OPERATIONS MANUAL

I. Introduction/Background

This document was originally drafted in 2014 to provide guidance to research assistants tasked with reviewing and abstracting data for a scoping review of peer-reviewed publications reporting patient outcomes after hospital discharge for ICU survivors. Results from this investigation are available in:


The exclusion criteria for this scoping review are listed in the bullet points below. Before entering data, check that the article has no exclusion criteria. If you are concerned that the article should not be included DO NOT fill out the review form except for the ‘Comments’ field at the end of the form (Section IV-17 of operations manual). Enter into this text box why you think the article should be excluded and save the record, in REDCap database, as ‘Unverified.’

**Articles should NOT be included for the following reasons**

- Non-human study
- No original data (e.g., systematic review, commentary, editorial)
- Published prior to 1970
- No physical, cognitive or mental health outcomes(s) assessed after hospital discharge
- Study population does not include people discharged from intensive care, including specialty units such as coronary care or burn units
- Study population does not include ANY adults (16 years of age and older)
- Study provided data on less than 20 patients
  - A paper must have collected ICF outcomes data on ≥20 patients at some point after hospitalization.
  - If it’s a big cohort with <20 patients, but at the first follow-up visit there were >20 patients, we want to include it.
II. Instructions for using REDCap: Editing a record / Entering article data

On the Weekly Assignment document, identify articles you are responsible for and the corresponding article ID. Enter the article ID in the field labeled: “Enter a new or existing study ID number” and hit enter.

While entering data, if you wish to return to the main page without making changes, either click the word Add/Edit Records on the left-hand side of the screen, hit the back button on your browser, or scroll to the bottom of the screen and click Cancel. See Appendix Figure 1 for a screenshot of the REDCap form.

After completing data entry for a particular article, save the record as ‘Unverified’. Unverified records are assumed to be complete and ready for comparison in the double data entry module. If you have not finished entering data about an article but wish to save the data which is already entered, save the record as ‘Incomplete’. Remember that changes can be made on records anytime even after saving as ‘Unverified’ or ‘Incomplete’.

III. Returning to an incomplete record

In the main menu, enter the article ID in the field “Enter a new or existing study ID number” and hit enter or click on the dropdown box next to the incomplete records and select the article ID that you wish to edit.

IV. Data Collection

1. Author List
   The last name of the authors of the paper should appear in this field when you open the record. If the field is empty, enter the last name of the first author using only letters. Do not include hyphens or accents in the name.
   If the author is listed as a group of people, enter the group name. For example: “Generic Coalition for Better Measurement In Research”

2. Is a corresponding author listed
   If the paper mentions the name of an author to send correspondence to, select ‘yes’. If a corresponding author is not mentioned, select ‘no’. If the email address of the corresponding author is not provided, select ‘no’.
If you select yes, 3 new fields will appear asking the last name, first name and email address of the corresponding author which you should fill appropriately.

3. Date Of Study Publication
   The date of study publication should appear in the field when you open the record. If the field is empty, enter the 4-digit year that the study was published in print.
   Note that many studies are E-published in a different year than they appear in print.

4. Is this study part of our systematic (not scoping) review of measurement properties? This will already be marked as yes or no when you open the record.
   If this field is marked ‘no’, proceed to the next field.
   If it is ‘yes’, there will be another field with the question – “Is the primary intent of this study to describe the long-term outcomes of ICU survivors, or to evaluate a measurement instrument?”
   If you think the primary intent of the study is to describe long term outcomes of the ICU survivors, choose ‘Describe long term outcomes’ from the dropdown menu and proceed to the next field.
   If you think the primary intent is to evaluate or compare measurement instruments, choose ‘Evaluate measurement instruments’ from the dropdown menu and proceed to the question Complete? at the end of the form (Section II of operations manual), select Unverified and click Save Record. Ignore all warnings about missing fields.
   If you are not sure about the primary intent, choose ‘Unsure’ and proceed to the next field.

5. Select your name
   Select your name from the list in the dropdown menu.

6. Is this paper written in a foreign language?
   This will already be marked as yes or no when you open the record.

1. This refers to a systematic review of measurement properties that was conducted simultaneously. Results were published in: Robinson KA, et al. A systematic review finds limited data on measurement properties of instruments measuring outcomes in adult intensive care unit survivors. J Clin Epidemiol 2017; 82:37-46.
If the article is written in a language that you do not read very well, proceed to the question **Complete?** at the end of the form (Page 1, section II of operations manual), select **Incomplete** and click **Save Record.** Ignore all warnings about missing fields. Let your team leader know the article requires a multi-lingual data abstractor.

