# REACT Data Annotations

Version 2.0 (01/07/2020)

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Edited by: Keith Kennedy

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Data extract is provided as an Excel spreadsheet with the data for each questionnaire on a separate worksheet.

Useful items:

* StudyStage:
  + 3 == Baseline
  + 6 == Followup1
  + 7 == Followup2
* All baseline questionnaires have to be completed before randomisation can occur
* On Baseline, FU1 and FU2 the first two questionnaires (About you and GHQ) are **not** dependent on another questionnaire being completed, all other questionnaires require completion of the GHQ.
* Data Flow:

| **Point** | **Description** |
| --- | --- |
|  | Is the person being cared **for** in a REACT area |
|  | Patient information sheets made available |
|  | Is the participant eligible for the study.  **Note:** This is the first point that we start being able to link data to a participant |
|  | Participant consent, E-Mail address and name |
|  | Confirmation that the provided E-Mail address is correct |
|  | Participant postal address and telephone contact details |
|  | Confirmation that Contact number is correct |
|  | Complete all nine questionnaires |
| Image result for randomise | Participant prompted to randomise – stage == randomisation (becomes randomised when randomisation has occurred)  Once randomised the subjects account in the intervention site is created. |
|  | 12 week follow-up |
|  | 24 week follow-up |

* Participants may withdraw at any time by completing the withdrawal form or by contacting the study team.

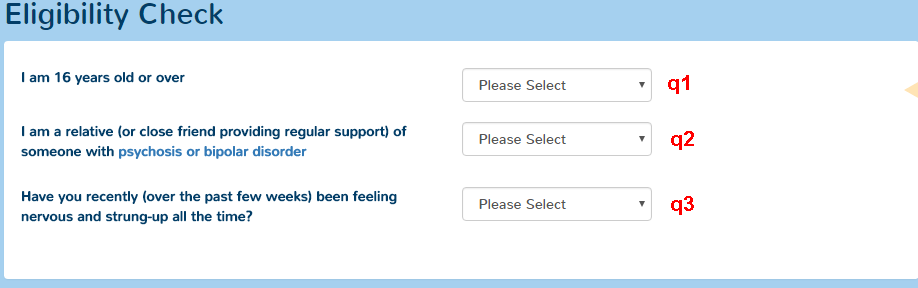
1. **Subject Map**

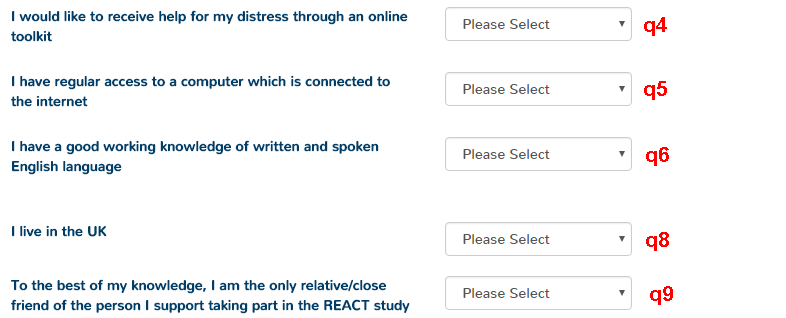
* Subject details and status within the study

| **Column** | **Description** |
| --- | --- |
| ConsentId | Number used to link data for subjects |
| StudyStage | Where in the trial is the subject |
| RandomisationNumber | Randomisation Number – allocated at completion of baseline |
| RandomisationArm | Should be blank for stats extracts |
| ToolkitLastAccessedinLastWeek | Flag to let us know if they have accessed the Toolkit in the last week |
| BaseLineCompleted | Which questionnaires have they completed:  None = 0,  AboutYourCircumstances = 1,  GHQ = 2,  RelativesWellBeingAndSupport = 4,  ED5D5L = 8,  CSRI = 16,  BreifIPQ = 32,  BriefCope = 64,  AboutYourRole = 128,  AboutYou = 256  A complete set will have the number 511 |
| FU1Completed | As baseline, but for Follow-up 1 |
| FU2Completed | As baseline, but for Follow-up 2 |
| LastAccess | Last access timestamp (dd/mm/yyyyy HH:mm:ss) |
| BaseLineComplete | Date baseline completed (dd/mm/yyyyy HH:mm:ss) |
| Randomised | Date Randomised (dd/mm/yyyyy HH:mm:ss) |
| FU1Complete | Date FU1 completed (dd/mm/yyyyy HH:mm:ss) |
| FU2Complete | Date FU2 Completed (dd/mm/yyyyy HH:mm:ss) |
| NumFU1Emails | Number of FU1 E-Mails sent |
| NumFU2Emails | Number of FU2 E-Mails sent |
| FU24Rando | 24 week randomisation Number |
| FU24Allocation | 24 week allocation (should be blank for stats) |

1. **Eligibility**

* Is the subject eligible for the study?
* ScreenNum is generated by the system
* All questions to be answered before the form will submit
* Additional questions appear if q3 is answered as “Rather more than usual” or “Much more than usual”
* Q7 was removed prior to the start of the study
* Links to subjects going forwards are in the study database, they are not displayed to stats.





1. **Exclusions**

* List of when subjects have been excluded based on answers to questions on forms that lead to the “sorry” react is not for you …
* This includes q3 on the eligibility check, it also includes data from the eligibility check where the subject was not eligible, but the application allowed the user to submit data

|  |  |
| --- | --- |
| **Column** | **Description** |
| eligibilityId | Generated by system, can link to the eligibility table, but only if the eligibility form has been completed |
| FailureDate | Time point at which issue was recorded (dd/mm/yyyy HH:MM:ss) |
| FailurePoint | Point at which failure occurred |

1. **RedFlags**

* Automated E-Mails that are sent by the system to a participant if they answer specific questions:

|  |  |  |
| --- | --- | --- |
| **Form** | **Question** | **Trigger Values** |
| GHQ | Q24 | "Much more than usual" |
| GHQ | Q25 | "Definitely has" |
| GHQ | Q27 | "Much more than usual" |
| GHQ | Q28 | "Definitely has" |
| Relatives Well Being | "wellBeing\_qa29" | "A lot" |
| Relatives Well Being | "wellBeing\_qa30" | "A lot" |

* Only one E-Mail is sent per form, irrespective of the number of triggers that fire.

|  |  |
| --- | --- |
| **Column** | **Description** |
| ConsentId | Use to link to the same column in the subject map |
| StudyStage | Stage of the study at which the data were collected (3/6/7) |
| FlaggedItems | Questions on which the trigger fired |
| AddedOn | Timepoint data stored (dd/mm/yyyy HH:MM:ss) |

1. **Risk Status**

* What risks have been identified and recorded by the react supporters
* The database records the subject, this is not reported to stats.

| **Column** | **Description** |
| --- | --- |
| newID | Consent identifier |
| Risk type | 1 = SupporterRisks  2 = TmRisks |
| IdentifiedFrom | Medium risk was identified from (e.g. phone) |
| IdentifiedOn | Timepoint data stored (dd/mm/yyyy HH:MM:ss) |
| Category | Recorded Category |
| ActionTaken | Action taken |
| ActionTakenOther | If action taken is “other” then this field contains the free text description |

1. **Withdrawals**

* List of people who have withdrawn from the study
* Subjects withdrawn by the administrator (due to an E-Mail being sent or a phone call will include “(Administrator Action)”

| **Column** | **Description** |
| --- | --- |
| ConsentId | Use to link to the same column in the subject map |
| Opt | Level of Withdrawal:  1 := “I don’t want to complete the measures at this followup but I am happy to be contacted for the 24 week followup”  2 := “I don’t want to complete the questionnaires at this followup and DO NOT want to be contacted for the 24 week followup” |
| Reason | Reason for withdrawal |
| DateAdded | Timepoint data stored (dd/mm/yyyy HH:MM:ss) |

1. **About You**

* Form will not save if all questions that are visible are not completed.
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Actual text for answer saved in database, with the exception of Gender (Q2) which has the following map:

Value="", Text="Please Select"

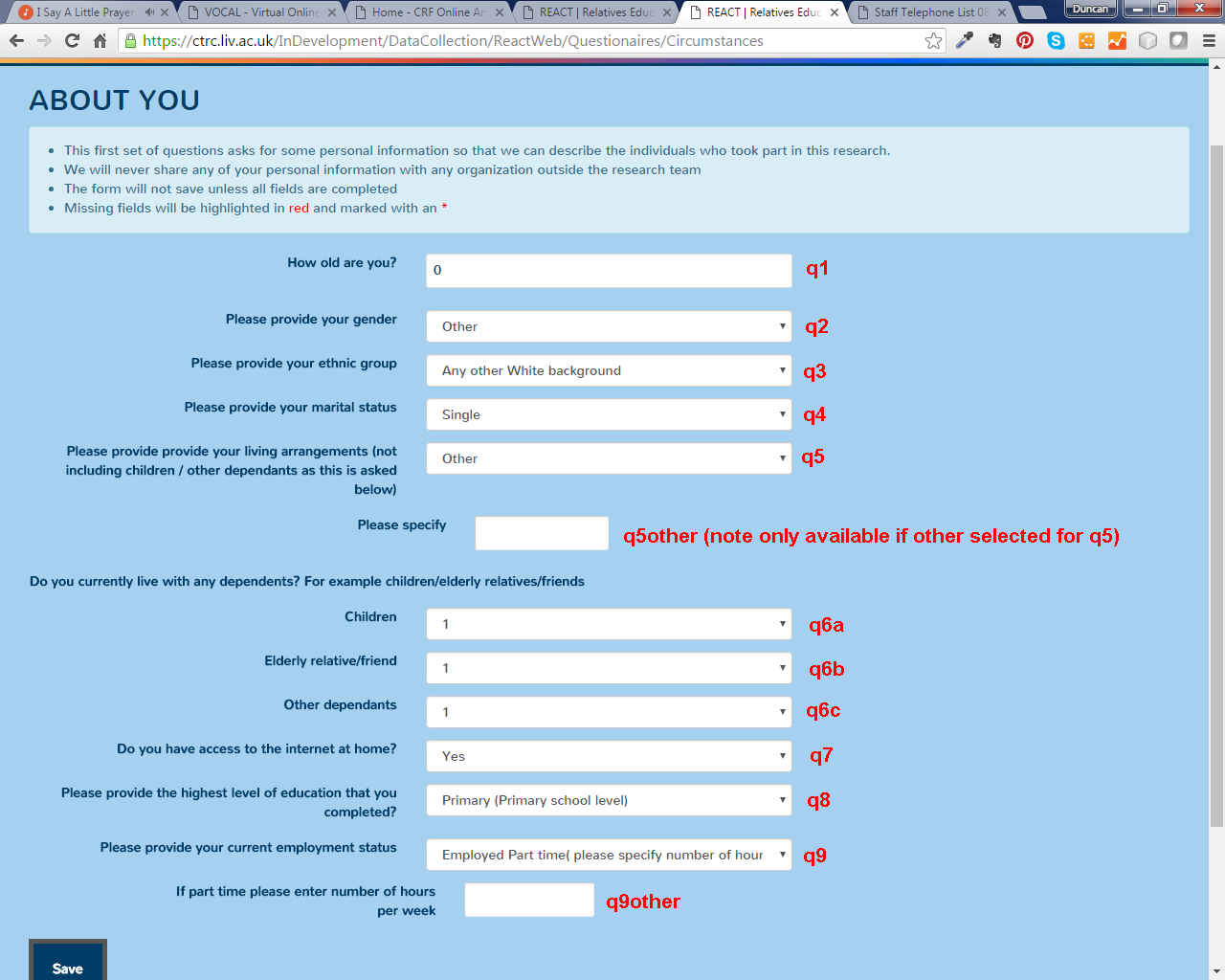
Value="1", Text="Female"

