# **Modifying a Project in Production**

\*\*\*Warning: Altering a database that is in Production can cause data loss\*\*\*

When a project is moved to production, the expectation is that the project's data collection plan has been finalized. This means that how data will be collected in the project (i.e. the data collection workflow), and what data will be collected in the project (i.e. forms and/or surveys), has been vetted, tested and validated to meet the requirements of the data collection plan and approved IRB protocol. As such, once a project has started collecting real data, minimizing change is important for both the reliability and dependability of the data, and the reliability and dependability of the how the project is set up to meet the requirements of the data management plan. Nevertheless, we understand that data collection is an iterative process, and sometimes changes need to be made to a project after data collection has already begun.

The PI (and/or their designated project team) is responsible for managing such production changes. You need to ensure that project changes are within the scope of the data collection plan described in approved protocol, and/or consult with the IRB to determine if additional regulatory approval is needed before the changes can be implemented. Changes should first be conceptualize to better understand what needs to be done. You should evaluate the impact of form or survey changes on the data that's already been collected, the data collection workflow and the functionality that facilitates it, and the components of peripheral features the project team relies on for managing data collection. Lastly, you will need to validate that changes were implemented correctly and evaluate the outcome of the changes had the intended effect.

When you are ready to make changes to your project in production, it is important to note, that changes cannot be made in real-time as it is in the development system. In production, many aspects of how a project is set up to collect data are locked down or restricted, and a review process is imposed on modifications to forms and surveys. The REDCap software is designed this way as a guardrail to try to prevent users from making changes to their project that would have a detrimental impact such as creating a data loss or data corruption issue, invalidating functionality critical for data collection, and/or causing components of peripheral features the project team relies on for managing data collection to fail. The development system does NOT have these protections.

Therefore modifications to a project should be done via DRAFT MODE in the production project. When making changes via Draft Mode, there is a built-in safeguard against unintentional data loss (as previously noted above). This can ensure that users don't change fields mid-study (either accidentally or intentionally) that might potentially change the validity of the data or analysis, and will keep track of any changes that are made. For more information regarding common project changes and their potential impact, see the Common Project Changes section & Table 1.

While testing changes in the development system prior to them taking effect in production is not required, it is strongly recommended. Testing your changes is often the most effective way to determine the impact of your changes and to validate that your changes will have their intended effect. It is the only way to determine if it looks and behaves as intended, and allows you to review how the data collected would export, and/or see how components of peripheral functionality, like reports or data quality rules operate. Testing first is an especially good idea for changes that involve using advanced features, such as piping, action tags, field embedding, smart variables, or special functions, as well as using REDCap syntax to create compound logic statements for piping, branching logic or calculated fields. Even when the changes do not involve how the production project is set up to collect data, making changes to components of peripheral functionality designed to help manage data collection, such as creating new reports or data quality rules, can undermine the project team's efforts to use the test project to assess the impact of their changes. Thus, it is alway best practice that any and all production changes be tested in the development system before they are submitted in the production system (see Step 5, on page 12)

Testing data should include different scenarios. Some things to look for when testing for all possible responses that affect the logic:

- Branching logic Ensure your branching logic is functioning properly.
- Calculated fields Ensure your calculated fields are computing correctly
- Surveys and ASIs Ensure surveys can be accessed and distributed correctly, and ASIs are configured properly. These may have to be manually re-setup to be tested.
- Data Exports Export your test data to ensure you are comfortable with how it is formatted before you begin collecting real data

Third Party Input – Get a third party to enter data as well. Someone who was not involved in building the database will find errors that may otherwise be missed

\*\* Please Note: Testing in DEV will NOT show the potential critical issues involving changes field types of choice labels thus it is imperative that you throughly review this guide!

After changes are made a "summary of changes" page will be available, displaying a preview of all the fields that are added, removed, and/or modified. Any potentially critical issues will be flagged, drawing attention to changes that could result in data corruption or deletion. It is strongly recommended that you review this summary prior to submission as it is the responsibility of the PI (and/or designated project team) to verify the impact of such changes. Changes will NOT be tested by the REDCap Administrator.

Once you are ready to submit your changes for approval, click 'Submit Changes for Review'. The REDCap Administrator will automatically get notified. If changes are not considered 'higher-risk', then REDCap Administrator will process the request as is, and you will receive an email confirmation when those changes have taken effect.

