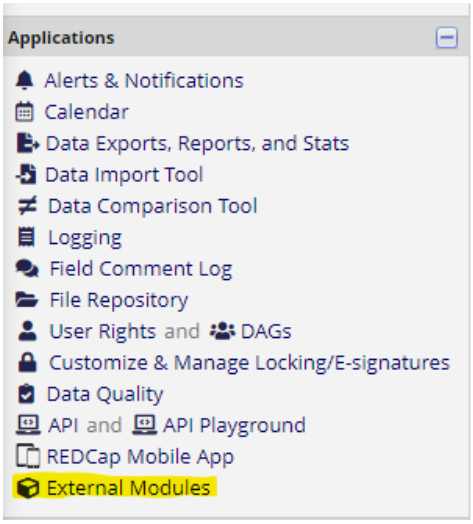
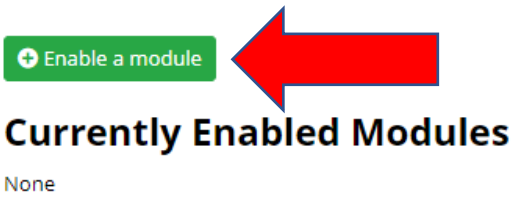
SOPs for REDCap External Modules: CheatBlocker and QuotaConfig Combined

A. Add the modules to your REDCap project:

1. Open your REDCap project that you want to use the modules in.
2. In REDCap, underneath the "Applications" header on the left-hand sidebar, click "External Modules."
3. Then, click the green button that says, "Enable a Module."

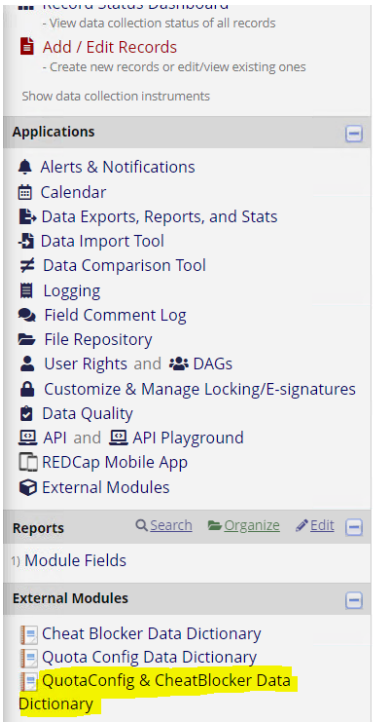


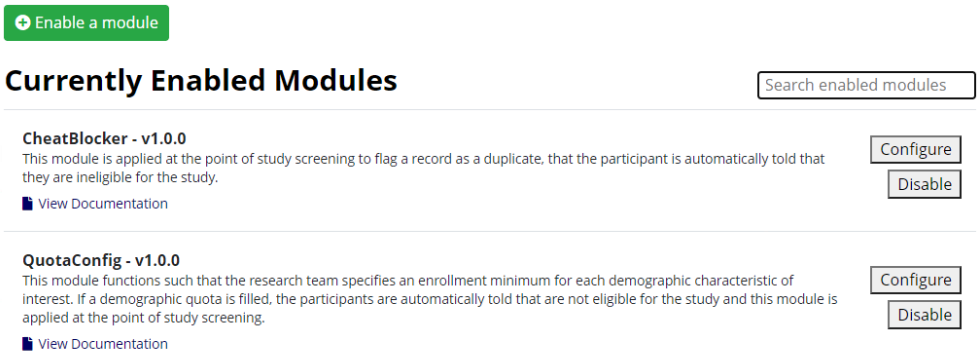


4. Search for "CheatBlocker" and click the "Enable" button.
5. Search for "QuotaConfig" and click the "Enable" button.

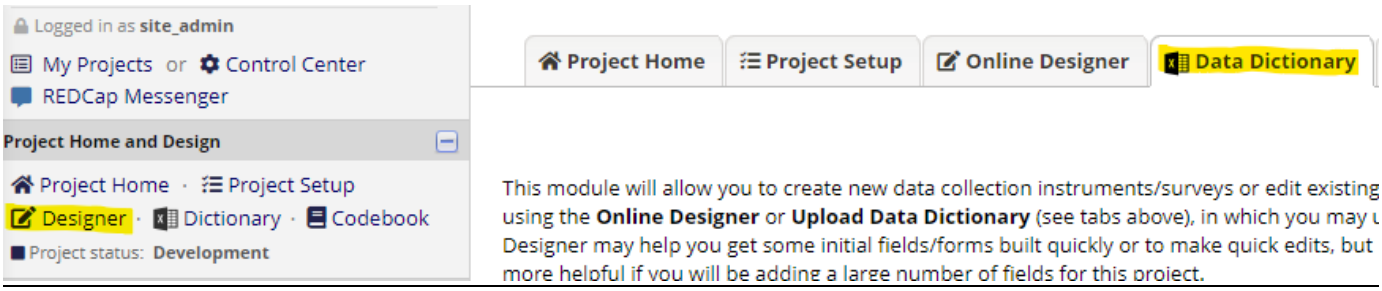
B. Add the variables to your project that will be used to customize the modules:

1. On the left -hand sidebar in the External Modules section, click "QuotaConfig & CheatBlocker Data Dictionary" to download a .csv file of variables you will need to use this module. Save this "QuotaConfig_CheatBlocker_data_dictionary.csv" file to your computer.