Value="2", Text="Male"

Value="3", Text="Other"

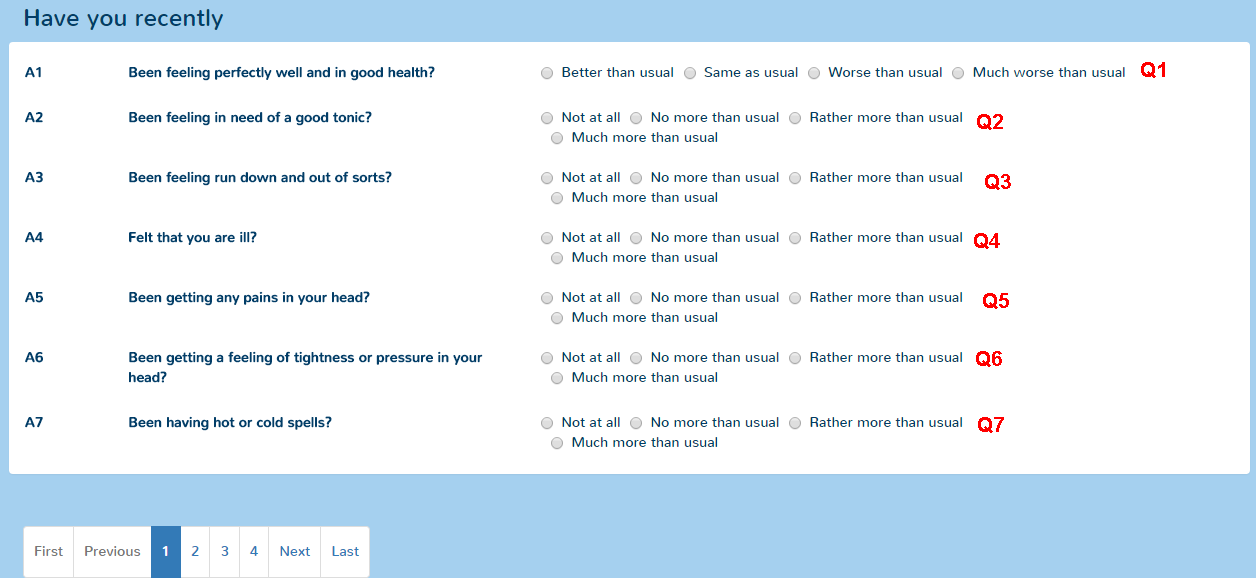
Value="4", Text="Rather Not Say"

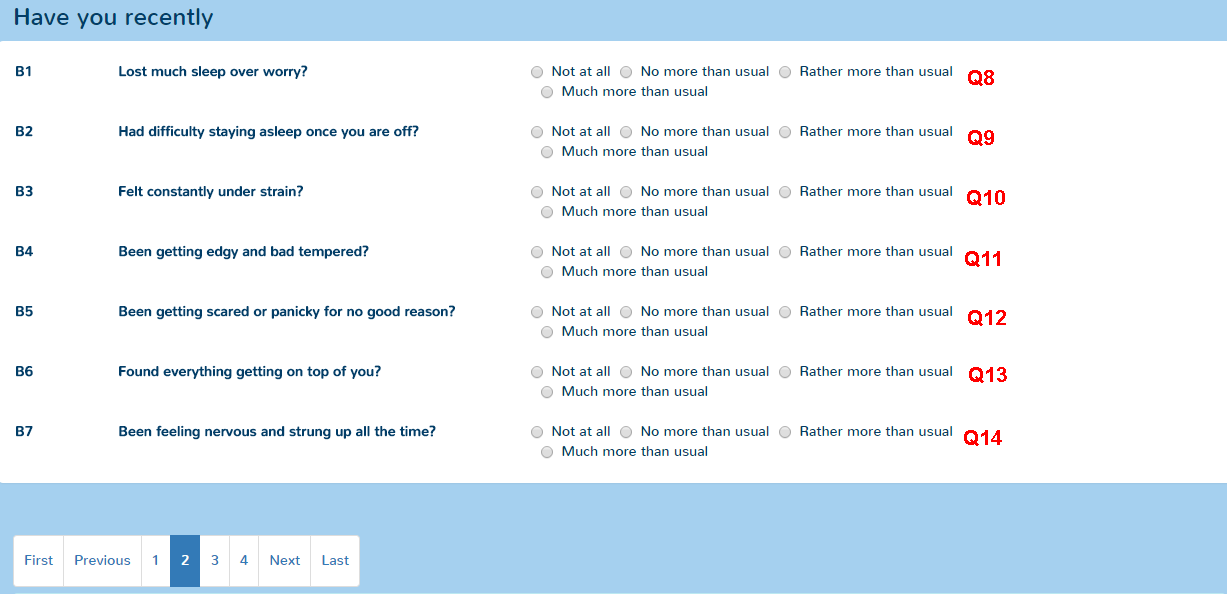
* The options for Q

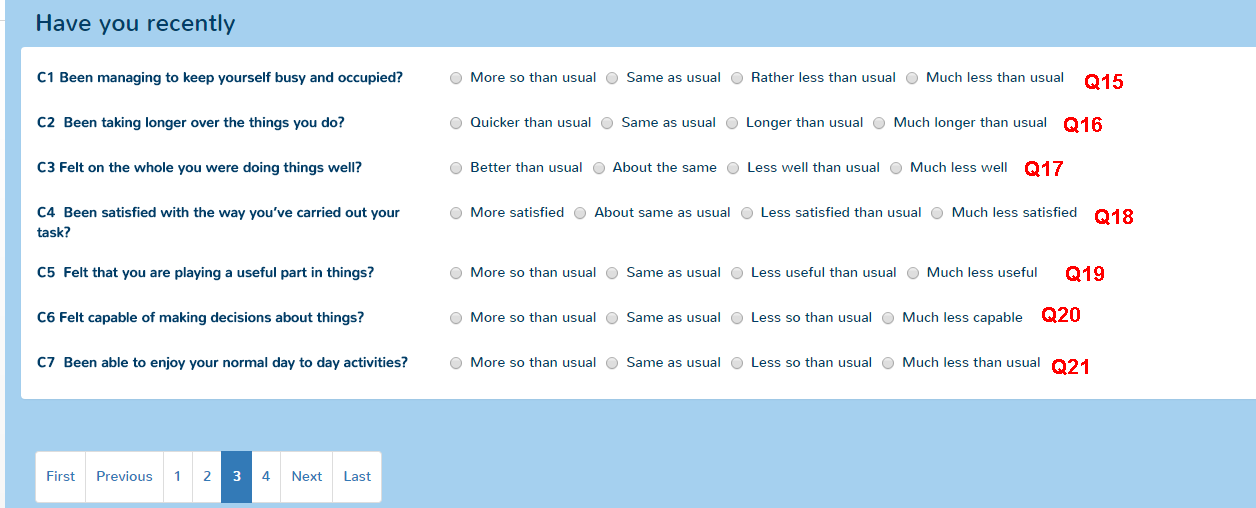


1. **GHQ**

* Form will not save if all questions that are visible are not completed.
* Each section must be completed before you can move to the next section
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* EnteredBy – will be 0 if before change implemented, if non zero then identifies who entered, if greater than 9000 will be a member of the study team. Study team Id’s are not available in the download.
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Actual text for answer saved in database



