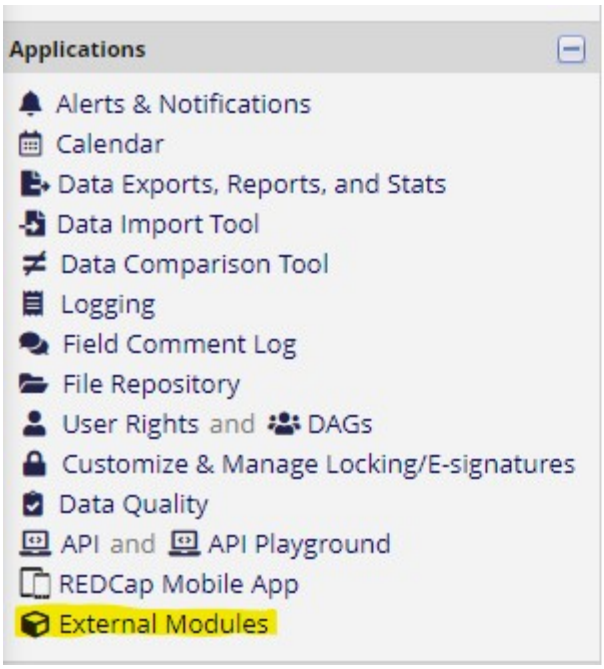
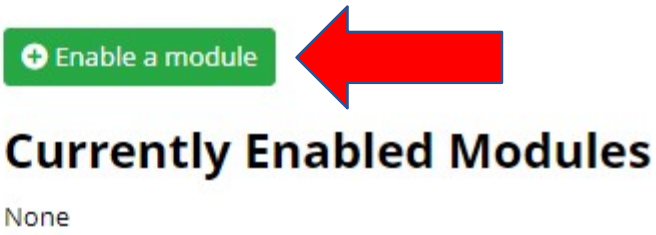
SOPs for REDCap External Module: QuotaConfig

A. Add the QuotaConfig module to your redcap project:

1. Open your REDCap project that you want to use the QuotaConfig module 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."

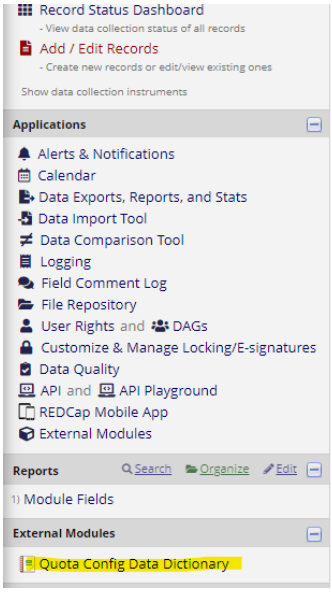


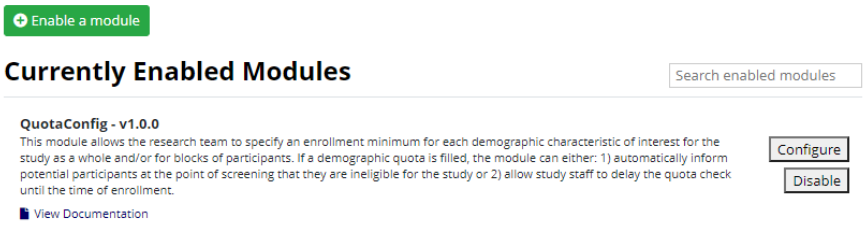


4. Search for QuotaConfig and select the "Enable" button.

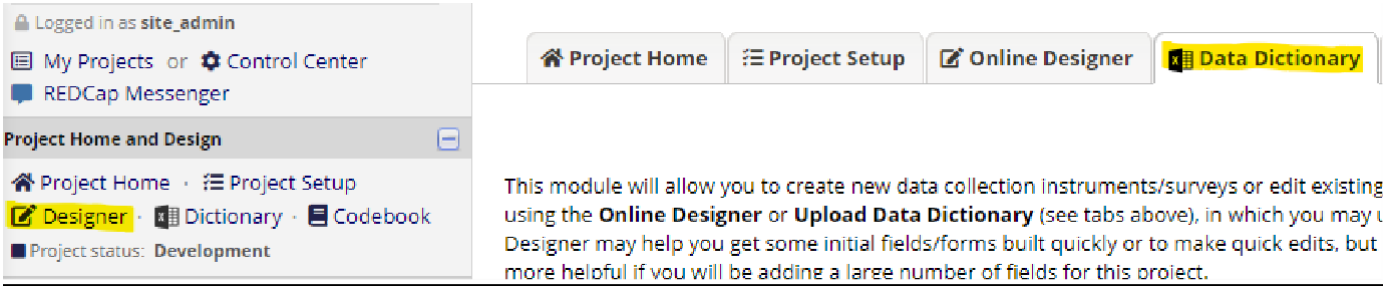
Add the variables to your project that will be used to customize the QuotaConfig module:

5. On the left -hand sidebar in the External Modules section, click "Quota Config Data Dictionary" to download a .csv file of variables you will need to use this module. Save this "Quota_Config_data_dictionary.csv" file to your computer.