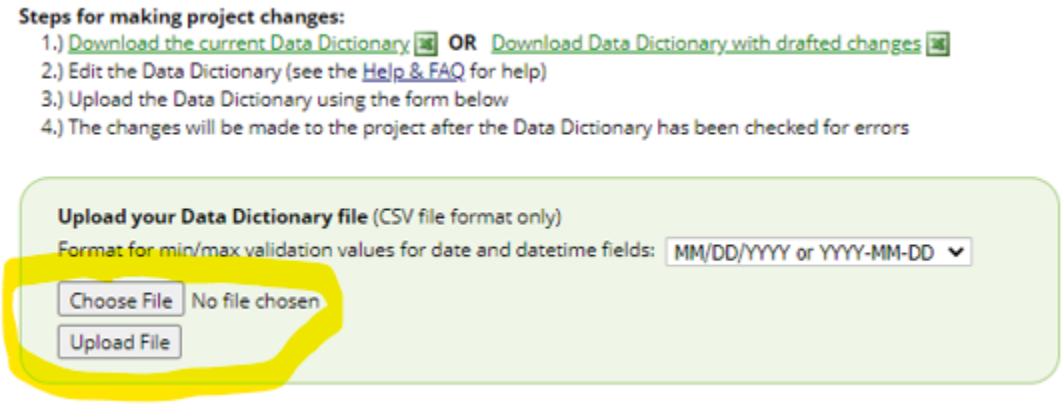




2. On the left-hand sidebar under the header “Project Home and Design,” click “Designer” and then open the “Data Dictionary” tab.



a. If your project has no forms/variables in it yet, click “Choose File” button near the bottom of the page (shown below), and then upload the .csv file you just saved to be your project’s Data Dictionary.
b. **OR,** if you already have forms/variables in your project,
    i. click the green “Download the current Data Dictionary” link shown below,
    ii. open your downloaded Data Dictionary and the .csv file you saved from above,
    iii. then copy and paste the rows from the new .csv file into your existing Data Dictionary
    iv. Finally, re-upload your Data Dictionary with the quota config and cheat blocker variables now added, by selecting the “Choose File” and then the “Upload File” buttons circled below.



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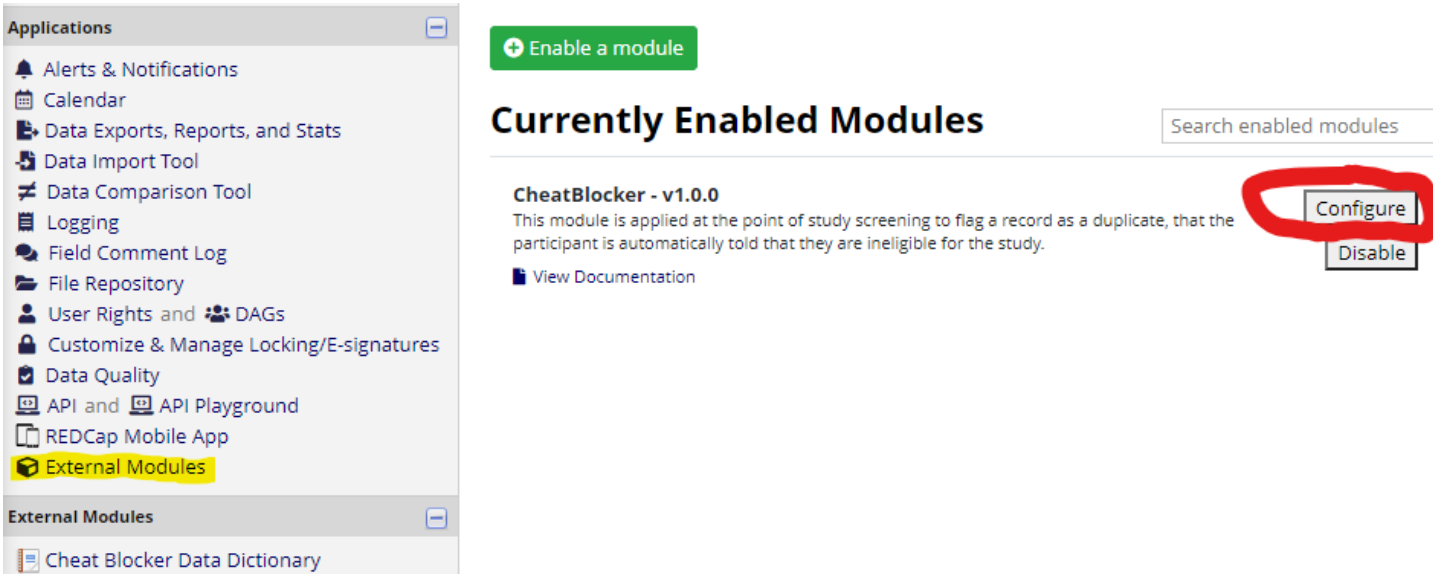
c. **Important tips to allow the modules to work correctly:**
    i. You must add or move any other variables that you wish to use to “catch” duplicates or for the quotas you wish to set to the “Demographics” form that is part of the QuotaConfig_CheatBlocker_data_dictionary.csv file; the module cannot use variables found on other forms in the project. It is OK to have demographic information on other forms, if those variables are not needed to identify duplicates.
    ii. Do **not** re-name the form or **any** of the variables from the QuotaConfig_CheatBlocker_data_dictionary.csv file, as these are used behind the scene by the module, and it will not work correctly if you change these names. You can however *delete* demographic variable rows (DOB, Race, BMI etc.) that you do not need.
    iii. Mark all added variables that will be used as criteria to catch duplicates as “Required” so that blank fields do not show up as matches in the duplicate check.

3. After you upload the new data dictionary, you can also make changes to the project by using the Online Designer, also under Project Setup. If you are not familiar with creating instruments and variables in REDCap, here is a short tutorial provided by REDCap.