If any critical issues are flagged, you will receive an email from the Administrator to confirm that you want to commit to the changes. Again, these critical issues can be reviewed in the "summary of changes". You can confirm these changes as is, or request to keep the drafted changes made thus far, but place it back in Draft Mode for users to make more changes, or request to erase all the drafted changes made, and revert back to before Draft Mode was enabled.

Upon approval, data dictionary snapshots are automatically created with each revision. They are archived, tracked, and can be compared with other revisions in a detailed view via the 'Project Revision History' tab. It is **strongly recommended** that each data dictionary snapshots also be saved externally. These snapshots can be useful to allow you to revert all your fields back to a specific point in time, if desired, by taking the snapshot from the Revision History page and uploading it on the Data Dictionary Upload page. Additionally, whenever data dictionaries are uploaded into the project (even via API metadata import), a snapshot of the current data dictionary is taken before committing the new data dictionary. This allows you to remain worry-free that your fields/forms will be preserved automatically, even in the case of an accident occurring (e.g., wrong data dictionary was uploaded). The production's data dictionary can also be uploaded to the development project so they can in sync with one another.

#### **Common Project Changes**

### Adding New Survey

It is the responsibility of the PI (or their designated project team) to evaluate the impact of adding new surveys on: 1) the data that's already been collected, 2) the data collection workflow, including how the project is set up to send out surveys and collect responses, 3) the existing functionality that was tested and vetted during the development phase that impacts or is related to sending out surveys and collecting responses, and 4) the components of peripheral features the project team relies on for managing sending out surveys and collecting responses. You need to determine if how your participants will access the new survey involve or require any of the following:

- Adding a new invitation
- Adding a new connection that has conditions
- · Both existing participants and new participants to complete it

If any of above listed items are true, make sure to first create test records in the test project, completing any existing surveys that may impact how the new survey will be distributed. Expect extra effort if you are adding a new distribution method that was never set up and tested when the project was in development.

## **Changing Events**

It is the responsibility of the PI (or their designated project team) to: 1) identify any potential barriers to making the event changes, 2) uncover the potential of the event changes to have a negative impact on data that's already been collected or the project's existing setup, and 3) make a pre-determination about the kind of help that will be needed to both test the event changes in a test copy of the project and then implement the changes in the production project. Typically, the biggest risks in making changes to events involve the following:

- Removing an event or removing a form from an event, which will orphan off data that's already been collected and create a data loss
- Renaming an event or editing an existing form to event assignment in order to move a form from one
  event to another event, which will cause any dependent logic statements or syntactical references that
  invoke the event name in calculated fields, piping, branching logic, report filters, automated survey
  invitations, survey queue connections, etc., to fail

For these types for changes we recommend the following alternate solutions:

- Instead of removing an event, we recommend using the Form Display Logic tool to create conditional logic to disable data entry access to the forms assigned to the event you want to remove
- Instead of editing an existing form to event assignment in order to move a form from one event to another event, use the Form Display Logic tool to create conditional logic to disable data entry access to the form at the event you want to move the form from
- Instead of renaming an event, create a Custom Event Label to add a short helpful note or alternate name that will be meaningful to other users on the project
- For projects using surveys, making any changes to events heightens the risk of having a negative impact on the project and/or creating complexity that would require additional help because:
  - There are likely dependencies on features that are related to sending out surveys and collecting responses, such as Automated Survey Invitations, Survey Settings or the Survey Queue, all of which have their own learning curves
  - There is often a different effect of the changes on existing participants versus new participants that has to be accounted for

# Adding New or Modifying Automated Survey Invitations, the Survey Queue, or Survey Settings

REDCap allows any user who has permissions enabled for both Project Design and Setup user rights and Survey Distribution user rights to add new configurations or make modifications to existing configurations related to Automated Survey Invitations (ASIs), the Survey Queue or a form's existing Survey Settings without oversight. This means that these features are **NOT** locked down in such a way and users are not forced to enter Draft mode to make changes and submit them for approval. As such, the only guardrail built into the system to try to prevent users from making the kinds of changes related to ASIs, the Queue, or Survey Settings, which risk having a negative impact on the project, is secondhand, via the careful application of User Rights/accessibility privileges.

