbia entity for future use and Columbia researchers will not have direct control." Please identify the recipient and detail the confidentiality of the data transferred, as well as the data security utilized during transit.

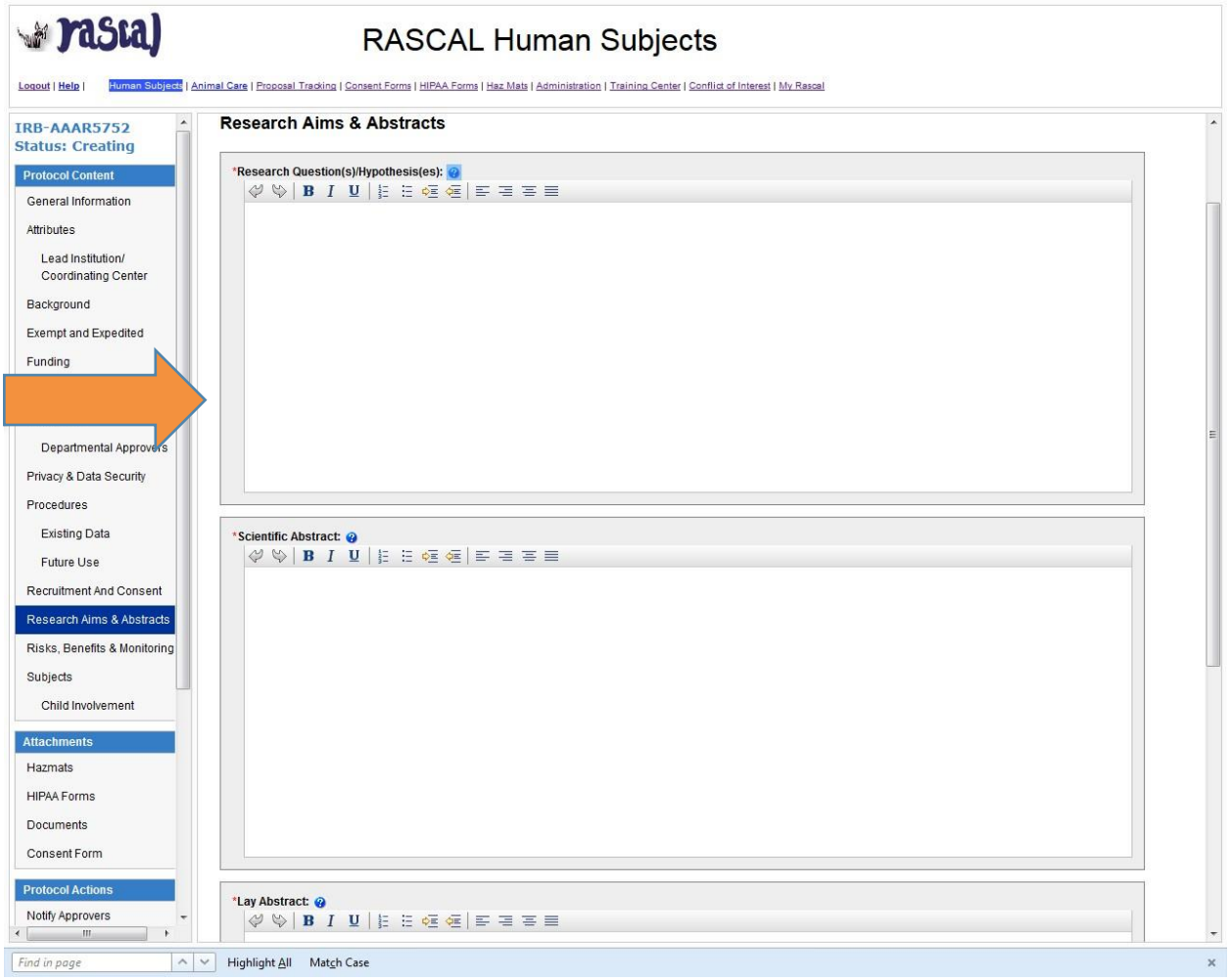
   **Note that transfer of data to an external site will likely require execution of a data use agreement. Please consult with CU SPA regarding the development/execution of a data use agreement prior to the transfer of data. The IRB just needs the final executed version prior to the data transfer.