**7. If this study analyzed a named cohort of patients, enter name here**

Sometimes, the study subjects in your article may be part of a named cohort study. Eg: A study aimed at determining prevalence of PTSD in survivors of Acute Lung Injury recruited patients from 2 ongoing studies namely ARDS Networks Long Term Outcomes Study (ALTOS) and Improving Care Of ALI Patients (ICAP). In such scenarios, enter the name of the study/studies from which the patients are recruited, in this field.

Sometimes, the study subjects in your article may be a part of a bigger unnamed cohort study. In such cases, you can enter the data in this field using the place of study or author name like the examples given below.

Eg: “subset of larger cohort study at Michigan state” or “subset of larger cohort study by Herridge et al”

**8. Which ICUs were patients recruited from?**

Select the ICU(s) from which patients were recruited. **You can choose more than one option.**

- If the study doesn’t mention a specific ICU and the patients are recruited from US hospitals, choose ‘**unspecified (US).’**
- If the study doesn’t mention a specific ICU and the patients are recruited from non-US hospitals, choose ‘**medical-surgical (generally non US).’** Note that some earlier studies mention ICUs in US hospitals with medical and surgical beds; in which case again, choose ‘**medical-surgical (generally non US).’**
- If the patients were recruited from a specified ICU not given in the options, choose ‘**other.’**
- If you choose **other**, a new field will appear asking you the question—**“What other ICUs were patients recruited from?”** - specify the name of the ICU here.
9. **Was a disease-specific ICU population enrolled?**

If the study recruited patients with a specific disease or condition, choose ‘yes.’ If patients were not recruited based on what disease they have, choose ‘no.’ If specific diseases are listed as exclusion requirements, select ‘no.’

If you choose ‘yes,’ a new field will appear asking you the question: “**Which disease-specific population was enrolled?**” Choose the suitable option. **You can choose more than one option.**

If the patients had a disease not given in the choices, choose other.

If you choose ‘other’, a new field will appear asking you the question: “**What other ICU disease population was enrolled?**” Type the name of the disease here.

**For example:**

i. If the study recruited patients from a medical ICU but excluded patients with dementia, cognitive impairment, or a primary neurologic diagnosis, choose ‘no.’

ii. If the study recruits patients from medical and surgical ICUs and look for PTSD and depression symptoms during follow-up, choose ‘no’.

iii. If the study recruits patients with ARDS from the ICU, choose ‘yes’ and choose ALI/ARDS in response to the question “**Which disease-specific population was enrolled?**”

iv. If it is a “study of CHF (congestive heart failure) patients who are dependent on chronic dialysis” the patients have a cardiac disease and also a renal condition. Choose ‘cardiac disease’ and ‘other’ and in the new field that appears, enter ‘renal disease’ or ‘dependent on dialysis’ or ‘renal failure.’

10. **What was the study design?**

From the dropdown menu, choose the appropriate study design. Note that if the study is part of the systematic review (Page 2, Question 3 of Operations Manual), and the primary intent of the study is to evaluate a measurement instrument, the study design may be complex and not fit well into any one category. If this is the case, select ‘unsure’ from the dropdown menu.
a) **Cohort studies**: A clinical cohort is a group of patients with a shared characteristic who are followed through time. *(Figure 1)* All cohort studies must have a defined starting point known as “time zero”. In most cohort studies analyzed as part of this systematic review, the cohort will be a group of ICU patients who are studied for months or years after being discharged from the hospital.