It is the responsibility of the responsibility of the PI (or their designated project team) to evaluate the impact of their changes related to ASIs, the Survey Queue or Survey Settings on: 1) the data that's already been collected, 2) the data collection workflow, including how the project is set up to send out surveys and collect responses, 3) the existing functionality that was tested and vetted during the development phase that impacts or is related to sending out surveys and collecting responses, and 4) the components of peripheral features the project team relies on for managing sending out surveys and collecting responses. Testing changes related to Automated Survey Invitations, the Queue or Survey Settings in the development project is strongly recommended. Some potential issues that may arise include:

- A change that causes a feature to fail in such a way that participants will not be able to complete their surveys such as condition/logic error
- Modifications of queue logic so a batch of surveys are no longer connected to each other, and after a participant completes the first survey in the batch, they cannot access any of the other surveys.
- A user makes a change to a feature that creates a regulatory issue that has to be reported, such as:
  - o A new ASI is added that sends survey invitations to participants who did not consent.
  - Survey Settings are changed to enable Save and Return without a code on a survey that captures PHI, allowing anyone with access to the survey link to return to the survey and view all the information the participant already entered.

### Enabling/Disabling Main Project Settings or Optional Modules

Most of the features that are foundational to how a project is set up to collect and store data, and that are grouped together in the Project Setup tab, are locked down in production. This includes:

- Main Project Settings
- Using longitudinal data collection with defined events
- Using surveys
- Optional Modules
- Repeating forms or events
- Auto-numbering for records
- Scheduling module
- Randomization module
- Twilio, MyCap

The ramifications of disabling or deactivating a main setting or optional module are typically far reaching and/ or profound, and as a general rule is **NOT recommended**. However, it is the responsibility of the PI (or their designated project team) to evaluate the impact of their changes that are related to deleting fields, forms, events or disabling a main project setting or optional module on: 1) the data that's already been collected, 2) the data collection workflow and the functionality that facilitates it, and 3) the components of peripheral features the project team relies on for managing data collection.

Below are some additional recommended guidelines and steps to follow when making changes to a production project:

- Do **NOT** delete fields. If there is a question you do not want future users to answer, we recommend using the "@HIDDEN" action tag in the "Action Tags/Field Annotation" section instead. This will hide the question from survey takers or data entry personnel but will not delete the question from the project.
- Do NOT change existing variable names (e.g. demo\_date, labs\_calcium, Survey\_firstname). Changing the variable name will delete all the data that was previousl collected for that variable. To restore data that has been lost in this way, revert to the previous/original variable name(s).
- Do NOT change existing form names (e.g. Demographics, Labs, Survey) via a data dictionary upload or form completeness data will be lost. Form names may be changed within the Online Designer without data loss
- Do NOT change the coding of answer choices such as:
  - Reverse-coding a question that was not previously reverse-coded.
  - O Adding additional options in the middle of a categorical variable, rather than at the end.
- Do **NOT** change field types to any other type of field will result in a loss of your existing data in those field
- Do **NOT** delete answer choices. If you would like to remove an answer, we recommend using the "@HIDECHOICE" action tag in the "Action Tags/Field Annotation" section instead. To use this action tag, enter "@HIDECHOICE='#'" where '#' is the number of the option you would like to hide. For instance, if you are requesting people select a day to schedule a study session, and the options are:
  - 1,Monday
  - 2,Tuesday
  - 3, Wednesday

but Monday is full, you would enter "@HIDECHOICE='1" in the "Action Tags/Field Annotation" section. This would hide "Monday" as an option for anyone else who accessed the survey.

Do NOT modify the codes (numbers before the answer choices) and/or answer choices for existing
Multiple Choice – Drop-down List (Only One Answer), Multiple Choice – Radio Buttons (Only One Answer),
or Checkboxes (Check All That Apply) fields or existing data will be lost and/or disassociated.

Example: (old values) (new/changed values)

1, Married
2, Single
3, Divorce
4, Separated
3, Separated
4, Divorce

Because the new value of "Divorced" is now '4,' any previous subject data that was entered as "4, Separated" will now be given the value of "4, Divorced" because REDCap only looks at the codes (1, 2, 3, 4, etc.) and not the answers after the codes.

Example: (changing from a Yes – No field type to a Multiple Choice – Drop-down list (Only One Answer) or Multiple Choice – Radio Buttons (Only One Answer) field type)

(old values:) (new/changed values)
0, No 2, No
1, Yes 77, NA

Because the new value of "No" is now '2,' any previous "0, No" answers will now be disassociated because "0, No" no longer exists (see example above). To retain the data for the subject's with "No" as the answer to this question/variable, one has to recode "No" as '0.' Or, for each subject that had "No" as the answer, one has to re-enter the data for each of these subjects. Those with "Yes" answers do not need to be re-entered.