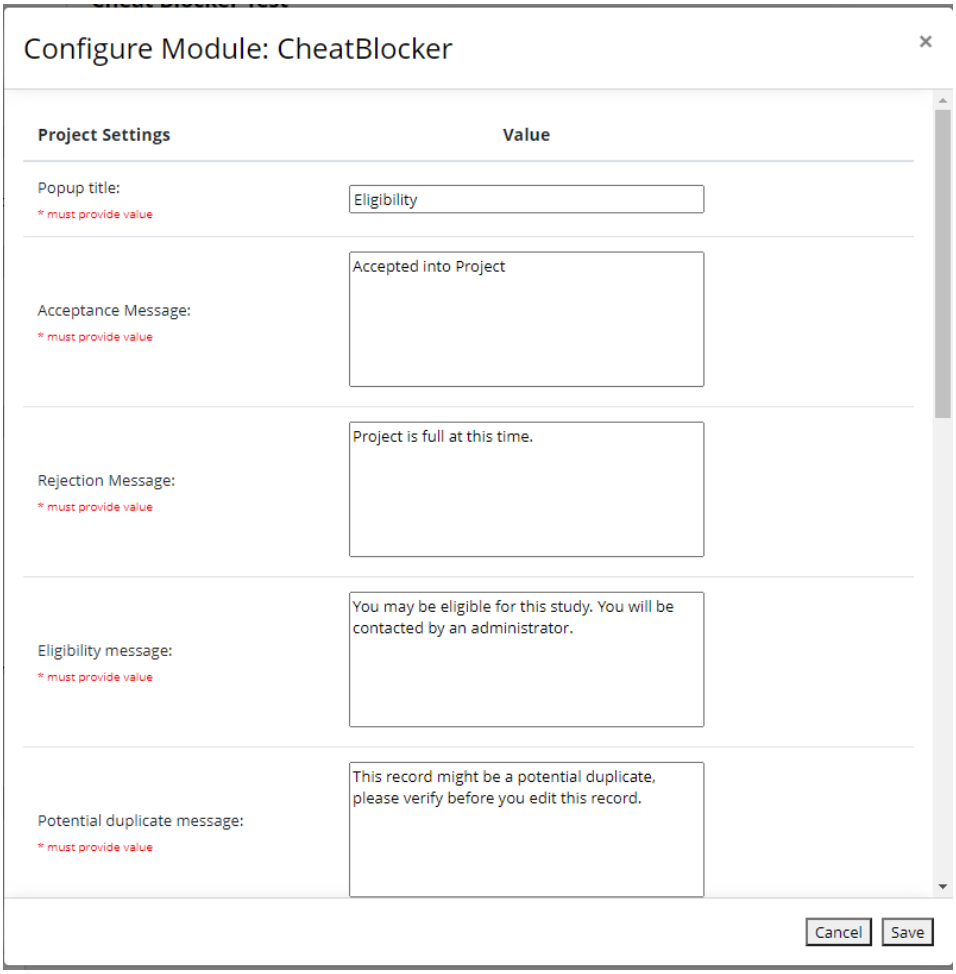
C. Customize the modules for your project one by one:

CheatBlocker:

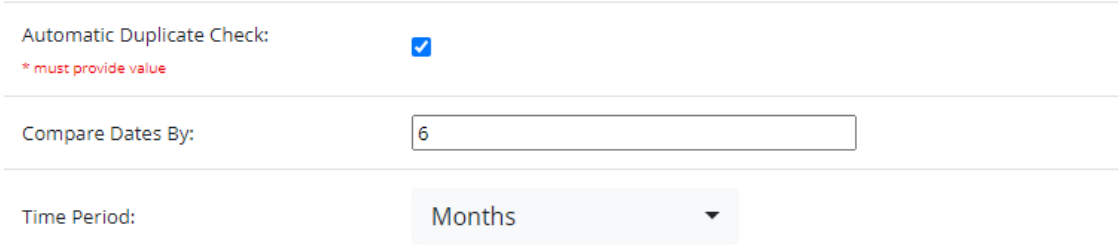
1. Under “Applications” on the left-hand toolbar, click “External Module” and then click the “Configure” button next to the “CheatBlocker - v1.0.0” module.



2. The dialogue box below will then open:



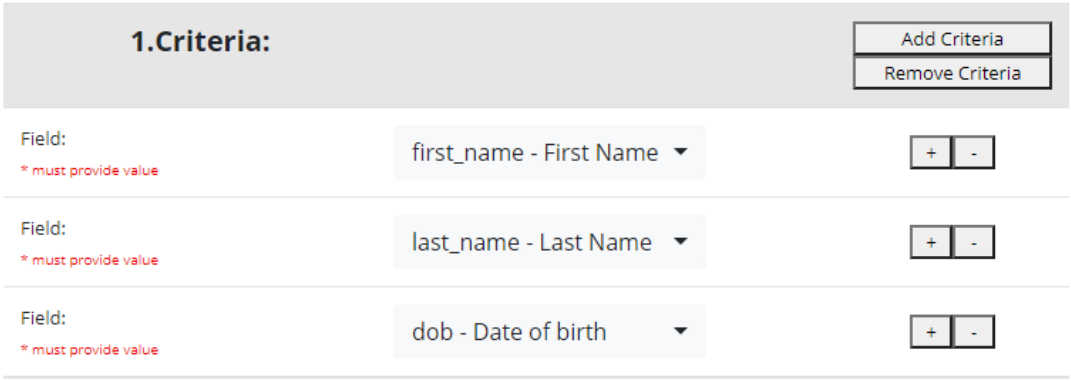
3. Customize the messages you want to pop up when someone fills out your survey to let them know if they are eligible or possibly eligible, based on duplicate criteria you will set up below. A screenshot of the default messages is above.
4. Select whether you want the Duplicate Check to occur automatically, or not (screenshot below).
    a. If you **check** the box beside "Automatic Duplicate Check," individuals filling out your survey will receive **either** the customized message that you put in the "Acceptance Message" or the "Rejection Message" boxes above; if someone gets the "Rejection Message" they will not be able to continue with the survey.
    b. If you leave the box **unchecked** beside "Automatic Duplicate Check," **all** individuals filling out the survey will receive your customized "Eligibility Message."
        i. Study staff will then need to open each new record as they come in and look at the "Potential Record IDs" and "Potential Failed Criteria" fields to see if the module identified the record as a potential duplicate with any other existing record(s) and on what criteria.
        ii. If the study staff decides that the record is a duplicate, they should select "yes" for the "Duplicate Check" question; if the study staff decides that the record should not be considered a duplicate, they would select "no" to the "Duplicate Check" question.