Time zero will usually be discharge from the hospital (or the time of diagnosis of a relevant disease (e.g., ARDS)). The primary exposure of interest will be a treatment or experience that may, or may not, have occurred during their ICU stay, and the outcome(s) of interest will be diagnoses, events, or changes that occur after their ICU stay. In a prospective cohort study, exposures are identified at the beginning of the study and follow-up visits are used to measure the presence of outcomes. In a retrospective cohort study, exposures are identified (usually by reviewing medical records) after the outcomes have been measured. Both prospective and retrospective cohort studies should be recorded as ‘Cohort study.’ Examples of cohort studies are provided below.
i. **Prospective Cohort Study:** All patients admitted to an ICU with a diagnosis of COPD (exposure) between 2008 and 2010 are enrolled in a prospective cohort study. Every 6 months for two years after each patient is discharged, they are asked to return to the hospital and complete a series of pulmonary function tests (outcome). Some patients are returning for their 6-month follow-up testing while other patients are being discharged from the ICU and enrolled for the first time, but all patients are being followed through time and measured at approximately 6 month intervals after time zero (hospital discharge).

ii. **Retrospective Cohort Study:** All patients who are discharged from neurosurgical ICU are mailed the Beck Depression Inventory at 3, 6, and 9 months after hospital discharge. After analyzing the results of Beck Depression Inventory, the medical records of all patients who responded to the mailing are reviewed to determine if depressed ICU survivors were exposed to different treatments than non-depressed ICU survivors.

b) **Case-control study:** These studies are usually used to determine if there is any relationship between a condition and a risk factor. They have 2 groups: cases and controls. Controls are usually a group of people who are similar to the cases but lack the outcome. The outcome has already happened when people are...
enrolled in the study. The investigators then look back in time and determine the risk factors. (Figure 2)

c) **Randomized trials:** The key distinguishing feature of a randomized controlled trial (RCT) is that study subjects are randomly allocated to receive one or the other of the alternative treatments or interventions under study. (Figure 3) This happens after investigators have determined their eligibility to be in the study, but before the treatment or intervention begins.

![Figure 3: Randomized Trial](image)

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d) **Cross-sectional studies:** Cross-sectional studies assess outcomes at one point in calendar time for all study participants. Importantly, the time since being in the ICU at which the outcome is assessed is often different for every participant in the study. Some participants may have been in the ICU recently, while others were discharged years ago! The goal of cross-sectional studies is usually to assess the prevalence of a specific outcome in the study population. Examples are provided below:
a. Traditional Cross-sectional study: All patients discharged from 8 surgical ICUs between 2002 and 2010 are mailed a survey asking about their ability to perform activities of daily living (ADLs) in 2011.

b. Test-retest study: All patients discharged from 8 surgical ICUs between 2002 and 2010 are mailed a survey in late January 2011 asking about their ability to perform activities of daily living (ADLs) and items from the Barthel Index. All patients who respond to the survey are mailed a second letter in early February of 2011 asking them to complete the Barthel Index again. Although it is true that participant outcomes are being assessed at two points in time, for the purposes of this systematic review, please code this study as being a cross-sectional study.

If the article does not describe a cohort study, case-control study, randomized trial, or cross-sectional study, choose “other” from the drop down menu. When you choose “other”, a new field will appear – “Describe study design here.” BRIEFLY describe the study design here.

11. Was mortality captured during follow-up?
If the article includes information that was collected by checking death records on whether participants died during follow-up choose ‘yes.’

If a study specifically mentions the number of people dead during follow-up and the number of people lost to follow-up, and no data is provided on how the dead were counted, you should choose ‘yes’ and consider the number of people lost to follow-up as alive.

If an article does not measure mortality as such, but accounts for all the patients being alive at follow-up, then choose ‘yes’.
If the article does not include information on when patients died during follow-up, choose ‘no.’ If during a study, the researchers find out a few participants are dead only when they attempted to contact the patient for a follow-up interview, choose ‘no’. If the investigators send mail or e-mail to all enrolled patients and do not
explicitly state which patients who do NOT respond to the e-mail are dead, choose ‘no’. If it’s not clear to you whether the article provides information on mortality during follow-up, choose ‘unsure’.

12. **How many ICU survivors were eligible for follow-up at hospital discharge?**

Enter the number of patients who are eligible to participate in the study, consent to participate, and are alive at the time of hospital discharge. If the article only provides information on consented participants alive at ICU discharge, but not hospital discharge, enter the number of participants alive at ICU discharge. Some studies will identify eligible patients by reviewing patient medical records or administrative data but not attempt to consent patients or obtain data on long-term outcomes until many years after hospital discharge, while other studies uses survival after ICU discharge as an eligibility criteria. When this is the case, enter the number of eligible patients alive at the time of hospital discharge identified using medical records or administrative data.