It is only acceptable to **add choices** (answers) to Multiple Choice – Drop-down List (Only One Answer), Multiple Choice – Radio Buttons (Only One Answer), or Checkboxes (Check All That Apply) field

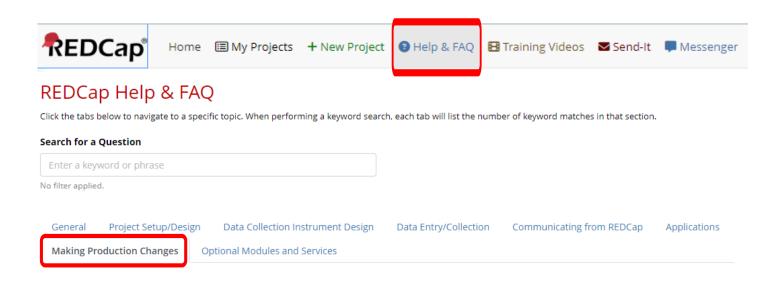
- New fields held in draft mode CANNOT be embedded elsewhere on the form or survey to which the new
  fields are being. To embed new fields, first add new fields to a form or survey and submit the changes,
  and then, go back into Draft Mode and apply field embedding. Do NOT drag and drop a new instrument
  into first position record\_id or change or move this variable name doing so will delete all of the data in
  your project.
- The record\_id field should always be the first field of your first instrument in the project, because the record\_id field is what REDCap uses to link together all the data in a particular record. If you drag and drop a new instrument into the first position in the list, it can move this all-important record\_id field and delete all your data.
  - When you create a new project, the record\_id is the first field in the default "Form 1" that comes with every new project. If you wish, you can rename the record\_id variable name (to something such as study\_id or participant\_id) as soon as you create the project. But once you start entering data, changing the variable name of the record\_id field will delete all of the data in your project, because you've essentially deleted the key that allows REDCap to understand where the data belongs.

Additional types of changes and its associated data impact are detailed in Table 1.

Table 1.	Change	Change	
Metadata	Type	Data Impact	
Variable / Field Name	Add new	No data impact. New field will be added to all records.	
Variable / Field Name	Delete	Possible data loss. Deletes the field and ALL the data entered for that field	
Variable / Field Name	Rename	<b>Possible data loss.</b> REDCap views this action as the equivalent to deleting a variable and adding a new variable. Data is deleted	
Form Name Note: "back end" Form name (data dictionary ex:"baseline_data") does not appear on screen "front end" form label displays on screen (ex: "Baseline Data")	Add new form	No data impact. New form/fields will be added to all records.	
Form Name	Rename form	Possible data loss. The data dictionary renames the form name. All form status values (unverified, complete) for ALL records will be reset to "Incomplete". The Online Form Editor will NOT change the form name and only renames the form label, preserving the form status for all records.	
Field Units	Add, Modify, Delete	Changes field unit label. Label is not displayed on form.	
Section Header	Add, Modify, Delete	Not directly associated to any data collection variable. Descriptive text.	
Field Type	Modify	Possible data loss. Depending on the change, data can be deleted. Examples of changes that can be made without data loss: Radio buttons to drop downs; Drop downs to Radio buttons  Examples of changes that can be made with data loss: Radio buttons to check boxes; Text box to calculated field	
Field Label	Modify	Possible label mismatch. Change to question caption may change the meaning of data previously entered (ex: changing "happy" to "unhappy"). Examples of changes that do not require confirmation: Spelling corrections, Format changes	

Metadata	Change Type	Data Impact
Choices (codes)	Add	No data impact. New choice will be added to all records.
Choices (codes)	Delete	Possible data loss. Deletes the choice and ALL data entered as that choice
Choices (codes)	Recode	Possible label mismatch. Codes are not automatically remapped to new codes. Data entered remains the same in the database. Relabeling codes may change the meaning of data entered.
Calculations	Modify, Delete	Forms with saved calculated field values will <b>NOT</b> automatically recalculate when changes are committed. Values should be derived and confirmed in analysis. And all forms with values should be resaved to update stored values.
Field Note	Add, Modify, Delete	No direct data impact. Descriptive text.
Text Validation Type	Add, Modify	Possible data loss. Data entered as free text or other type of validation text, may no longer be valid
Text Validation Type	Delete	Field becomes open text field.
Text Validation Min/Max	Add, Modify, Delete	No data impact since out of range data can still be saved.
Identifier? (mark as)	Add, Delete	No direct data impact.
Branching Logic	Add, Modify	Possible data loss. Fields that will be now be hidden due to updated logic that already contains data will prompt to erase data.
Branching Logic	Delete	No direct data impact (may impact missing data analysis). Fields will always be visible
Required Field (mark as)	Add, Delete	No data impact since data can still be saved without completion of required fields.