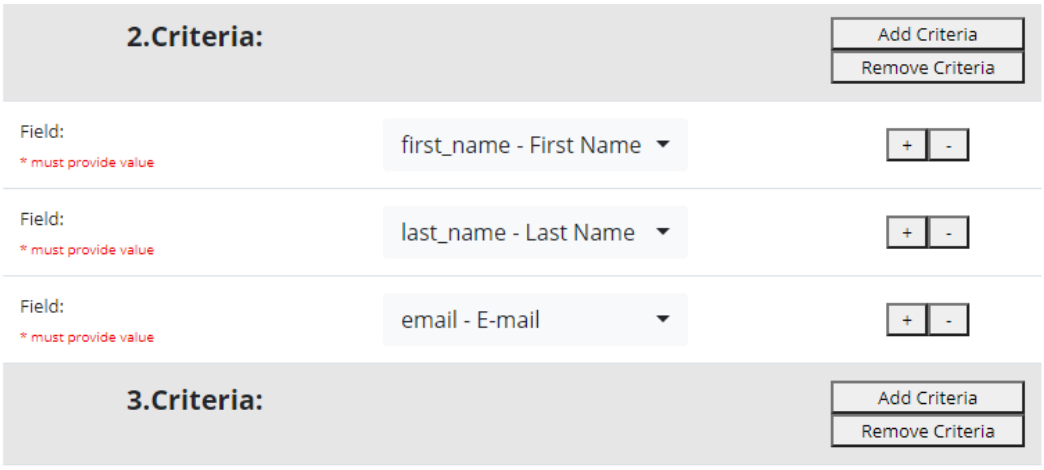


5. In the image above, you can also see the "compare dates by" field, which allows you to control which records are included in the cheat blocker check. In the scenario above, it would only check records that were submitted within 6 months from the day the screener was filled out.
    a. Using the "Compare Dates By" feature is optional and may be beneficial if you want to allow for changes in eligibility criteria over time within an individual (e.g., if a person was feeling fine a year ago, but now is feeling depressed, or if a person had uncontrolled high blood pressure a year ago but it is now under control with medication.) If you leave this space blank, all records will be checked.

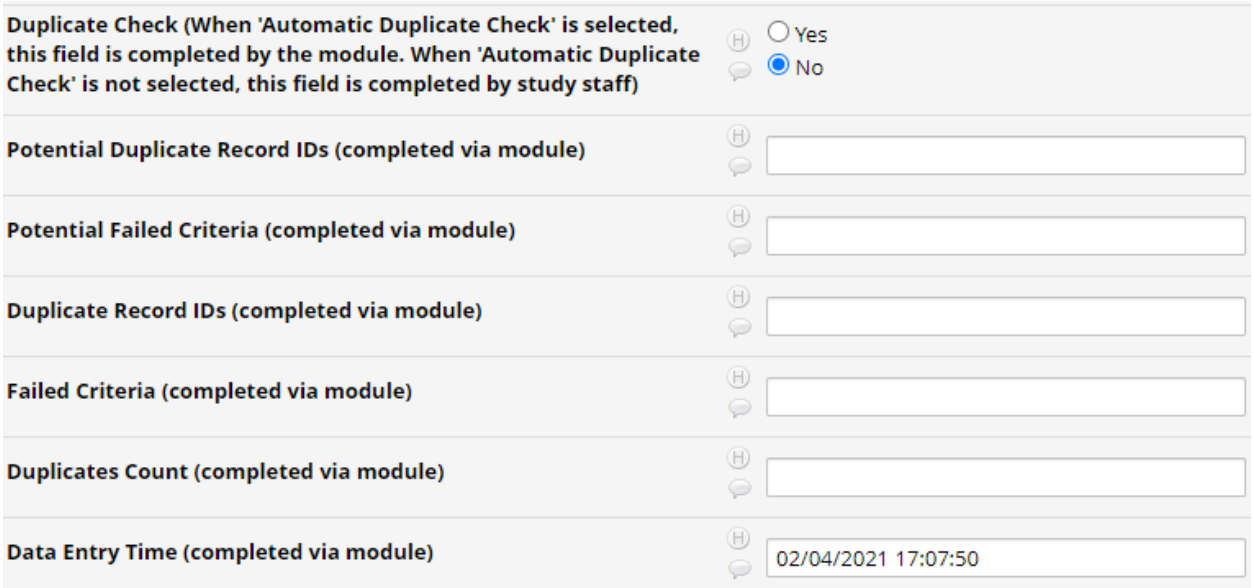
Finally, add your desired cheat blocking criteria to the project:

1. At the bottom of the page, you will enter your desired criteria to be used in checking for duplicate/cheat entries, by clicking the "Add Criteria" button on the right.