For example: In the study below (Figure 4), the number of ICU survivors eligible for follow-up at hospital discharge is 483.
Figure 4: Flow diagram for an example study with 483 eligible patients
13. Proportion of eligible patients alive at final visit

Abstractors should not enter data into these fields. They will be calculated automatically. The calculated values should not be changed.

14. How many ICU survivors were alive at the last follow-up visit?

Enter the number of patients alive at the last follow-up visit regardless of whether they were tested, interviewed, or measured. Many patients are likely to have died, withdrawn consent, or been lost to follow-up. The number entered must be less than or equal to the number entered in response to the question “How many ICU survivors were eligible for follow-up at hospital discharge?”

In cross-sectional studies, the time of administration of questionnaires or testing can be treated as the last follow-up visit.

In a high quality cohort study, the investigators will account for all the people in the initial cohort at every follow-up point. However in some studies, investigators stop tracking whether patients who were lost or withdrew consent at initial follow-up visits were still alive at later visits. When this occurs, patients who refuse to participate, or who withdraw consent, are not assumed to be alive at subsequent visits.

For example:

i) 100 patients were eligible for follow-up at discharge. These patients are only measured one time, at 6 months after discharge. At 6 months, 10 were dead, 5 refused to participate, and 80 were assessed. The number of patients alive at last follow-up point is 80+5=85.

ii) In another study with multiple follow-up points, 100 patients were eligible for follow-up at discharge. At 3 months, 5 refused to participate, 10 were dead, and 80 were assessed. At 6 months, another 10 were dead and 70 were assessed. Here you cannot calculate the number of patients alive at the last follow-up point because you don’t know if the patients who refused to participate at the 3-month follow-up visit are dead or alive.
Figure 5: An example of a study where all patients are accounted for at all follow-up times.
Figure 6: A study that does not account for all the patients at all follow-up points.
15. How many ICU survivors were measured in any way at the last follow-up visit?
   Enter the number of patients measured, tested, or interviewed at the last follow-up visit. The number entered must be less than or equal to the value entered in response to the question “How many ICU survivors were alive at the last follow-up visit?” In cross-sectional studies the number of patients responding to the request for participation or completing the survey should be entered here.

16. Proportion of living patients at the last follow-up visit who contributed data to the study
   Abstractors should not enter data into these fields. They will be calculated automatically. The calculated values should not be changed.

17. OUTCOMES

   The questions in the outcome section of the form require you to choose the instruments that were used to measure study participants’ impairment, limitations, disability, or quality of life. You can choose multiple instruments measuring multiple outcome domains. If the instrument used to assess patient outcomes is not listed in the Outcomes section, you should think about what outcome domain the instrument is trying to assess. This may require looking up articles referenced in the paper describing the instrument or searching on the internet. If the authors created the instrument themselves, there may not be any references and you will need to determine which outcome domain the authors were trying to measure.

   Determining what domain an instrument is measuring will be easier if you understand how the WHO’s International Classification of Functioning, Disability, and Health (ICF) can be applied to long-term outcomes after critical illness (Figure 7). Under this conceptual model, critical illness may cause impairments - i.e the organ failures that are commonly the focus of critical care medicine. Impairments occur at the level of tissue damage. These impairments may then cause activity
Limitations in functional activities. Limitations in physical and cognitive abilities may, in turn, lead to restrictions in participation in social roles. There is a distinction between what a person can do in a standardized testing environment (activity limitations) and what can be done in the patient’s usual home environment (participation restriction). How a person feels about their status and pursuant adaptation may impair quality of life.

Consider the example of Mr. Jones, whose ICU-acquired weakness leads to atrophy of quadriceps (an impairment), resulting in reduced sit-to-stand ability (an activity limitation). Mr. Jones previously lived in a 2-level house with a master bedroom on the second floor. He can no longer climb the stairs to his bedroom (a participation restriction) and is unable to return home. This makes him profoundly unhappy and dissatisfied with his life (reduced quality of life).

Once you have determined whether the instrument is measuring an impairment, activity limitation, participation restriction, or quality of life, select “other” in the appropriate domain of the outcomes section and type the name of the instrument in the field “Specify, if other” which will appear.