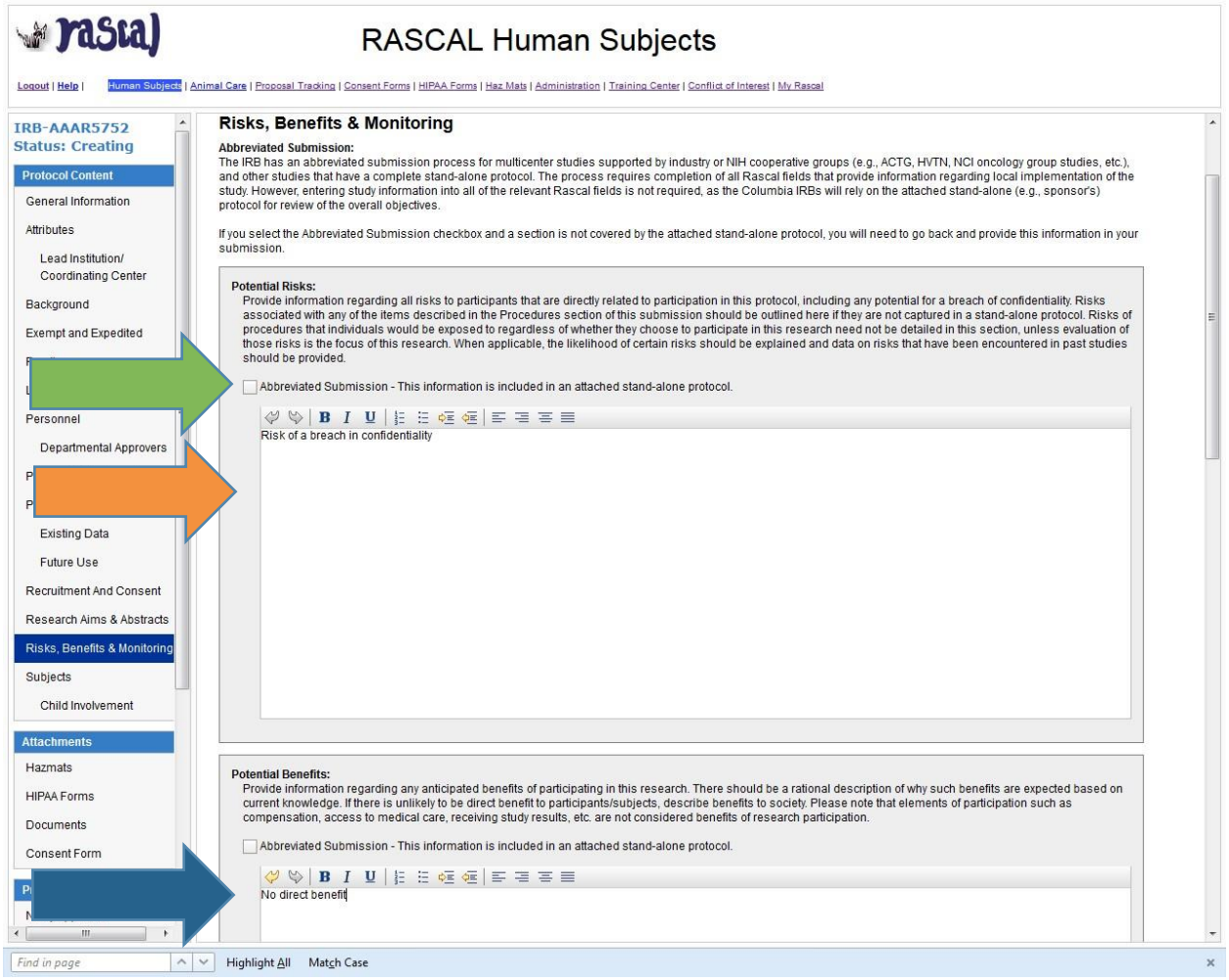
1) As this is a retrospective chart review that involves no interaction with subjects, please update this section to indicate, "[x] Study does not involve recruitment procedures".
2) As this is a retrospective chart review that involves no interaction with subjects, please select, "[x] A waiver of some or all elements of informed consent is requested".
3) Please select, "[x] This study qualifies for a waiver of consent as per 45CFR46.116(d)."