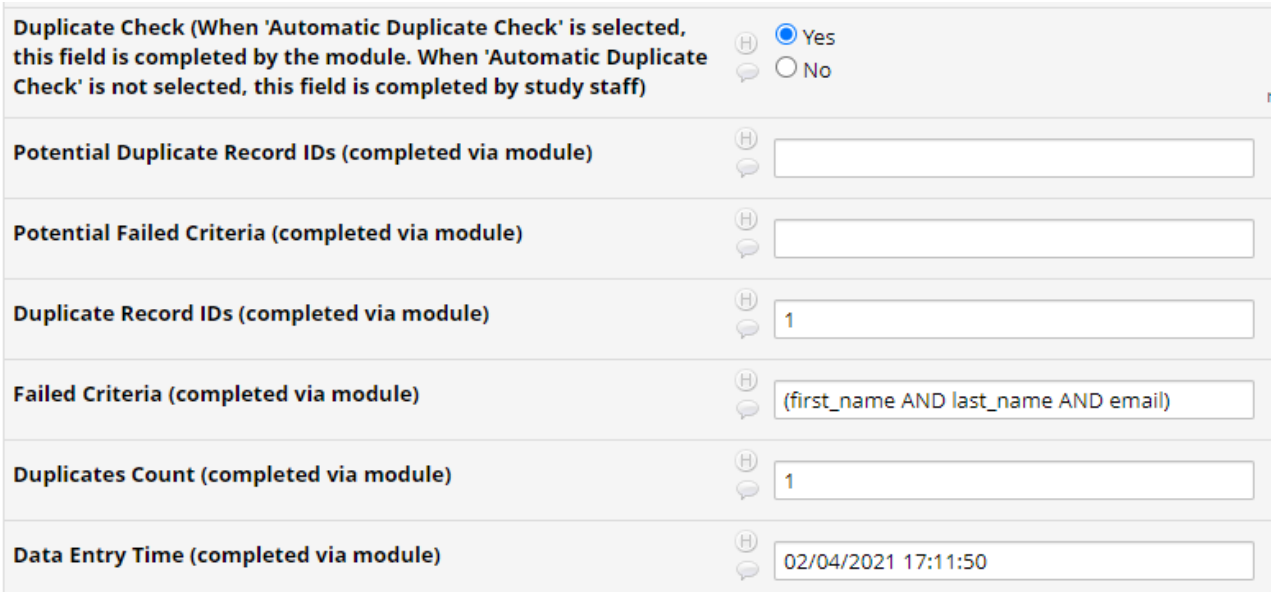




2. Under each criteria you will add the fields that, if duplicated, will result in a rejection.
    a. Within each set of criteria, click the "+" or "-" buttons to add or remove fields.
    b. The +/- buttons add "AND" statements.
3. To add a second set of criteria (an "OR" statement), you would click the "Add Criteria" button to the right of "1. Criteria:".
    a. In the example above, it will reject entries with matching first name, last name, and date of birth (Criteria #1), OR those with matching first name, last name, and email (Criteria #2).
4. Be sure to click "Save" to save your criteria before closing out of the dialogue box.
5. You can add as many sets of criteria as needed. This will be the number of different combinations of matching fields that will result in a Cheat Blocker rejection. You can test this using practice records and seeing if the desired pop up message appears.
6. You can also open any record and look at the bottom of the Demographics form, under General Comments, to see if someone passed the duplicate test or not, and if they failed it, what other record(s) it matched
    a. Example of a Passed Duplicate Check:



b. Example of a Failed Duplicate Check (and why it failed):



c. Example of a Potential Duplicate (when the box next to "Automatic Duplicate Check" is left blank):