If the instruments is a modified/shortened version of the original instrument, you can choose the original instrument. For example, if an article measures quality of life using a modified SF-36, you can choose SF-36 from the list of instruments given.

If participants were asked about employment status during follow-up, select ‘return to work’ from the list of disability measures.

If outcomes are assessed using a named instrument which is not an option in the data collection form, check the Appendix at the end of the operations manual to see if it has already been categorized.

If an instrument is custom-made, and not listed in the Appendix, it should be categorized based on what you perceive it to measure and not just what the authors claim it measures. For example if a study uses a custom-made questionnaire to assess quality of life, but all the questions in the questionnaire ask
about self-care activities, you can categorize the instrument as “other” under participation restriction, even though the article says quality of life. **Note that this applies only to custom-made instruments and this issues should always be described in the “Comments” section at the end of the form** (see Section IV-17 of operations manual).

If a custom-made questionnaire contains questions from multiple validated instruments, but does not contain all the questions from any instrument, you should NOT mark those instruments. For example, if a study uses a neuropsychological battery and it is composed of 2 questions from MMSE, 2 questions from Wechsler adult intelligence (WAIS), and 2 questions from Wechsler Memory Scale (WMS), you should not mark any of those instruments. Mark “Other” and then explain the test in detail. However, if the homemade instrument contains ALL the questions in the MMSE plus four new questions, mark MMSE and “Other” and then explain that new questions were added to the MMSE.

If you come across articles dealing with Sense of Coherence Questionnaire and Freiburg Questionnaire of coping with illness, you do not need to classify them.

After selecting any instrument in the outcomes section, the following fields will appear.
a) How were these measures of impairment/limitations/restrictions/quality of life assessed during follow-up?

For this project, follow-ups are the assessments that take place after hospital discharge. Assessments that take place during hospitalization/at hospital discharge should not be counted as follow-up for this project. If the assessments were made during face-to-face interviews, choose ‘in-person’. If they were made by sending questionnaires via mail, choose ‘by mail’. If the patients were assessed by...
interviewing over the phone, choose ‘by phone’. If the assessments were made by reviewing the patient charts and medical records, choose ‘chart review’. If the assessments were made by some other method than the ones explained above, choose ‘other.’ If the assessments are made by sending e-mails, choose ‘other.’ If the assessments were made by sending the questionnaires to or calling up the general practitioners of the patients choose ‘other’.

If the details are given but they are not clear, choose ‘unclear’.

You can choose more than one option.
The question is asking about “HOW the data was gathered”, NOT “Who provided the data”. So if they interviewed a proxy by phone, the answer is still ‘by phone’.

b) Was at least one measure of impairment/limitations/restriction/quality of life assessed at baseline?

If the instrument was used to assess a patient’s impairment/limitations/restriction/quality of life prior to hospital admission, choose ‘yes’. Else, choose ‘no’.

If a study uses an instrument different from the one used at follow-up, to measure the same outcome at baseline, choose ‘yes’.

For example:

a) a study uses PTSS-10 to measure PTSD symptoms (impairment) at follow-up and used another scale (TERS-Transplant Evaluation Rating Scale) at baseline which also assesses PTSD symptoms also, choose ‘yes’.

b) a study which measures participation restriction and disability at follow-up, using Katz activities of daily living (ADL), also measures employment status (return to work-which is a measure of participation restriction) at baseline, choose ‘yes’.
Any mention of baseline status in the same category as the follow-up will count as a baseline measure. The baseline assessment can be in the body of a custom-made questionnaire administered during follow-up. For example a simple custom-made questionnaire might be composed of 2 questions:

1) How is your QOL now?
2) How was your QOL before admission to the hospital?

This counts as an assessment of quality of life at baseline.

Another example is “Return to work.” If the investigators ask about work status before admission and if the participant returned to work afterward discharge, you should count this as a baseline measurement and a follow-up assessment.