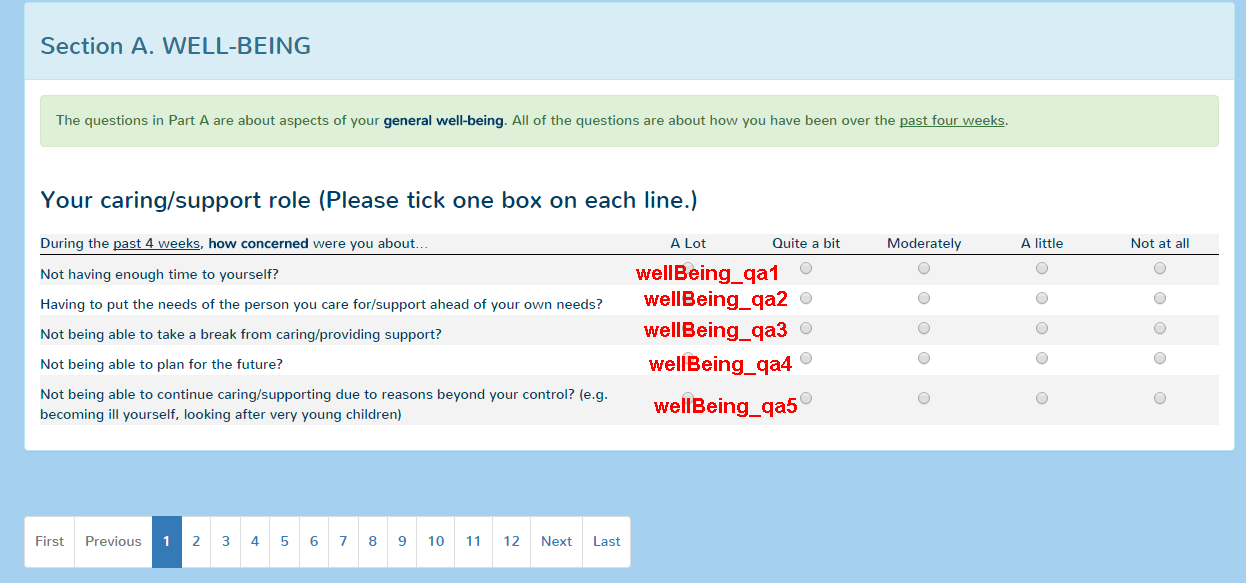


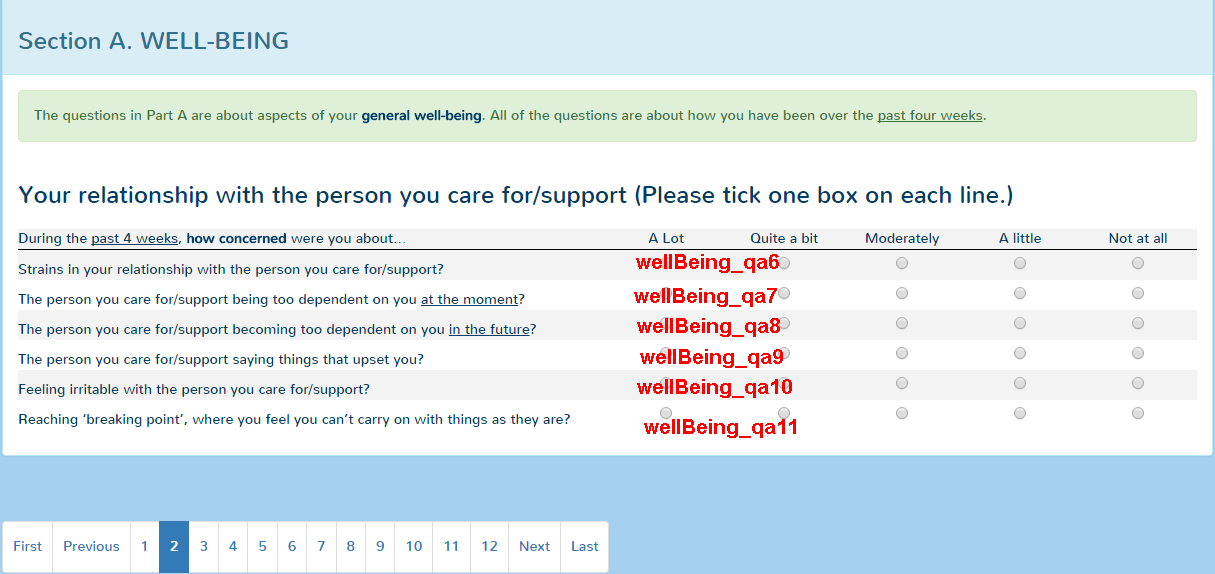


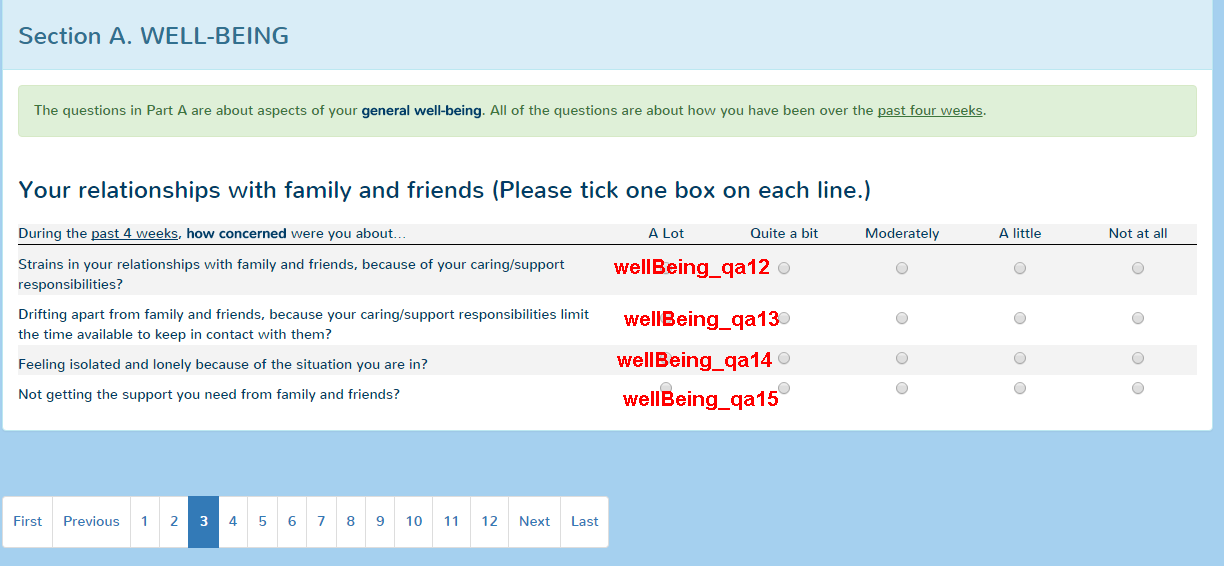


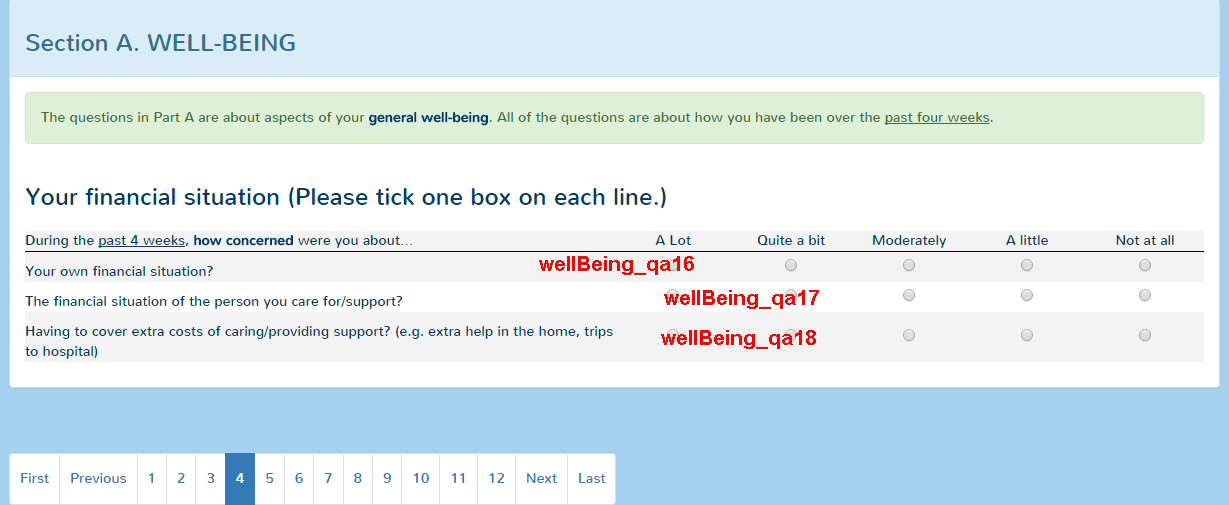
1. **Relatives Well Being and Support (WellBeing)**

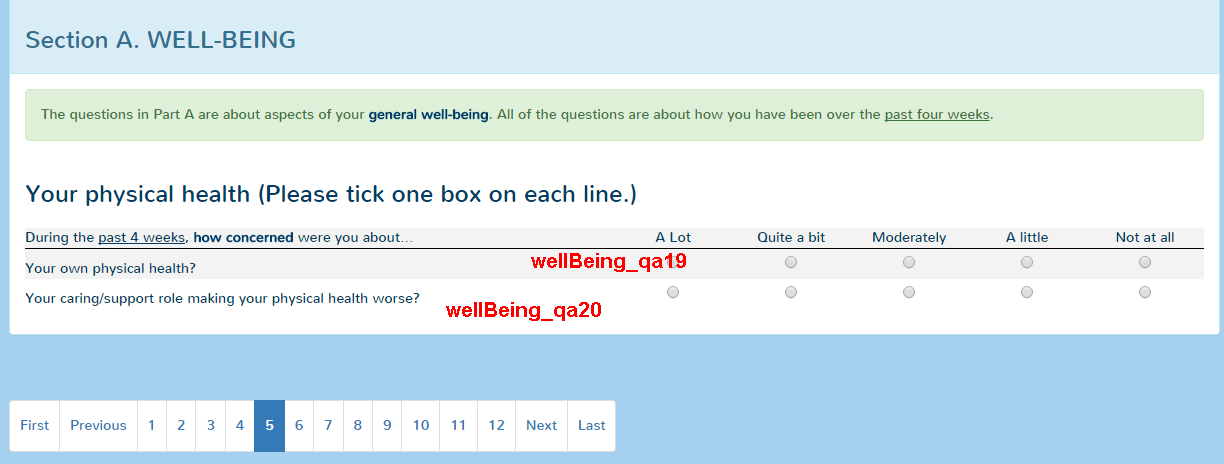
* Form will not save if all questions that are visible are not completed.
* Each section must be completed before you can move to the next section
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* Actual text for answer saved in database