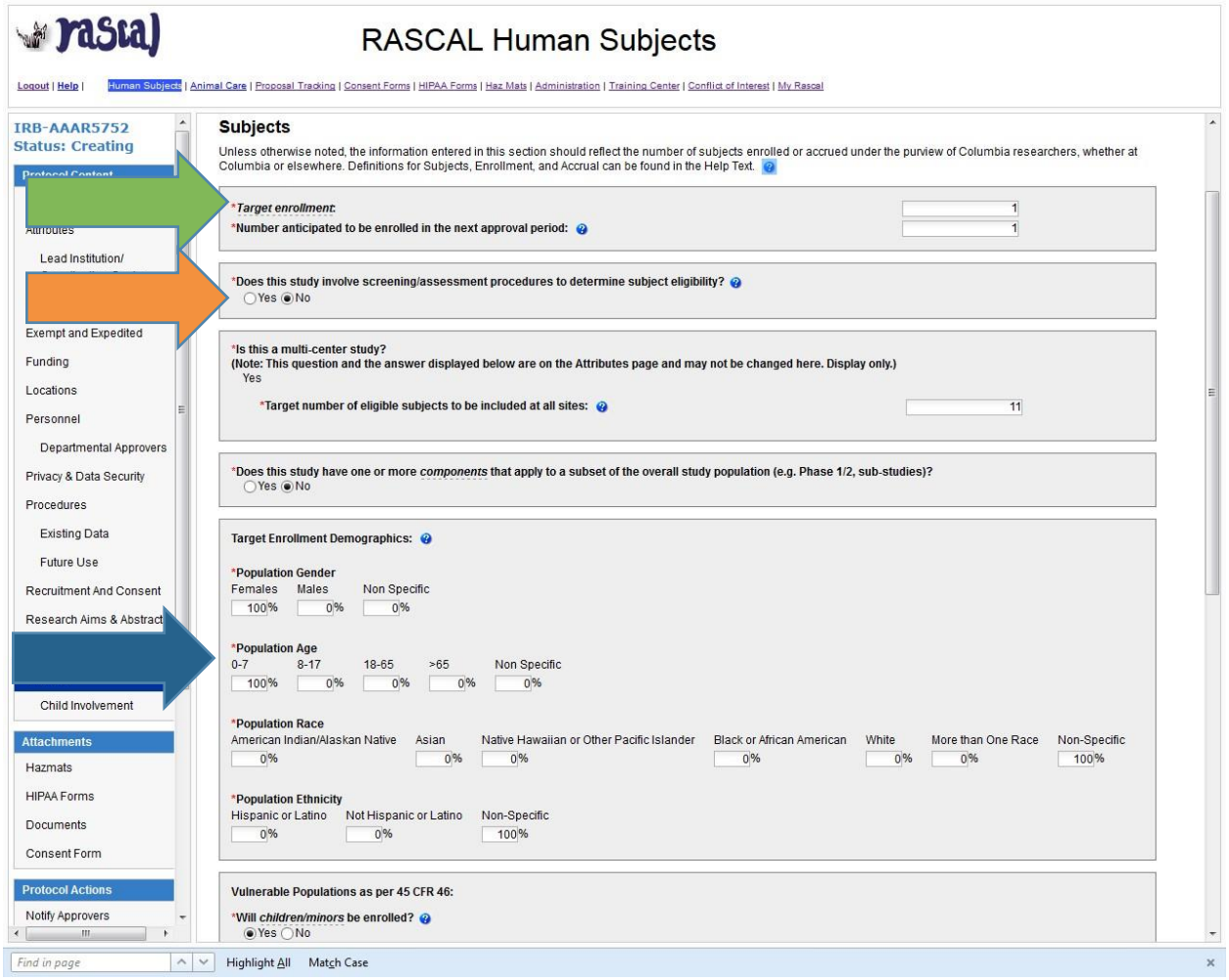
1) Please justify how each of the regulatory criteria are satisfied. It is not sufficient to simply state, "retrospective record review". Please note that while the fifth justification may appear as an optional field, it is required for all studies submitted on or after January 21, 2019.
2) Please select, "[x] Language of subjects is unknown/irrelevant".
3) Please indicate, "No" to the field that asks if surrogate consent is proposed.



1) Please complete all fields found on this page. Note that it is not sufficient to refer to a standalone protocol in these fields. Please utilize the blue question mark icon for information about what is needed in each field.