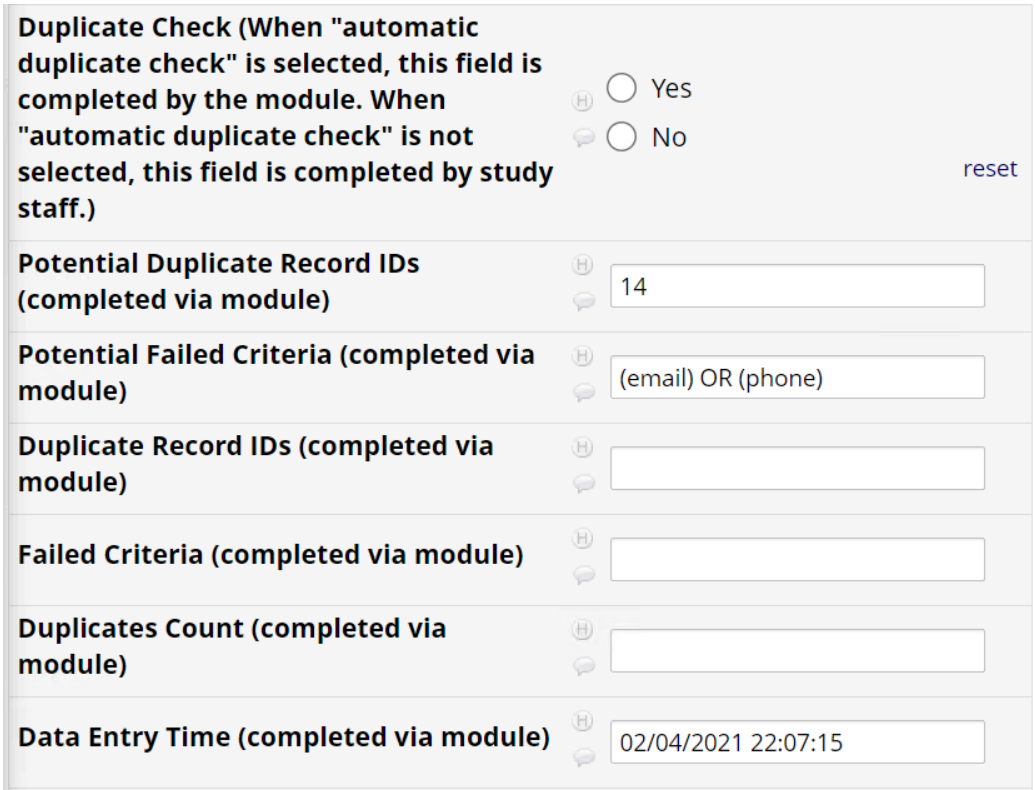
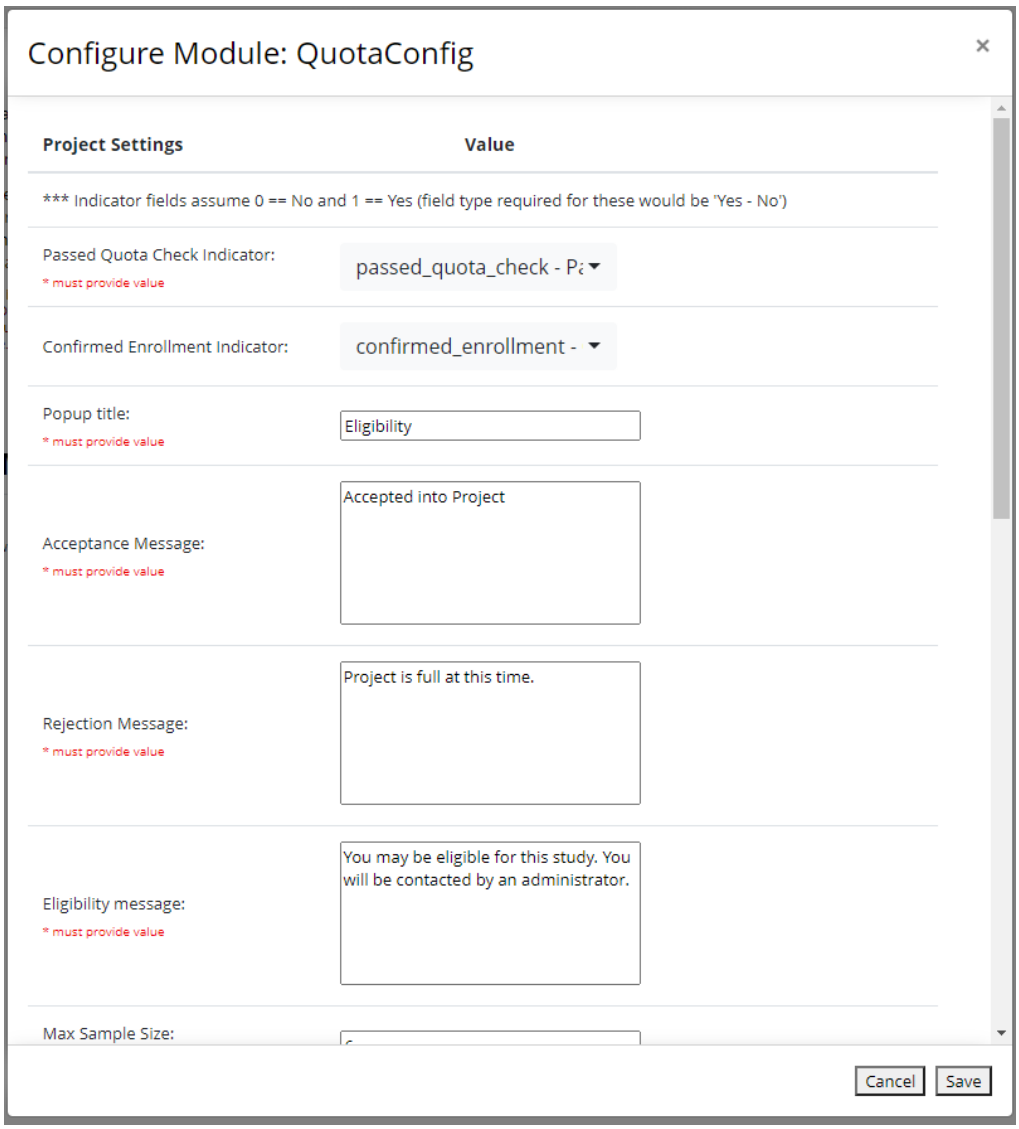


Figure 1: You can see the duplicate check field is blank, the staff will need to fill this out after making the decision if the ppt is a duplicate or not.

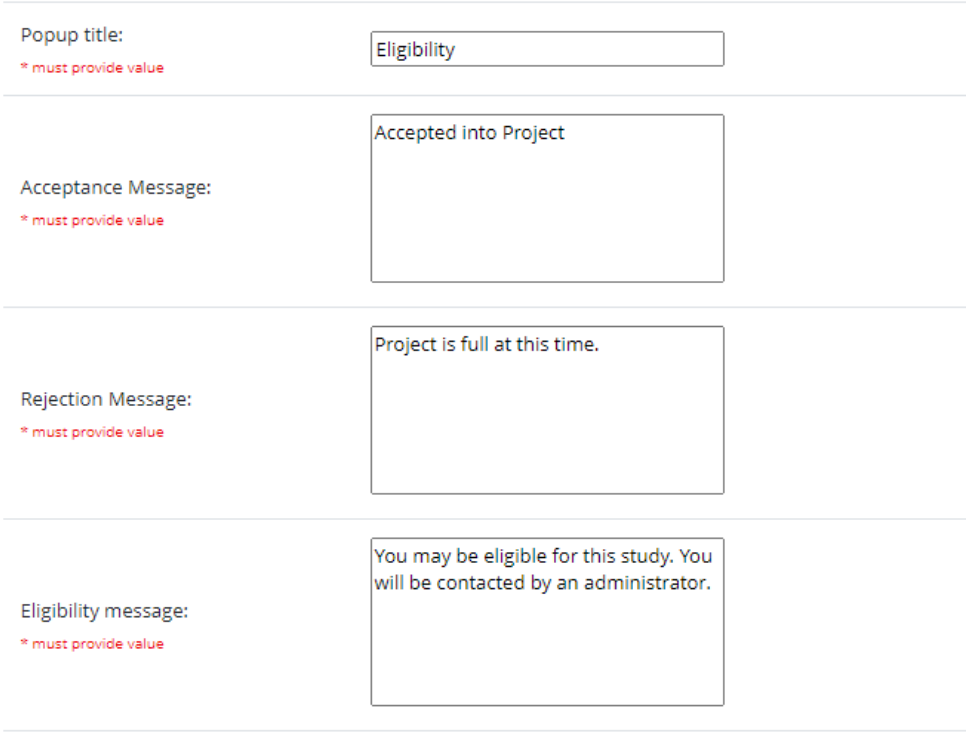
Once you complete the duplicate yes/no it will appear like the corresponding photo above.