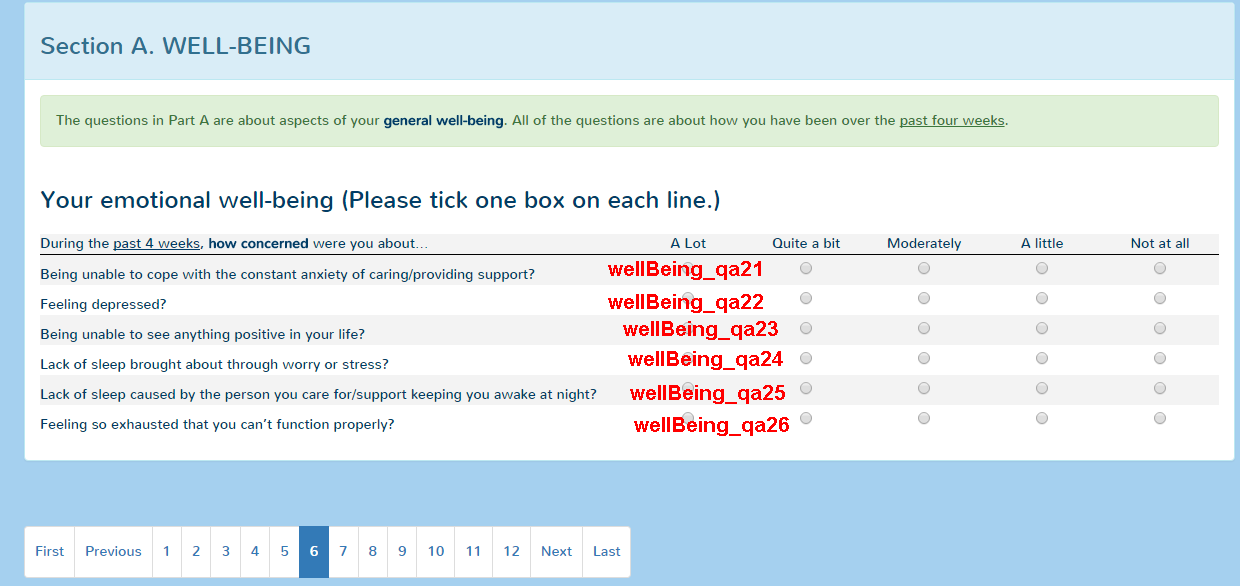


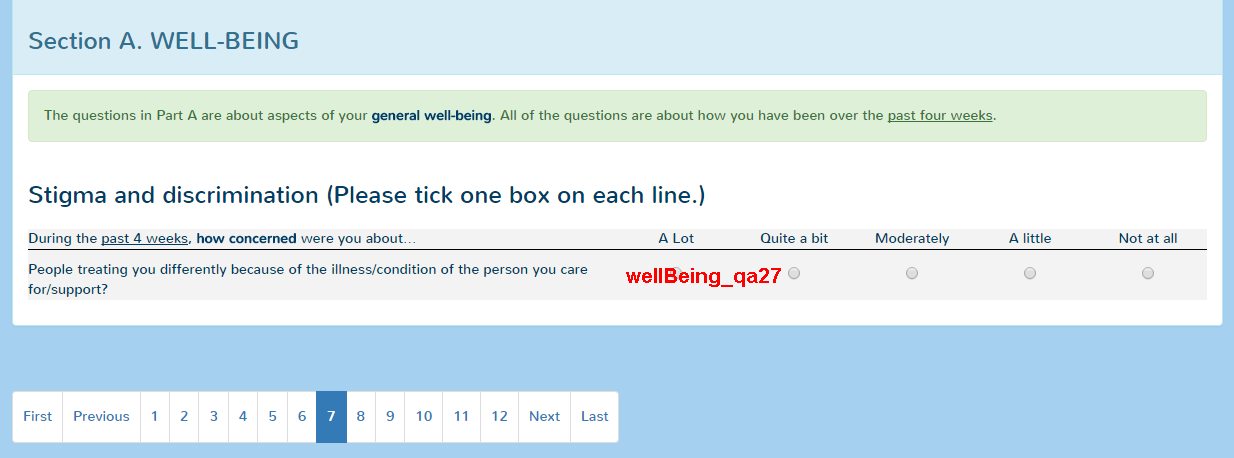


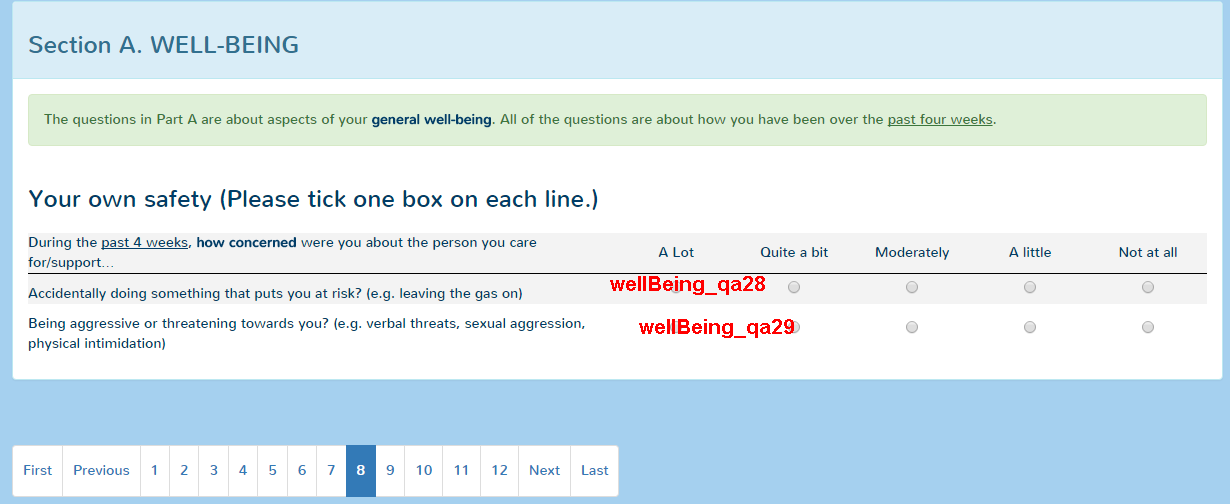


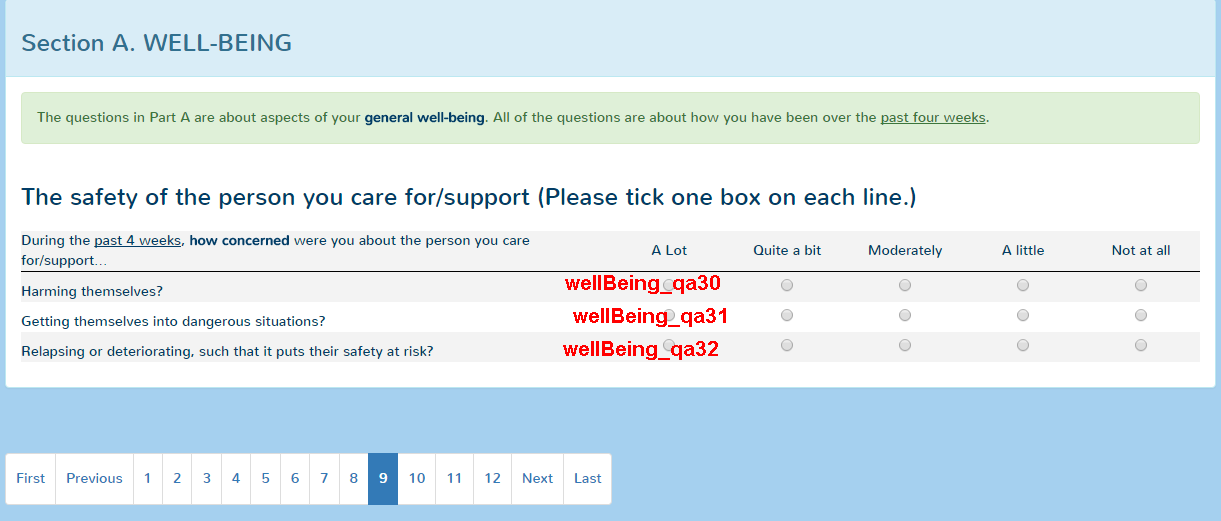


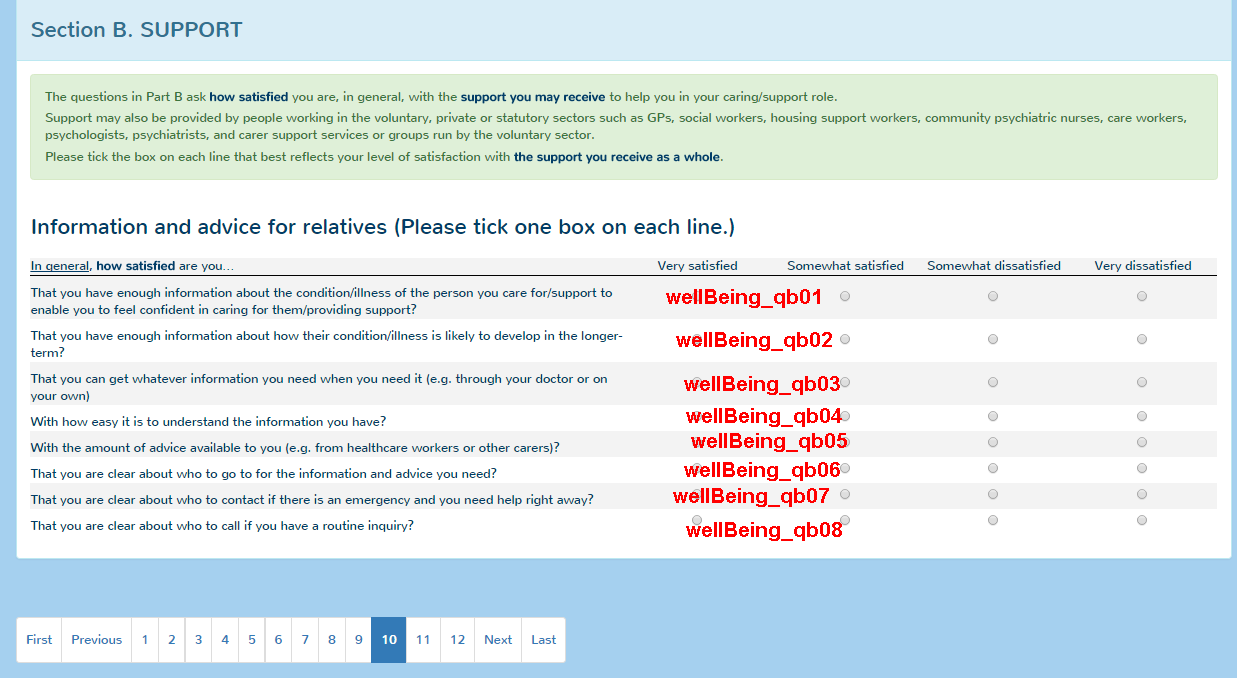


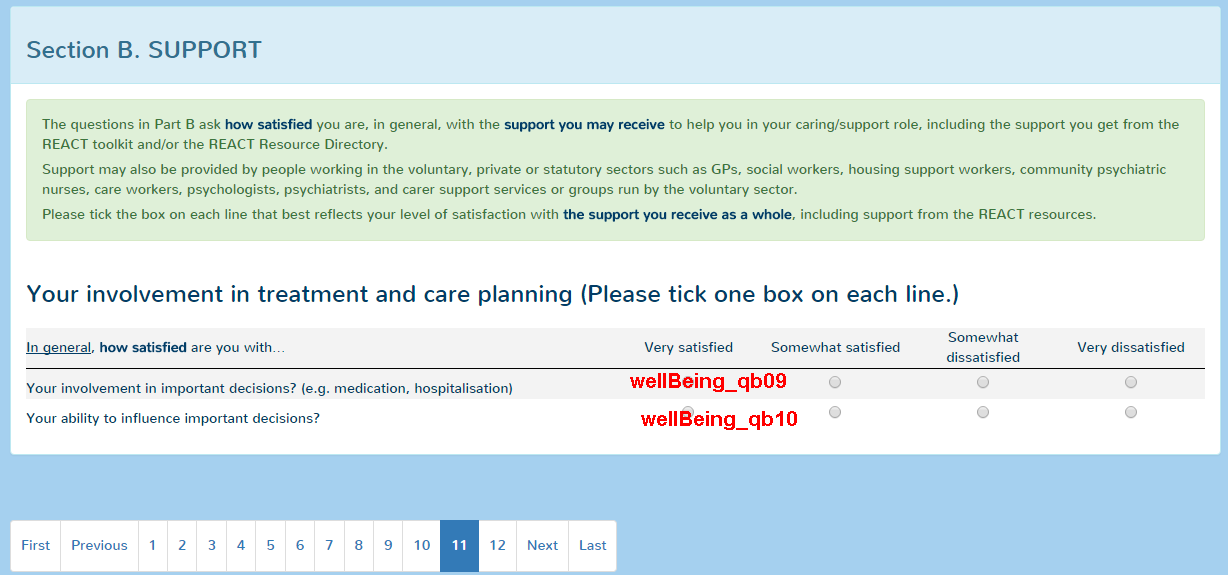


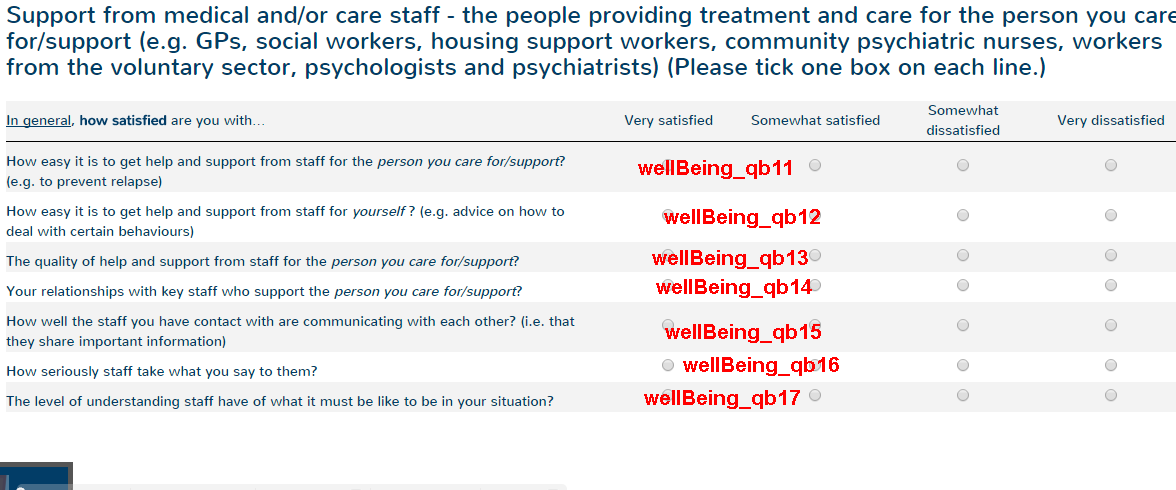