For further assistance, please make sure to check the **REDCap Help & FAQ** section located at the top of the Main REDCap page:



\*\* If changes need to be made to your eConsent, please review the eConsent Versioning Guide for further guidance.

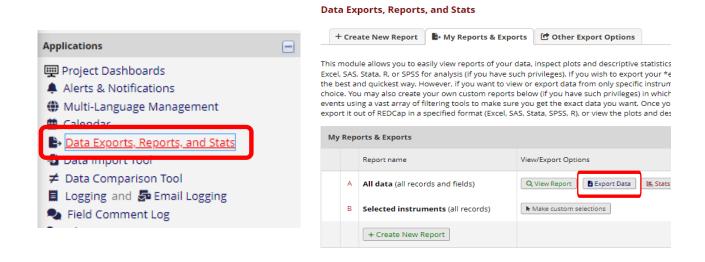
Additional free training materials and resources:

- REDCap Training Videos
- UCH REDCap webpage

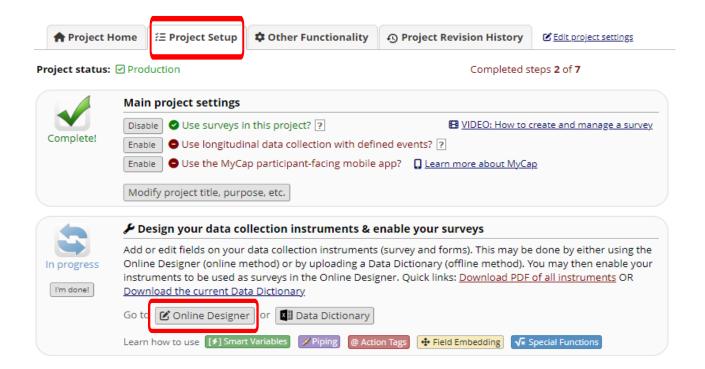
# Steps for Making Changes to a Project in Production

1. Make a copy of the project's existing data. This can done via Data Exports, Reports, and Stats. File will automatically be save to your download folder - save to an appropriate location, do not change file type.

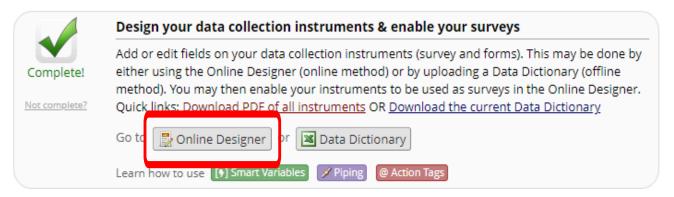
Click **HERE** for tutorial on how to use Data Exports, Reports, and Stats .



2. Go to the Project Setup page and Download the Current Data Dictionary. File will automatically be save to your download folder - save to an appropriate location.



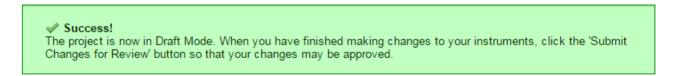
# 3. Click on 'Online Designer'



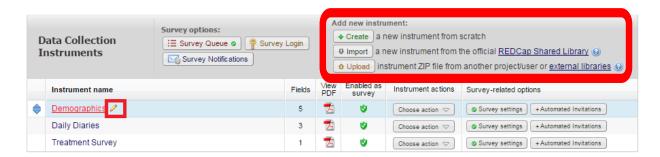
The system will navigate the user to the Online Designer tab. Click on 'Enter Draft Mode'



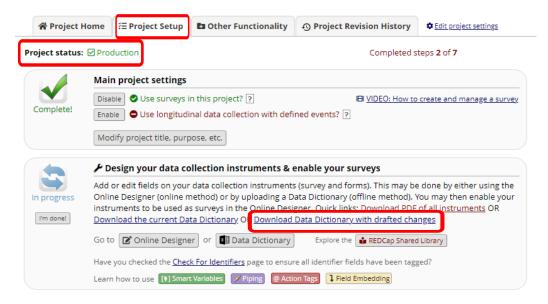
The system will provide a green Success notification that you have entered the Draft Mode.