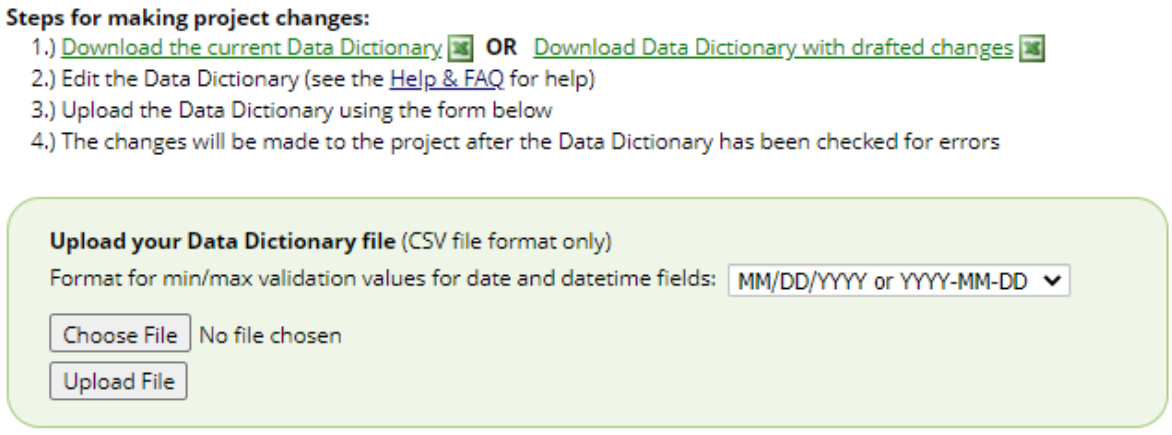




6. In REDCap, underneath the “Project Home and Design” header on the left-hand sidebar, click “Dictionary”



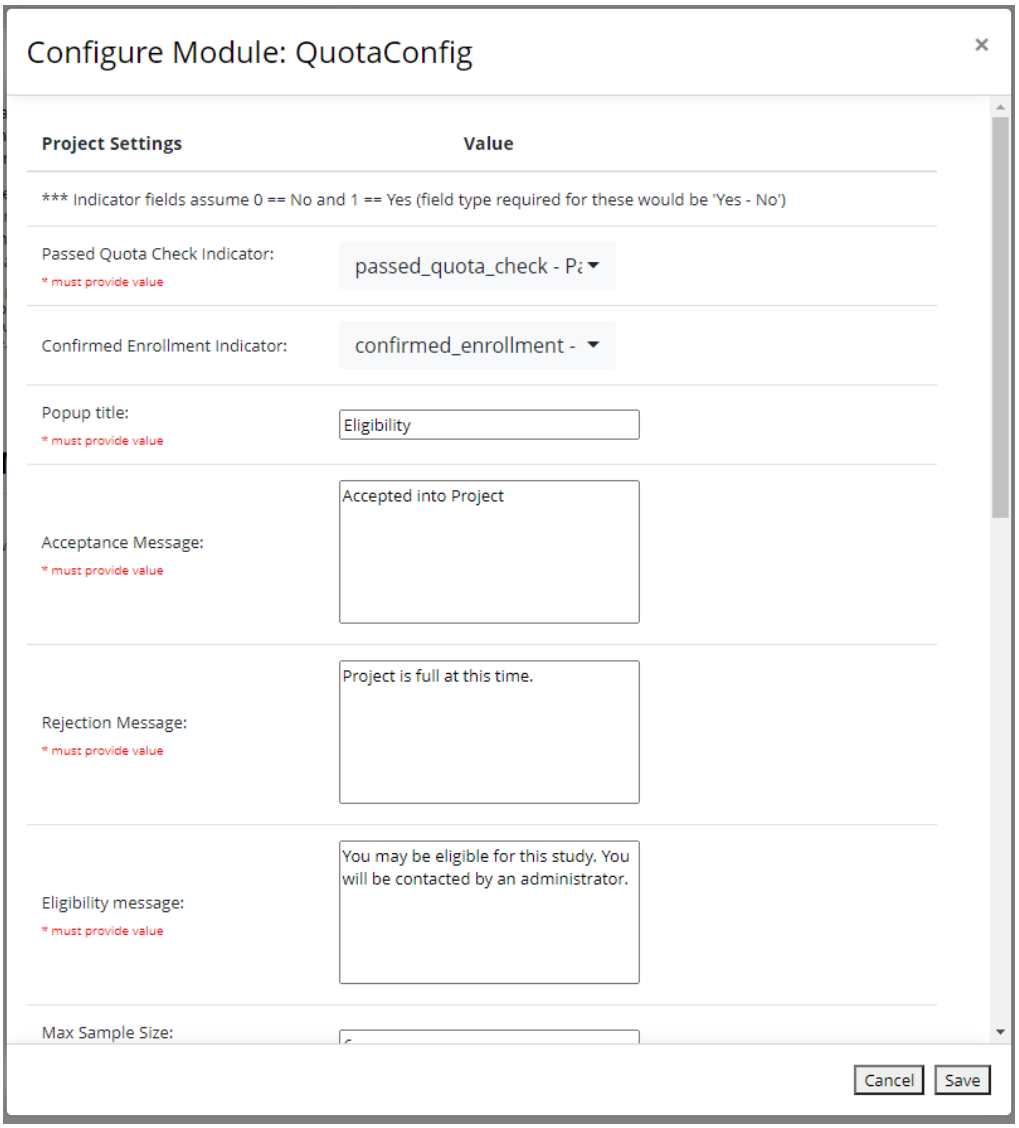
7. If your project has no forms/variables in it yet (you haven’t started building it yet), click “Choose File” button near the bottom of the page (shown below), and then upload the .csv file you just saved to be your project’s Data Dictionary.
8. **OR,** If you already have forms/variables in your project,
    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, excluding the top row.
    iv. If you already have fields, make sure that you are not uploading duplicates, you need to use the field that will actually contain the data, ie. If you already have a record id field (most do) then do not add it again, that goes for all of the included fields. If they already exist, do not add a duplicate field.
    v. Finally, re-upload your Data Dictionary with required QuotaConfig fields added.
    vi. To do this: Under “Upload Your Data Dictionary File” click “Choose File” navigate to the combined data dictionary, click “Upload File”
    vii. Make sure that your “passed_quota_check” field is in the measure with the questions being used for the quotas.
    b. These variables must be in the same measure that your screening questions are being answered in. IE if you or your participants are filling out a screening survey, the field “passed_quota_check” must be in that same measure in redcap.



9. Variables can also be added/modified manually 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.

B. Customize the QuotaConfig module for your REDCap project:

1. In REDCap, underneath the "Applications" header on the left-hand sidebar, click "External Modules."
2. Click the "Configure" button next to the "QuotaConfig - v1.0.0" module. This will pop up the screen below:



C. Customize the module for your project:

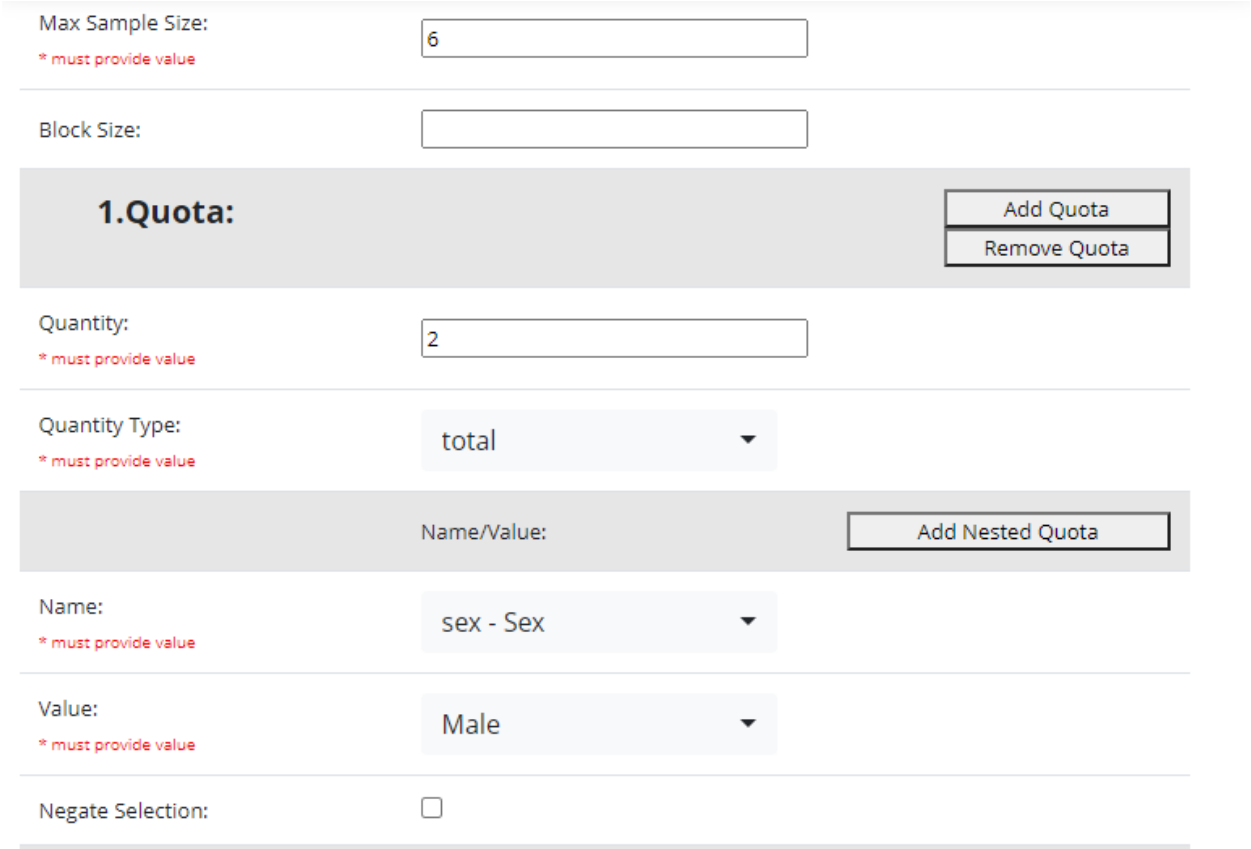
1. Select the variable you would like to use for the "Passed Quota Check Indicator." The standard is for this to be the yes/no (1/0) variable "passed_quota_check" already created in your project from the above steps. When a new participant fills out the questionnaire, this field will automatically be answered by the module to tell you if a participant passed the quota check or not.
2. 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.
3. 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.).

Popup title: * must provide value	Eligibility
Acceptance Message: * must provide value	Accepted into Project
Rejection Message: * must provide value	Project is full at this time.
Eligibility message: * must provide value	You may be eligible for this study. You will be contacted by an administrator.

D. <u>Finally, add your desired quotas to the project:</u>

1. Start by adding your max sample size for the study in the "Max Sample Size" box.



1. 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.*

2. 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.*
3. 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.

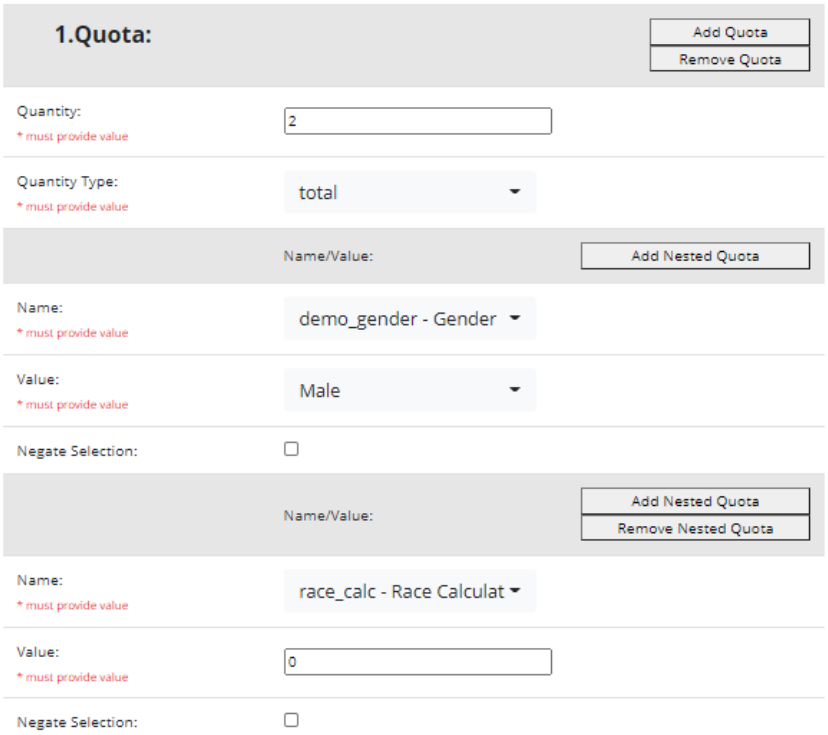


Figure 1 In my example, I am using a calculated field grouping races into two categories: white and non-white

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

E. <u>Testing Your Added Quotas:</u>

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.

F. Notes:

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.