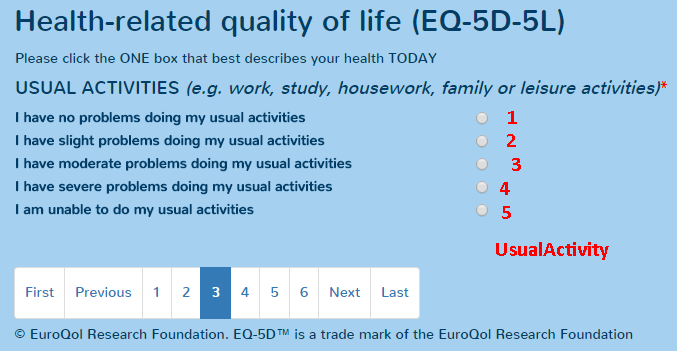


1. **EQ5D5L**

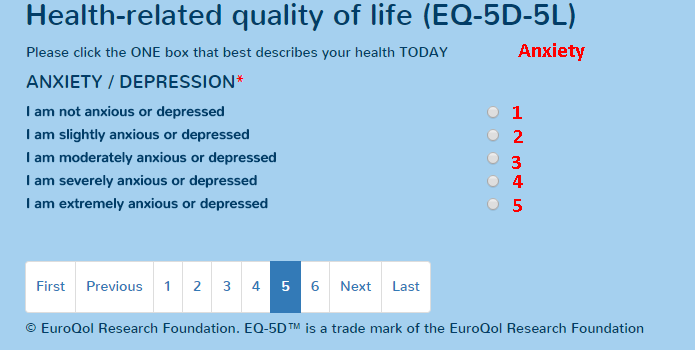
* Form will not save if all questions that are visible are not completed.
* Each section must be completed before you can move to the next section
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Data saved is numeric based on answer