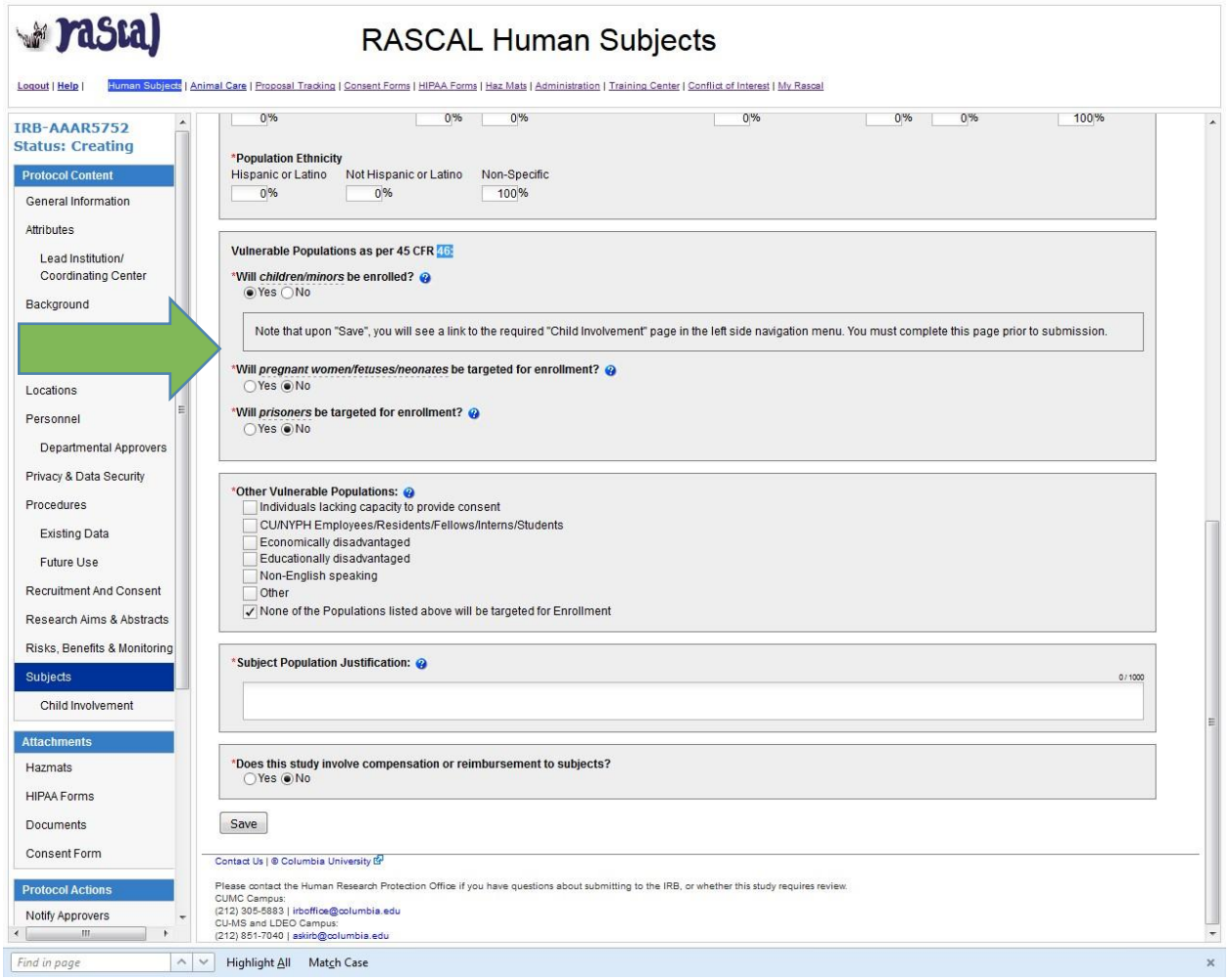
1) Select "[x] Abbreviated Submission" only if you have a separate standalone protocol that includes the relevant information.
2) The Potential Risks section should include the potential for a breach in confidentiality.
3) The Potential Benefits section should state that subjects will likely receive no direct benefit. This section may include potential benefits to future populations.