If the custom-made questionnaire asks about change in quality of life as a single item, and the choices are “Worse, Better, Same”, do NOT choose baseline, since it is only measuring the change, and NOT the baseline quality of life.

i. **Were baseline impairments/limitations/restrictions/quality of life measured using the same instrument that was used during follow-up?**

If the baseline data was gathered using the same instrument which is used in follow-up, choose ‘yes’. Example: a study assesses quality of life at baseline and at follow-up using the SF-36 instrument

If the baseline data was gathered using a different instrument than the one used at follow-up, choose ‘no’. Example: a study assesses disability at baseline by asking about employment status and at follow-up using Instrumental activities of daily living (IADL)

If the study uses more than one instrument to measure outcome during the follow-up, and you choose “yes” for this question, please specify in the comment section which one of these instruments were used at baseline.
ii. How was the baseline data on impairment/limitations/disability/quality of life gathered?
If the data was gathered before ICU admission, choose ‘prospective’ from the dropdown menu.
If the data was gathered after admission to ICU, choose ‘retrospective’ from the dropdown menu.
Choose ‘not reported’, if details are not provided in the study.
If the details are given but they are not clear, choose ‘unclear’.

iii. Who provided baseline data on impairment/limitations/disability/quality of life?
If the data was gathered by interviewing the patient, choose ‘patient interview’.
If the data was gathered by interviewing the proxy (i.e. relative/spouse/friend), choose ‘proxy interview’.
If the data was gathered by reviewing the patient charts and medical records, choose ‘chart review’.
Choose ‘not reported’, if details are not provided in the study.
If the details are given and it is not clear to you, choose ‘unclear’.

*Note that you can choose more than one option*

c) What was the maximum number of follow-up visits at which impairment/limitations/ restrictions/quality of life was assessed?

Enter the maximum number of follow-up visits for any participant in the study.
For example: If a study assesses patients 3, 6, and 12 months after ICU discharge; the maximum number of follow up visits is 3.
If it is a cross-sectional study and it collects data only at one specific point of time, treat that time point as a follow-up visit and enter “1.”

For example: The study wants to assess the prevalence of PTSD in patients who were admitted in an ICU. They select the patient cohort and send questionnaires to all the patients admitted between Jan 2000 and Dec 2006. Even though the patients may be at different points of time since their ICU discharge, this should be recorded as 1 follow-up visit.

d) What was the maximum duration of follow-up on impairment/limitations/restriction/quality of life in months?

Cohort studies: If a cohort study follows assesses patients 3, 6, and 12 months after ICU discharge, the maximum duration of follow-up visits would be 12 months, even if the actual time of the last follow-up visit was not exactly 12 months for all participants. For example, if the actual date of the last follow-up visit ranged from 11 – 14 months, you should still enter 12 months.

If it is a cross-sectional study and it collects data at one specific point of time by sending questionnaires/phone interviews the mean or median number of months to survey or interview completion should be entered. If a range of completion times is given take the middle value within the range. For example, if a study reports that follow-up interviews were conducted between 11 and 15 months after ICU discharge, you were enter 13 (the middle of the range) in this field.

Example: The study wants to assess the prevalence of PTSD in patients who were admitted to an ICU. They select the patient cohort and send questionnaires to all the patients admitted between Jan 2000 and Dec 2006. The patients send back the filled questionnaires at a range of 2-18 months post ICU discharge. In this example, 10 months should be recorded as the maximum duration of follow-up.
18. If you have any concerns/comments regarding the article, enter in the last field - ‘Is there ANYTHING about this paper which requires additional reviews or concerns you? If so, describe it here.’
APPENDIX

The following instruments should be listed as “other” in their respective categories.

**Appendix Table 1**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INSTRUMENT</th>
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<tbody>
<tr>
<td>IMPAIRMENT</td>
<td>ICU Memory Tool</td>
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<td></td>
<td>T.O.P.</td>
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<tr>
<td>ACTIVITY LIMITATIONS</td>
<td>Tests measuring neuropsychological/cognitive impairments, such as Thurstone Word fluency or Rey Osterreith Complex Figure</td>
</tr>
<tr>
<td>PARTICIPATION RESTRICTION</td>
<td>Canadian Cardiovascular Society Grading Of Angina Pectoris Functional Performance Inventory (FPI) Functional Assessment Of Chronic Illness Therapy(FACIT)</td>
</tr>
<tr>
<td>QUALITY OF LIFE</td>
<td>Brief Illness Perception Questionnaire P.O.L.O.</td>
</tr>
<tr>
<td></td>
<td>Functional Limitation Profile (FLP) is same as Sickness Impact Profile (SIP)</td>
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</table>
Appendix Figure 1: Screen shot of the REDCap form used to abstract data for the scoping review.