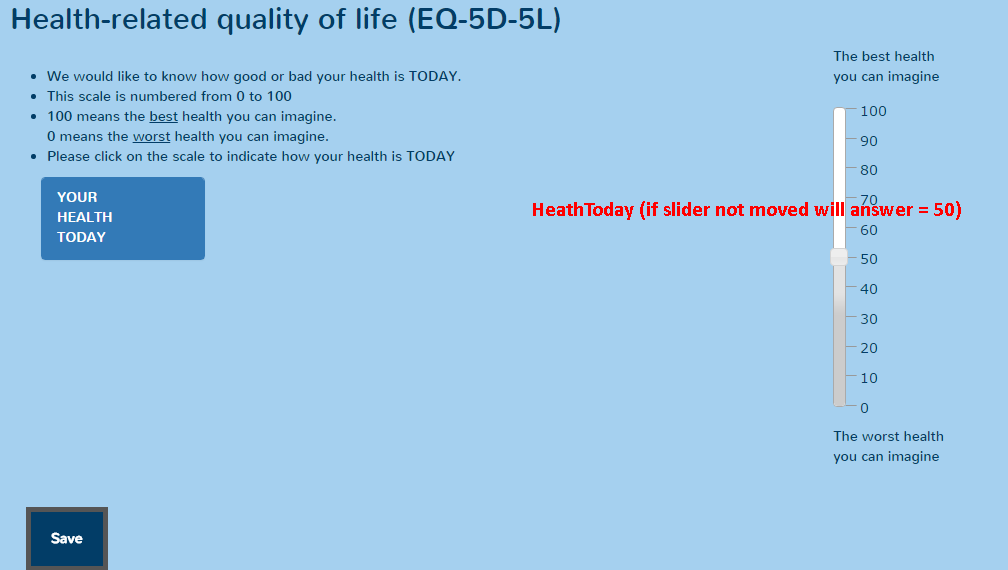






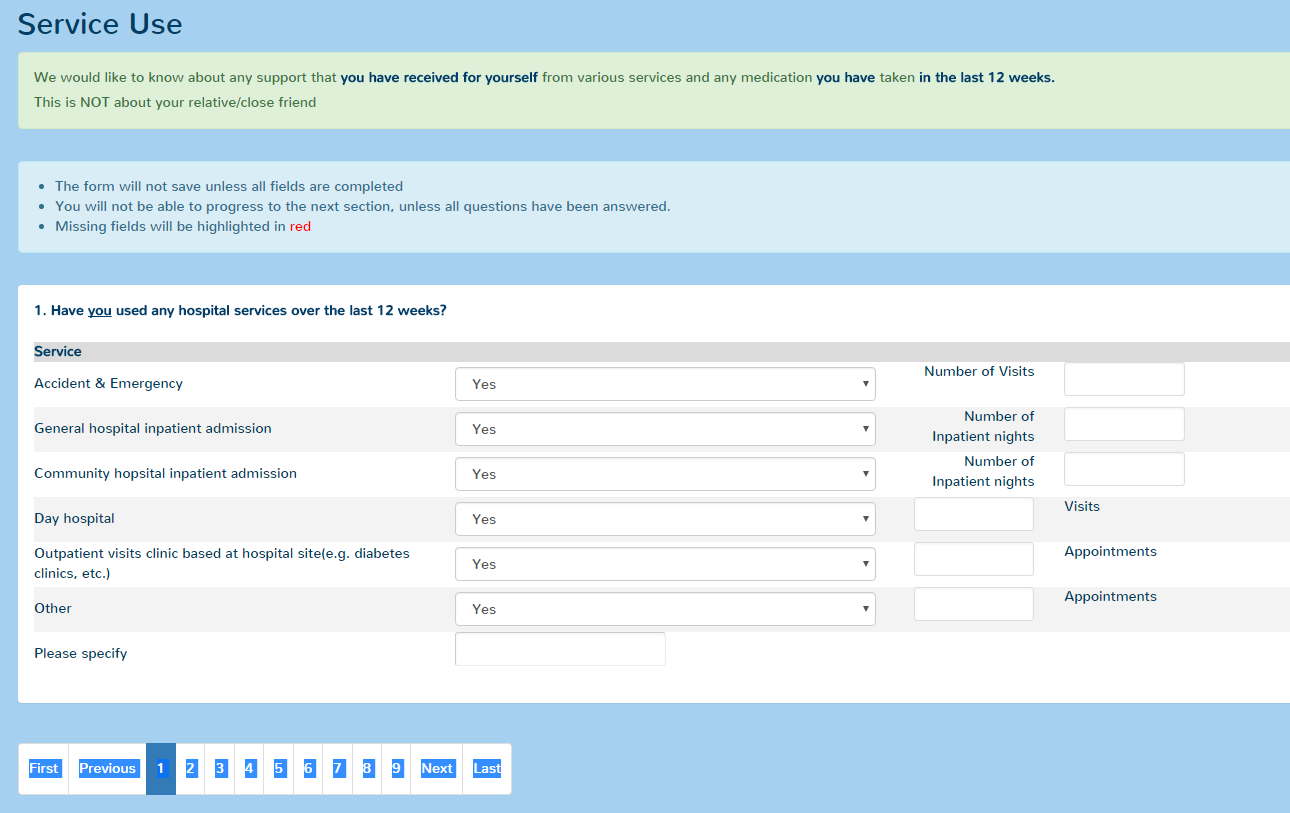






1. **Service Use (CSRI)**

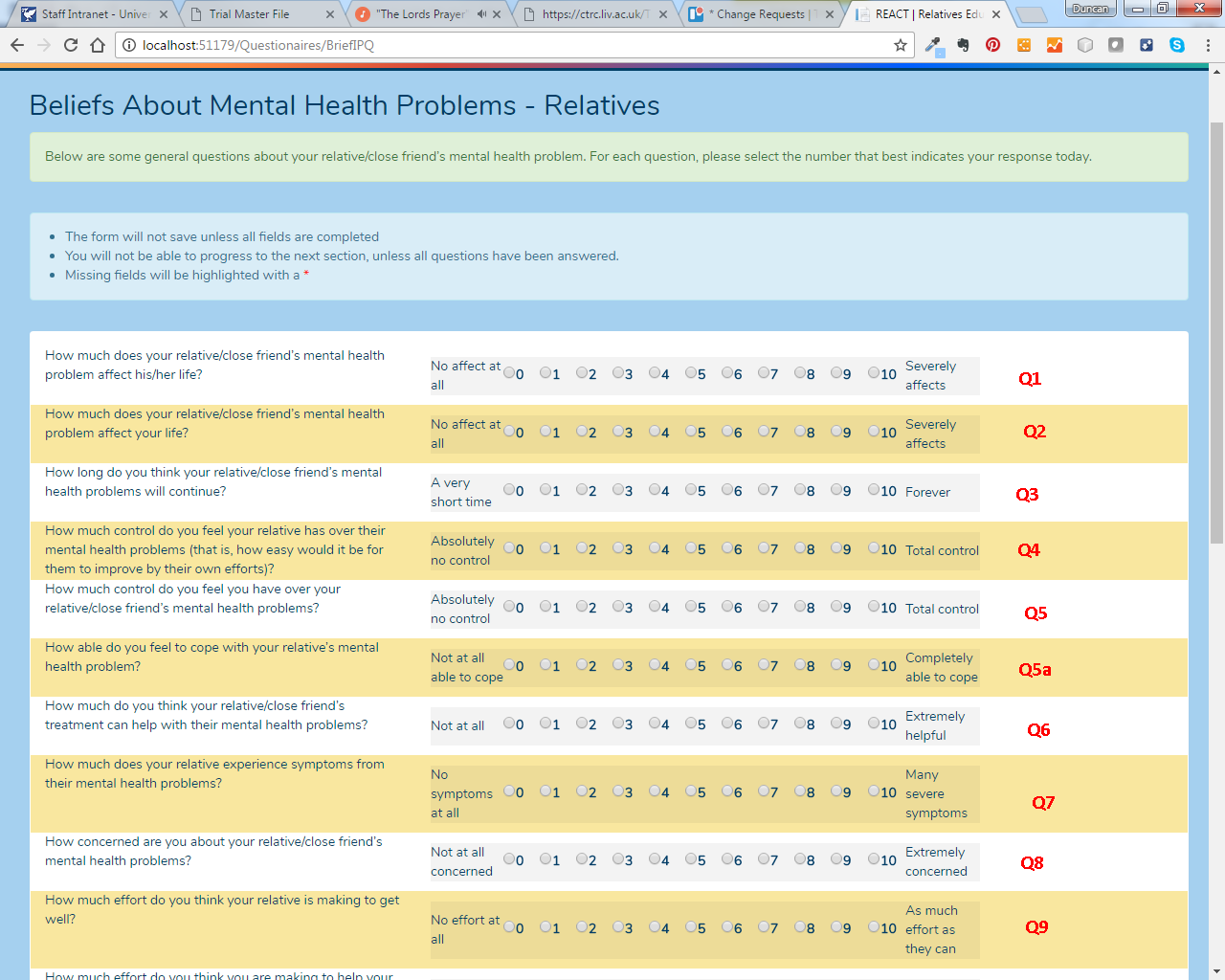
* Form will not save if all questions that are visible are not completed.
* Fields that are not visible will be empty
* Each section must be completed before you can move to the next section
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* Actual text for answer saved in database



|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Question** | **key** | **Values** | **Display** | **Validation** |
| Accident & Emergency | csri\_q1\_used\_acc\_emerg\_YN | 1 = Yes  0 = No | Yes | Required |
| Number of Visits | csri\_q1\_acc\_emerg\_num\_visits | As entered | csri\_q1\_acc\_emerg\_num\_visits = 1 | Number  Range = 1-96 |
| General hospital inpatient admission | csri\_q1\_used\_gen\_hosp\_service\_YN | 1 = Yes  0 = No | Yes | Required |
| Number of Inpatient nights | csri\_q1\_gen\_hosp\_num\_visits | As entered | csri\_q1\_used\_gen\_hosp\_service\_YN = 1 | Number  Range = 1-96 |
| Community hopsital inpatient admission | csri\_q1\_used\_comm\_hosp\_service\_YN | 1 = Yes  0 = No | Yes | Required |
| Number of Inpatient nights | csri\_q1\_comm\_hosp\_num\_visits | As entered | csri\_q1\_used\_comm\_hosp\_service\_YN = 1 | Number  Range = 1-96 |

1. **Beliefs About Mental Health Problems – Relatives**

* Form will not save if all questions that are visible are not completed.
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Actual text for answer saved in database





1. **Coping**

* Form will not save if all questions that are visible are not completed.
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Database mapping for answers are (value stored, text displayed to user):

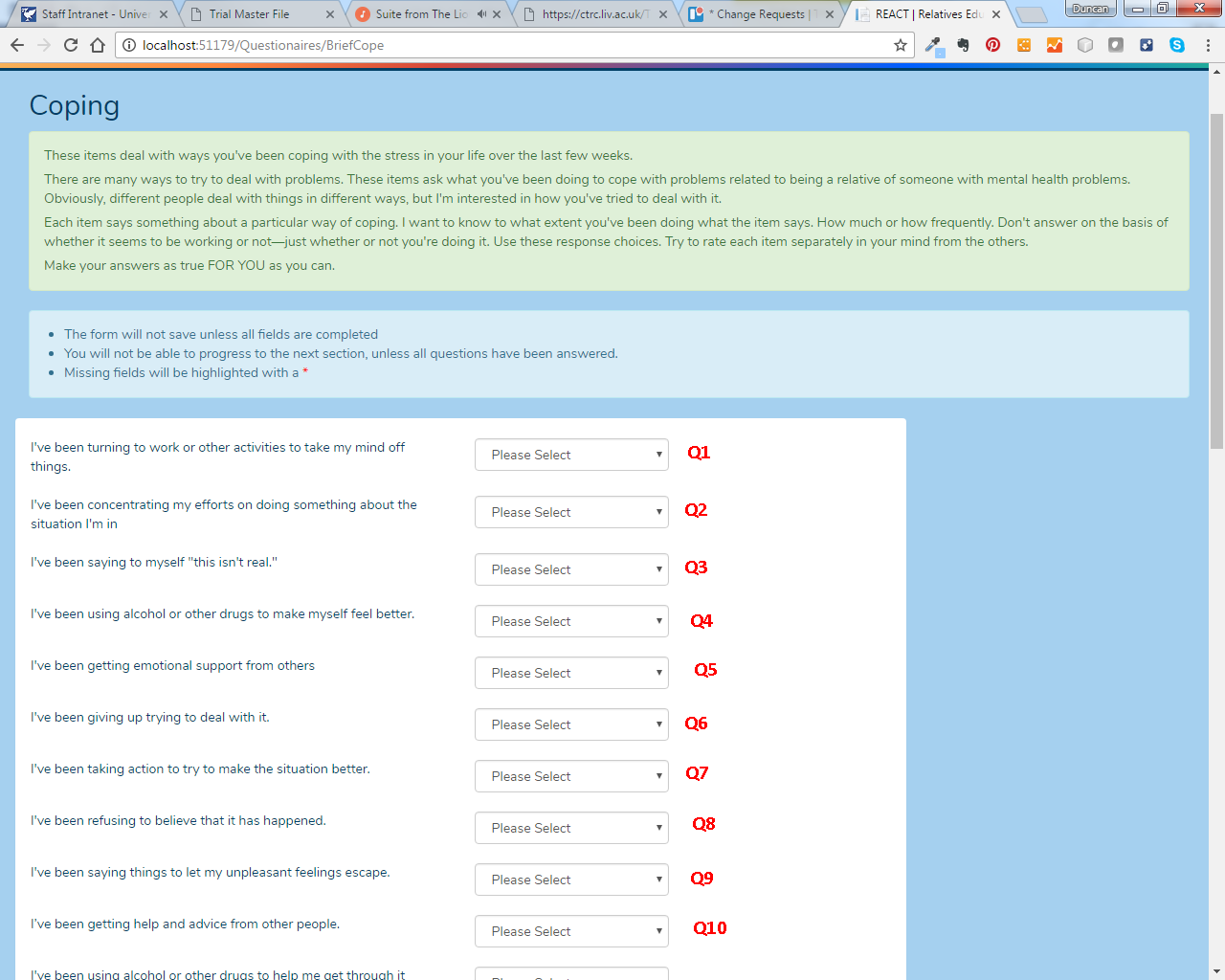
Value = "", Text = "Please Select"