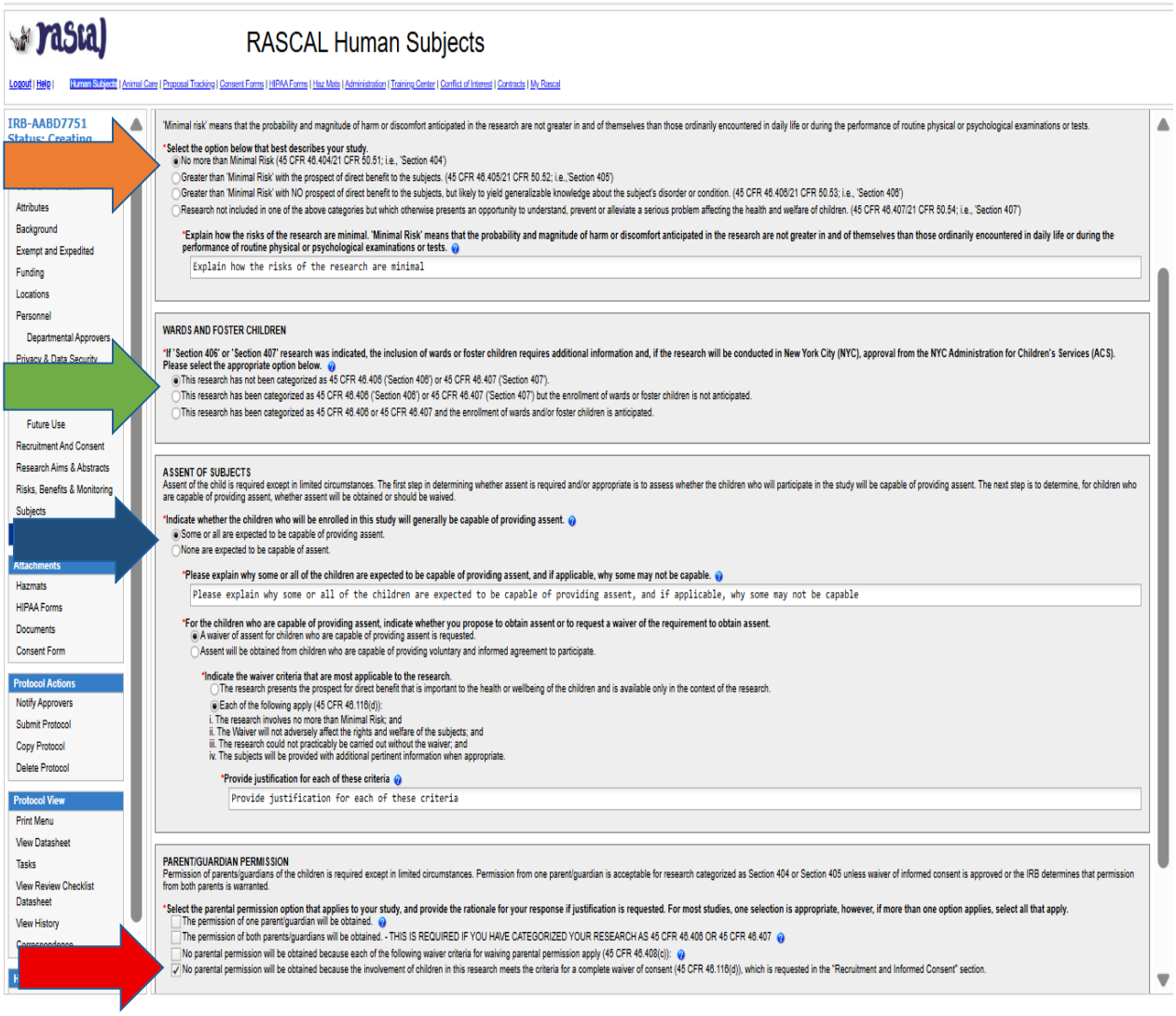
1) The target enrollment number should reflect the number of subjects you anticipate including in your analysis (e.g., the number of patient records accessed).

2) Only indicate, "Yes' to this field is you anticipate reviewing multiple records to determine eligibility of a subset of the total records accessed. If yes, please be sure that the target accrual number is lower than the target enrollment.