QuotaConfig

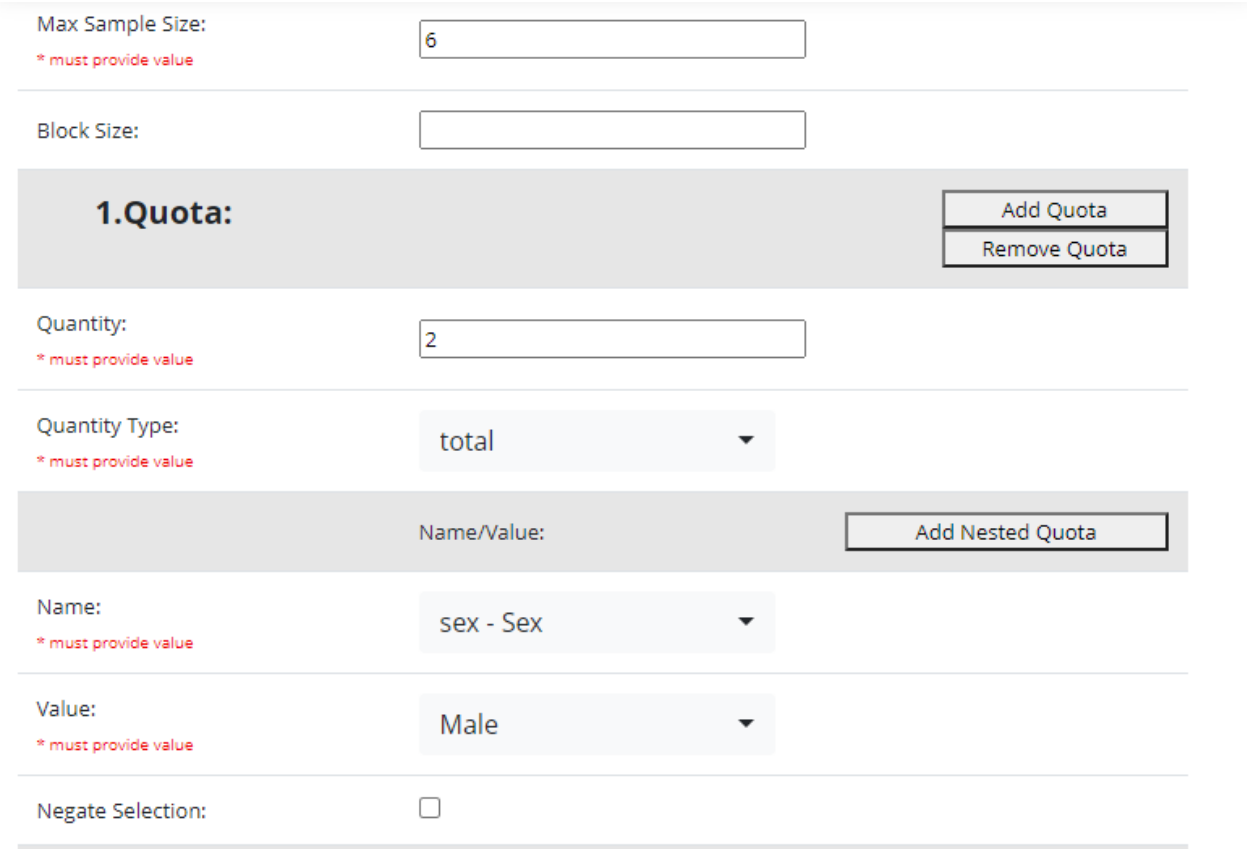
1. Under “Applications” on the left-hand toolbar, click “External Module” and then click the “Configure” button next to the “QuotaConfig - v1.0.0” module. This will pop up the screen below:



2. Select the variable you would like to use for the “Passed Quota Check Indicator.” The standard is for this to be the yes/no (1/0) variable “passed_quota_check” already created in your project from the above steps. When a new participant fills out the questionnaire, this field will automatically be answered by the module to tell you if a participant passed the quota check or not.
3. If your project has a delay between screening and consent/enrollment, select a variable for the “Confirmed Enrollment Indicator.” Again, this should be a yes/no field already in your project. It should be the “confirmed_enrollment” field you created above. This field will be hidden and used on the back end by the module.
4. Customize the title and messages that pop up when someone completes the survey to let them know if they passed the quota or not and if they are eligible for the study or not (screenshot of the default messages below). Acceptance means they were automatically accepted into the project and passed the quota. The rejection message means they were automatically rejected and failed the quota. The Eligibility message means that the record needs review (they were not automatically accepted or rejected, specifically for delayed enrollment.).



5. Finally, add your desired quotas to the project:
6. Start by adding your max sample size for the study in the “Max Sample Size” box.