4. Make changes to the Forms/Instruments by hovering over the Form/Instrument and clicking on the pencil icon. Or if you need to add new instrument/s, select the appropriate option under 'Add New Instrument'

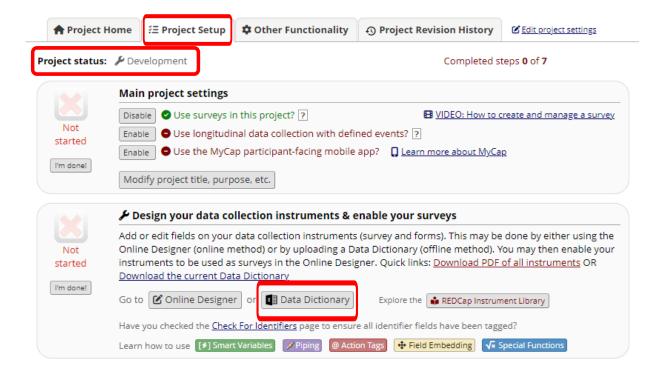


5. **If** you decide to test the changes prior to them taking effect, you need to go to the **Project Setup** page and **Download Data Dictionary with drafted changes**. File will automatically be save to your download folder - save to an appropriate location, do not change file type.

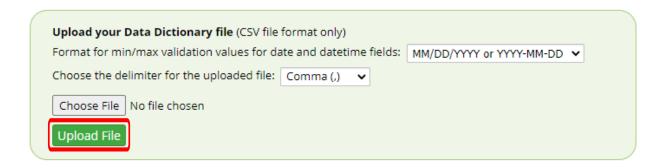


Then, you will need to upload the Data Dictionary with drafted changes to the development project.

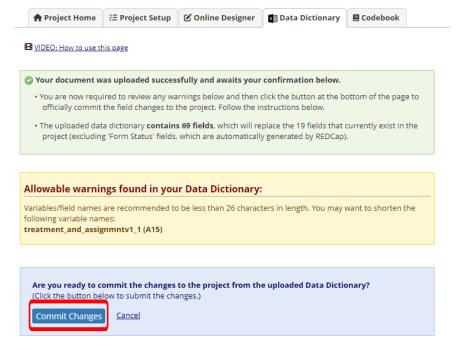
Go to the **DEVELOPMENT** project. Go to the Project Setup page and click on Data Dictionary.



In the **DEVELOPMENT** project: Upload your Data Dictionary file: first choose the file, then select upload.



A brief summary and any applicable warnings will be displayed for your review. Once you are ready to commit the changes to the development project, click 'Commit Changes' or you can cancel and the project will revert back unchanged. \*\* Please Note: Testing in DEV will NOT show the potential critical issues involving changes field types of choice labels thus it is imperative that you throughly review this guide!



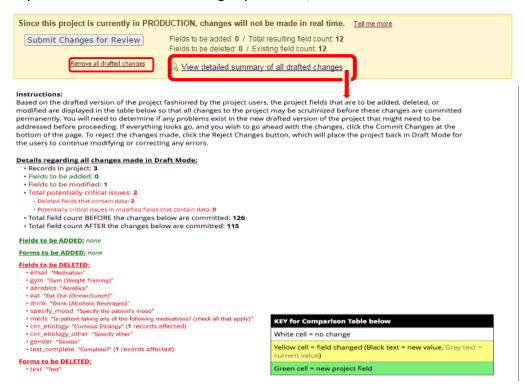
The system will provide a green Success notification indicating that the upload has been committed.



You are now ready to test the changes in the development system. As a reminder NO real data can be entered.

6. Once all of the changes have been completed and you are satisfied with your production project, go back to the Online Designer page in your PRODUCTION project. You can view all of your changes before you submit them via 'View detailed summary of all drafted changes'

If you want to remove the changes you made, click on 'Remove all drafted changes'



7. If you are satisfied with your changes, click on 'Submit Changes for Review' for approval. This will automatically email the UCH REDCap Administrator and notify them that project changes have been requested.



The REDCap Team will process your request. If no potentially critical issues are found, your changes will be approved. If potentially critical issues are flagged, then you will be notified to review and confirm the requested changes. You will be notified by email when your changes have been committed to the project.

8. After your changes have taken effect, you should download a new copy of the Data Dictionary and upload it to your project in development, so that your development project is a mirror copy of your production project (if it not so already and/or if you chose not to test your changes). You should also save the file externally.

<sup>\*</sup>If a user creates a new instrument while a project is in production, all users in the project will have 'No Access' rights to the new instrument(s) by default.