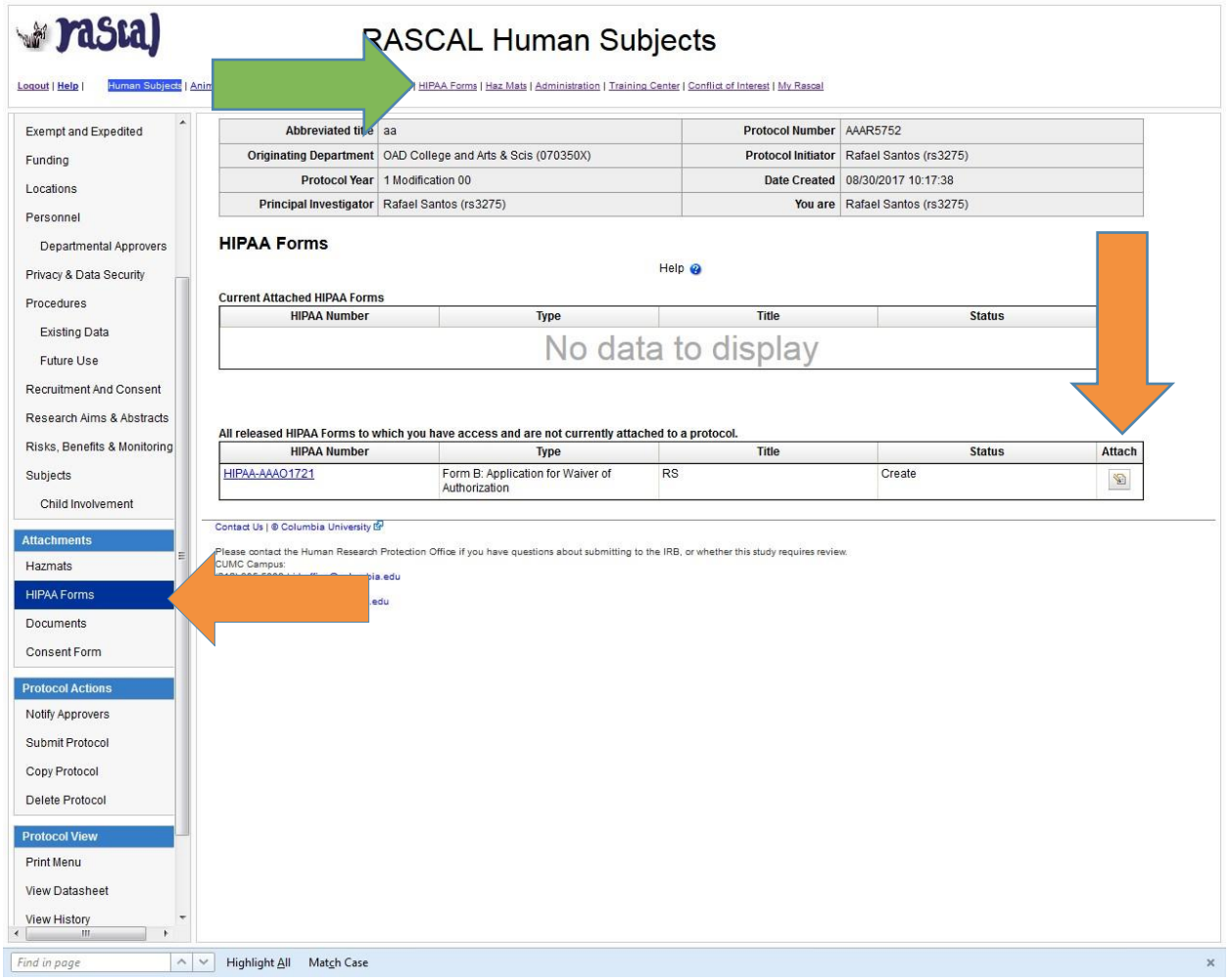
3) Please include your demographics. If you do not have specific targets for any field, please indicate "100% Non-Specific"