7. Optionally, you can also add a “Block Size” which will split the quota checks into “blocks” of participants to ensure equal enforcement of your quotas throughout the course of study enrollment. The Block Size is the number of entries there will be in each “block.” *IE if your max sample size is 500, but you want to guarantee equal enrollment over time, set the block size to something smaller, and it will enforce the quota within each block, instead of only over the entire 500 ppt study.*
8. Below this you will add your desired quotas, by clicking the “Add Quota” button on the right.

a. Add the quantity for the quota and the quantity type -- you can select quantity to be a set number of participants or a percentage of the participants that the module will require.
b. *In the example above, we have it set to only allow 2 males into the project. We also have the max sample size set to 6, so it will only allow in four females before it starts to exclude them to ensure room for the 2 required males.*
c. Then you will select the field that you want the quota based on*. Above, you can see we have it based on Sex and limited the number of Male (value field) entries into the project.*

9. You can also add select "Add Nested Quota" to add additional criteria to your main level quota.
   a. In this example, if we want only 2 White Males in our study, we would add the variable "Race" as a nested quota under Sex and select "White" as the value. Nested criteria are "AND" statements.

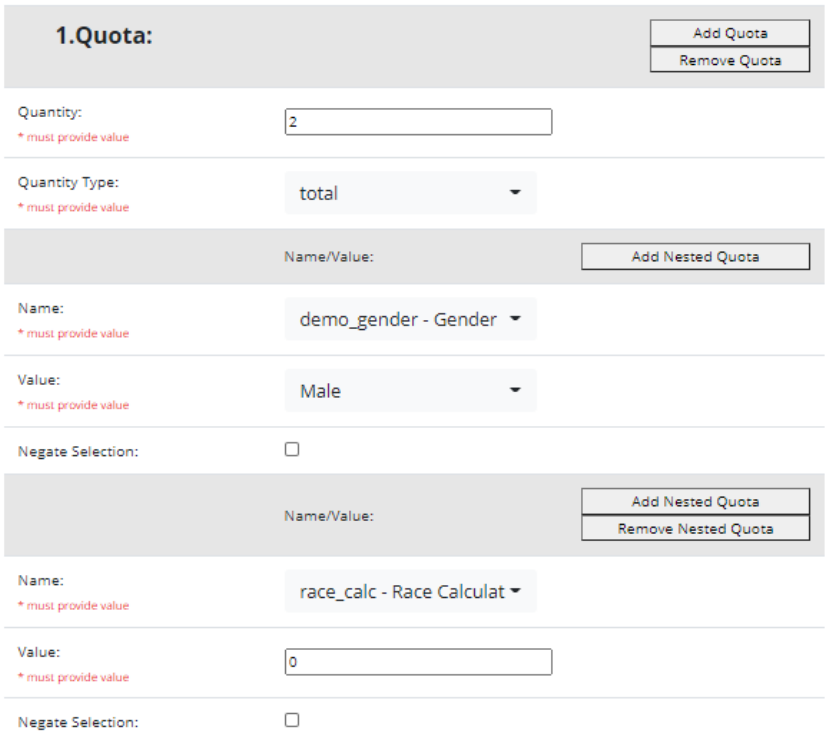


Figure 2 In my example, I am using a coded field grouping races into two categories: white and non-white

10. To add a second quota (an "OR" statement), you would click the "Add Quota" button to the right of 1. Quota above.
11. You can add as many quotas as needed.

D. Testing Your Added Modules:

1. To test your quotas, first, make sure that all the correct fields are added into your quota config module and are all in the demographics form in the data dictionary. IE if you want quotas based on sex, race, age, and location: make sure that all of those are included in the quota config module and are all located in the same form.
2. Also, start out by testing without "confirmed enrollment indicator" selected, so that the passed quota check field will be coded automatically when each record is saved. Once you are comfortable with this process, you can turn it back on to test the final method. You will have to create the records, then verify that they were enrolled, in order for the passed quota field to be coded.
3. Start small: make your max sample size, or block size, and quota numbers small, so you can easily add records that will fill up the quota.
4. Add records to the project imitating the population you are looking for/the people who you think will fill out the screener.
5. Check that it is allowing in the correct number of people in each quota and kicking out people as necessary.

6. Adjust your quota config module and continue testing until you are sure they are working properly. You may have to delete the records you created in order to easily retest.

NOTES:

1. When testing both the modules together, these are some things to expect:
    a. When one module is automatic and the other is not, the eligibility message shows up instead of acceptance/rejection message.
    b. The modules default so that the popup title/acceptance/rejection/eligibility message from the quota config are displayed when both modules are enabled

List of data dictionary fields and their uses:

1. passed_quota_check "Passed Quota Check Indicator" – filled out by module to show whether a record passed the quota check
2. confirmed_enrollment "Confirmed Enrollment Indicator" – filled out by module, hidden, only used on the back end
3. block_number "Block Number (completed via module)" – automatically assigns a record a block number when using blocks
4. participant_enrolled "Participant Enrolled (completed by study staff)" – staff fill this out when the participant is fully enrolled in the study, used for delayed enrollment by module.
5. duplicate_check "Duplicate Check (When "automatic duplicate check" is selected, this field is completed by the module. When "automatic duplicate check" is not selected, this field is completed by study staff." – when using delayed enrollment (automatic duplicate check will be left blank) you fill this out after making your determination.
6. failed_criteria "Failed Criteria (completed via module)" – show which fields were duplicates with other records
7. duplicate_record_ids "Duplicate Record IDs (completed via module)" – show the record ids of the records that had duplicate matches with the current record
8. pot_duplicate_record_ids "Potential Duplicate Record IDs (completed via module)" – show the record ids of the records that had potentially duplicate matches with the current record
9. duplicates_count "Duplicates Count (completed via module)" – shows the number of records that have duplicate matches with the current record.
10. data_entry_time "Data Entry Time (completed via module)" – shows the time the entry was completed