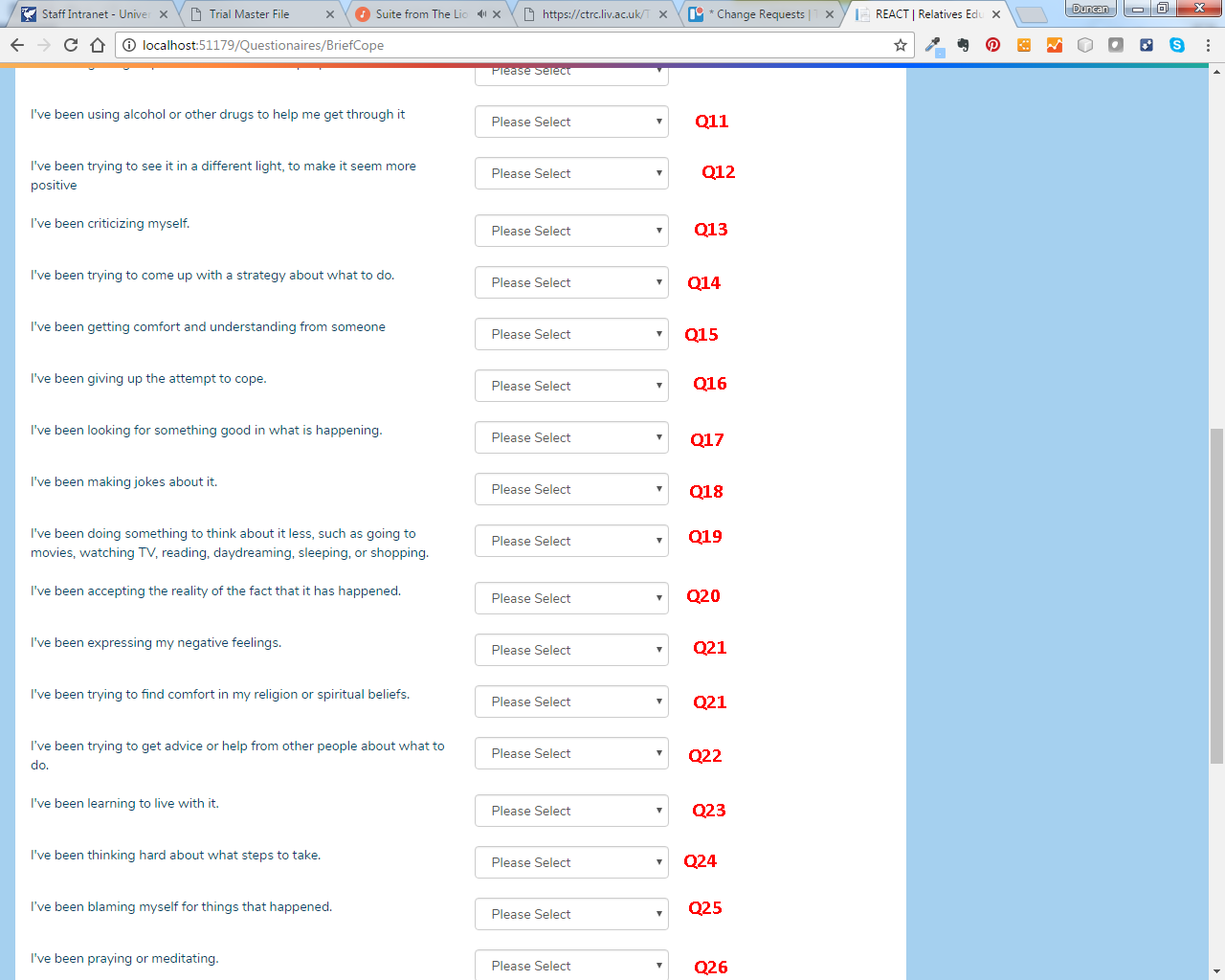
Value = "1", Text = "I haven't been doing this at all"

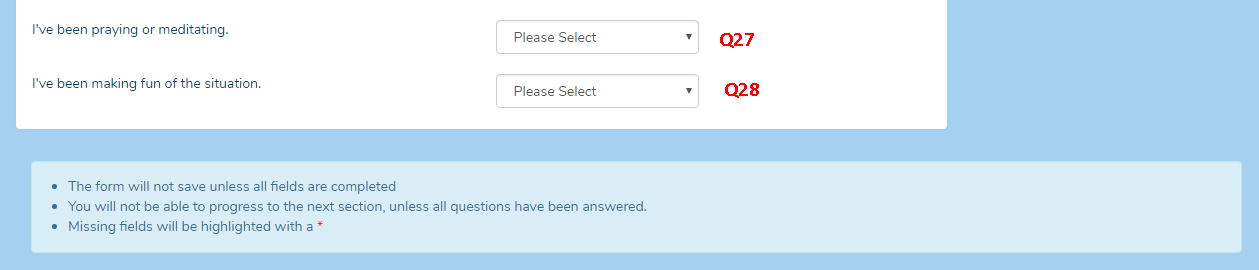
Value = "2", Text = "I've been doing this a little bit"

Value = "3", Text = "I've been doing this a medium amount"

Value = "4", Text = "I've been doing this a lot"