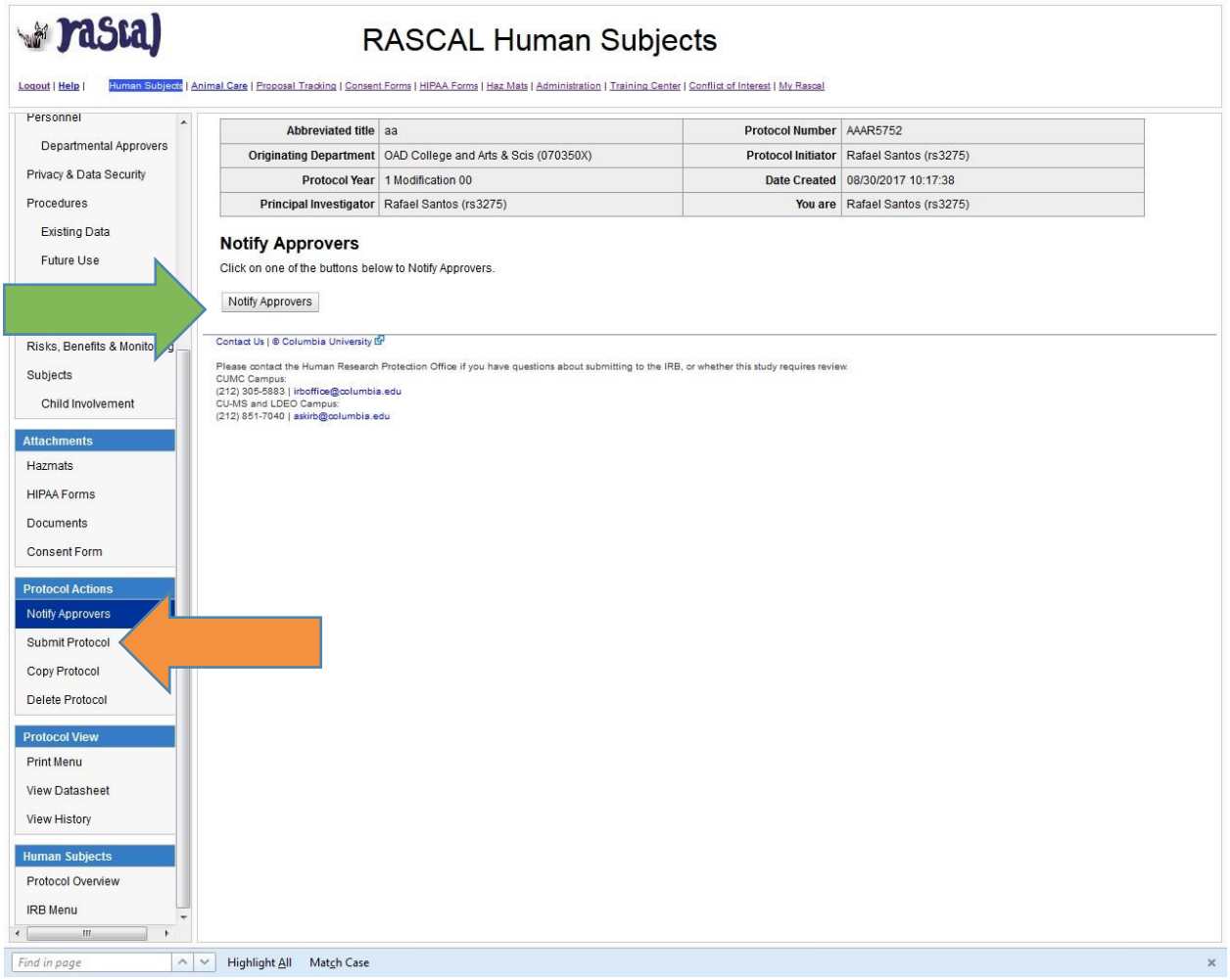
1) Please identify any vulnerable population whose medical records will be utilized in the study.



1) If you previously indicated on the Subjects page that children/minors will be enrolled, the subsequently generated page shown above will appear. Please select 'No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')'
2) Under Wards and Foster Children, please select 'This research has not been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407').'
3) Children ages 7-17 are generally considered to be capable of providing assent. If you anticipate including charts from children ages 7-17, please indicate 'Some or all are expected to capable of provided assent' and then select 'A waiver of assent for children who are capable of providing assent is requested.'
4) Under Parental/Guardian Permission, select 'No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent"



1) Please create a HIPAA Form B (Waiver of Authorization) within the HIPAA Forms module in Rascal. Please ensure that the justification provided for each of the criteria is consistent with what is described in the protocol. Please also ensure that item #2 explicitly indicates when PHI will be destroyed (e.g. at the conclusion of the research) and that item #3 explicitly indicates that no reuse/disclosure of PHI will take place, unless there are plans described within the protocol for future use/disclosure of PHI.
2) Please access the HIPAA Forms link within your protocol and attach/submit the HIPAA Form B.



1) Select “Notify Approvers”
2) Once all staff have approved, you will be able to submit to the IRB by selecting the “Submit Protocol link”.

**Tip: Access the Protocol Overview page to ensure that the study status has changed from “Creating” to “Submitted”.