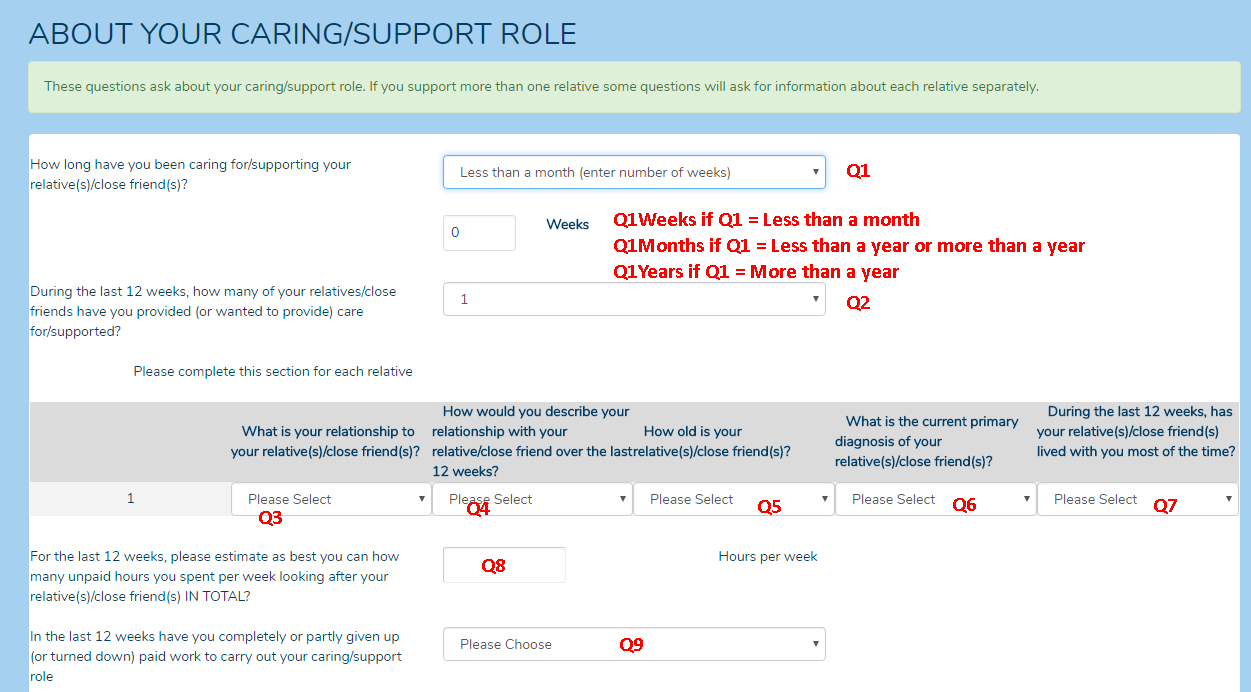


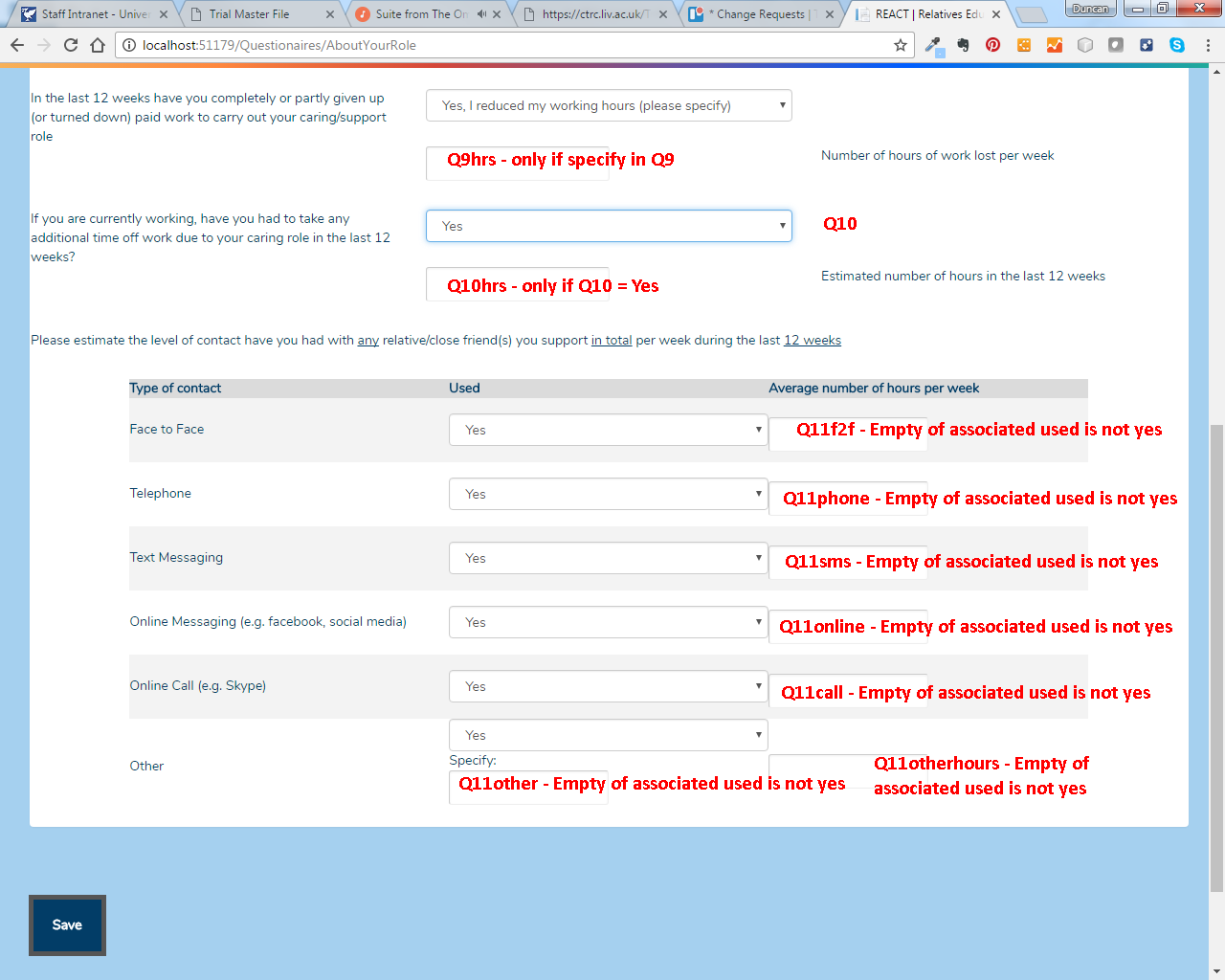




1. **ABOUT YOUR CARING/SUPPORT ROLE**

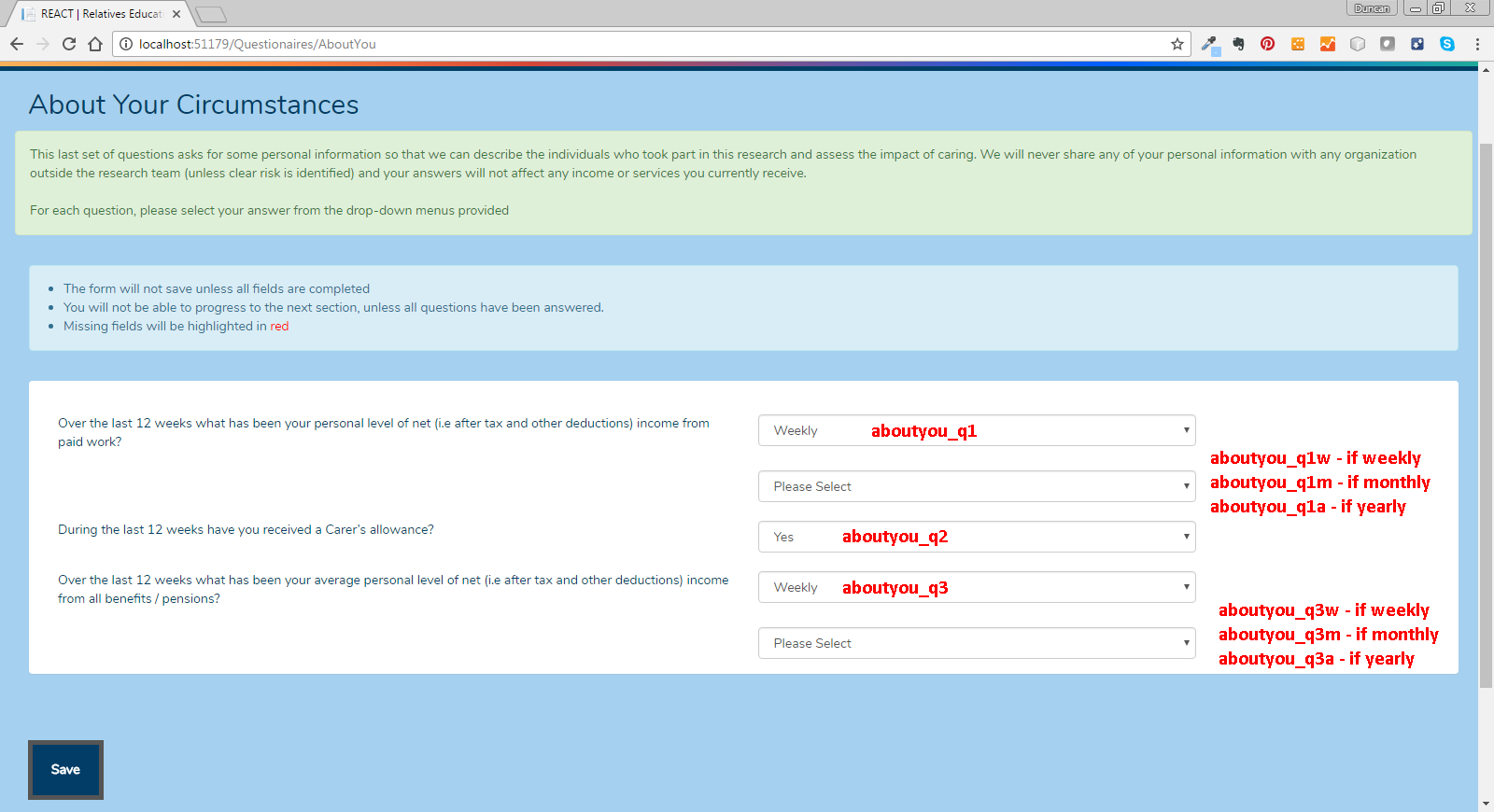
* Form will not save if all questions that are visible are not completed.
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Actual text for answer saved in database
* For questions, the data from each row is separated by a “|”, e.g., one row would be “|Close” but two rows would have “|Close|Close”





1. **About Your Circumstances**

* Form will not save if all questions that are visible are not completed.
* SubjectId – Correlates to ConsentId in the table “SubjectMap”
* Timepoint
  + 3 = Baseline
  + 6 = FU1
  + 7 = FU2
* AddedOn – Time point saved (dd/mm/yyyy hh:mm:ss)
* Actual text for answer saved in database



# Additional Data Descriptions for Database Extract

## Allocations\_24

This table contains allocations for week 24.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| StratID | Stratification identifier (always 1) |
| Block | Block number |
| Size | Block size |
| SeqInBlk | Sequence in block |
| Treat1 | 10/20 |
| Treat2 | Conditional/Unconditional |

## Allocations\_initial

This table contains allocation for baseline.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| StratID | Stratification identifier (always 1) |
| Block | Block number |
| Size | Block size |
| SeqInBlk | Sequence in block |
| Treat1 | 10/20 |
| Treat2 | Conditional/Unconditional |

## Consent

This table is used to record consent form data entry. Data is not recorded unless the subject consents to Q1-7. (Q8 is optional).

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| CompletedOn\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. Also note that there is a strange value for the patient with newID 1025 as it appears that the year is incorrect |
| Q1-8 | Responses to questions. 1=yes, 0=no |

## EmailFormat

This table hold templates used for emails sent from the web application.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| EmailType | A number that identifies the emails type.  ParticipantNotifyReactSupporter = 1  SupporterNotifyReactParticipant = 2  GenericSystemEmail = 3  MyDefinedEmail = 4  SendConsentForm = 5  RandomisationEmailTau = 6  RandomisationEmailIntervention = 7  ManageNotifications = 8  RedFlagParticipant = 9  ConsentFollowUp = 10  ActivationFollowup = 11  BaselineFU = 12  Week12FU1 = 13  Week12FU2 = 14  Week12FU3 = 15  Week24FU1Uncond = 16  Week24FU2Uncond = 17  Week24FU3Uncond = 18  Week24FU1Cond = 19  Week24FU2Cond = 20  Week24FU3Cond = 21  Week12Thankyou = 22  Week24ThankYou = 23  FinalThankyou = 24  Week12Chase5 = 25  Week12ChaseToday = 26  Week24Chase5 = 27  Week24ChaseToday = 28  ForgottenPassword = 1001  ResetPassword = 1002  EmailNewAdmin = 2048  NotifyActivationCodeContact = 2049  ActivationDetailsEmail = 2050  SystemPasswordReset = 2051  Week24FU1Uncond10 = 5001  Week24FU1Uncond20 = 5002  Week24FU1Cond10 = 5003  Week24FU1Cond20 = 5004  Week24FU1Blinded = 5005  Week24FU2Uncond10 = 5006  Week24FU2Uncond20 = 5007  Week24FU2Cond10 = 5008  Week24FU2Cond20 = 5009  Week24FU2Blinded = 5010  Week24FU3Uncond10 = 5011  Week24FU3Uncond20 = 5012  Week24FU3Cond10 = 5013  Week24FU3Cond20 = 5014  Week24FU3Blinded = 5015  Week24FUManualSMS = 6000  Week12FUManualSMS = 6001  Week12PartialCompleteVoucher = 9000  Week24PartialCompleteVoucher = 9001  Week24PartialCompleteThankYou = 9002 |
| Description | Description of email types |
| FromAddress | From address used for email |
| FromName | From name used for email |
| Subject | Email subject |
| Body | Email text |
| VersionNumber | Version number of email template |
| EditedOn\_onset | Number of days after CreatedOn (rounded to nearest day). Note where this is negative this indicates the number of days prior to CreatedOn. |

## EmailPrefs

This table captures email preferences for participants.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| Emails | A number that identifies email preferences for the participant:  All = 2  Weekly = 2  Fortnightly = 4  Monthly = 8  SMSWeekly = 1024  SMSFortnightly = 2048  SMSMonthly = 4096 |
| LastUpdate\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. Also note that there is a strange value for the patient with newID 1025 as it appears that the year is incorrect. |
|  |  |
|  |  |

## Page Views

Table containing details of page views for the forum website hosted outside of LCTC.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| URL | URL of page viewed |
| TimeVisited\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation |

## Subject\_contact

Table containing details of contact details submitted to the system.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| HearFrom |  |
| ActivationCodeSentOn\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |
| ActivationCodeEnteredOn\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |
| CompletedOn\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |

## Subjectcontacts

Table containing details of contact made to participants

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| Type | Method contact was made with (e.g. SMS) |
| Notes | Free text notes related to contact |
| ContactAt\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. Also note that there is a strange value for the patient with NewID 54 as there seems to be an error in the year that it was added. |
| DateAdded\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |

## Voucher

Table containing details related to vouchers.

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| VoucherValue | Value of voucher |
| IsAllocated | Value denoting allocation of voucher. 0=no, 1=yes |

## Phone 12/24 (GHQ completed over the phone)

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| Date\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |

## Post 12/24 (GHQ returned by post)

|  |  |
| --- | --- |
| **Column** | **Description** |
| newID | Consent identifier |
| Date\_GHQ\_sent\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |
| Date\_GHQ\_received\_onset | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |
| Completed\_onset (only for 24) | Number of days after randomisation (rounded to nearest day). Note where this is negative this indicates the number of days prior to randomisation. |

## Postcodes, Postcodes\_extra, Postcodes\_recat, Postcodes\_Scotland

Contain postcode data used to link to deprivation index

## Watched

Contains 5 second interval data indicating when videos were watched