Medical Condition Form

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Form Sections	Special Considerations	Where/Jump To?
Medical Condition	None	[Yes/No]

3

Form Properties	Yes/No
Visit name?	N/A
Primary form of visit?	N/A
Are subjects allowed more than 1 of this form type?	Yes
If yes, allow entry of another after submission?	Yes
Is the investigator required to sign off on the form?	No
Separate review/submit link?	No
Will the form display/include a summary page upon submission?	No
Will the form display/include a show full form page upon submission?	Yes

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Medical Condition Section

Section Properties	Yes/No
Primary section of form?	Yes
May the section be saved and finished later?	No
Is the section editable?	Yes
Is the section viewable?	Yes
Is the section printable?	Yes
Is the section updateable?	No
Should the section be pre-populated with data from the most recently submitted form?	No
What is the primary date field for the section?	N/A

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8 ***Medical Condition***
9 **tblMedicalConditionDE**
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11 For notes and comments on annotating validations see "Standard Development & Field Validations" in IOMWiki.
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Subject ID: PtID

Namecode: Namecode

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Previously Entered Data (programming note: also use for signoff)

Pre-existing Conditions

Condition	Approx. duration pre-enrollment	Treated with medication	Status/Resolution
ParentMedCondListID	MedCondPreStartCat	MedCondPreStartTreat	MedCondResolution

Medical Conditions Identified after Enrollment

Condition	Diagnosis Date	Treatment	Status/Resolution
ParentMedCondListID	MedCondDiagDt	MedCondTrt	MedCondResolution

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Previously Entered Data --- data resolution	
Grid grouping	IF MedCondPreStart = yes display data in "Pre-existing Conditions" grid IF MedCondPreStart = no display data in "Medical Conditions" grid
MedCondDiagDt	IF MedCondDiagDtUnk display 'Unknown' ELSE MedCondDiagDt IF MedCondDiagDtApprox append ' (approximate)' to display
MedCondTrt	IF MedCondTrt = 'Other' display 'Other: ' + MedCondTrtOtherDs Else MedCondTrt
MedCondResolution	IF MedCondResDt display MedCondResDt IF MedCondResDtApprox append ' (approximate)' to display
Note	Column header text of "Status/Resolution" is being used to accommodate this grid to be used when data is displayed for templates 01 & 02. Which will be the case for protocols which did not update to use 03.

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17 *BM1(default): Estimate dates if necessary. If only the year is known, enter 'January' as the month. When day*
18 *of month is required but unknown, enter '1'. Enter all medication treatment at the time of enrollment and*
19 *started after enrollment on the Medications Form after entering the medical condition on this form. **End BM1***
20
21 *BM2 (default): Record medications in use during the study on the Medication Form. **End BM2***
22
23 **Medical Condition Information**

ParentMedCondListID	**1. Select Medical Condition _____** *Auto-complete textbox:* **DEReqd**
	Use reference below to view a list of Medical Conditions by system: *(Medical condition must be copied into question 1 - above.)*
	Uses MedicalConditionsReferenceCrf server control Add the following tag to display control on the template: <jaeb: MedicalConditionsReferenceCrf ID="MedicalConditionsReferenceCrf" runat="server" />
	Note: If the medical condition you are looking for is not in the list, please click here to send an email to request the condition be added to the list. (Link: Set Subject of email to 'DRCRnet – Add New Medical Condition', To: [ProjectNamemedcondlist@jaeb.org])
	Uses MedicalConditionsContactCrf server control Add the following tag to display message on the template: <jaeb:MedicalConditionsContactCrf ID="MedicalConditionsContact" runat="server" />

MedCondPreStart	2. **Present prior to study enrollment? DEReqd**
	    Yes No
	
	    If Yes then 2a(i, ii) required and 2b(i, ii) must be null
	    If No then 2b (i, ii) required and 2a (i, ii) must be null
	
	    2a. If YES (present prior to enrollment), complete the following:

MedCondPreStartCat	**i. Approximate duration prior to enrollment:** *dropdown from (tblValueList)*
	        -<=7 days, 8-14d, 15-30d, >30d- <=3m, >3m-<6m,>=6m-<12m, 18m, 2y, 3y, 4y,
	        5y, 6y, 7y, 8y, 9y, 10y, 11-20y, 21-30y, 31-40y, 41-50y, >50y

MedCondPreStartTreat	**ii. Treated with Medication Current Past Never** **2b. If NO (started after enrollment/randomization)**

MedCondDiagDt
MedCondDiagDtApprox
MedCondDiagDtUnk
	i. Date of diagnosis: ___ ___/___ ___/ ___ ___ ___ ___*dd/mmm/yyyy*
	      ☐Approximate ☐Unknown
	      If Unknown not checked then 'Date of diagnosis' required
	      Date of Diagnosis >= tblPtRoster.BirthDt (Use end of month since
	         MedCondDiagDt may be approximated)
	      If Unknown checked then 'Approximate' must not be checked and 'Date of
	         diagnosis' must be null

MedCondTrt
MedCondTrtOtherDs
	ii. Treatment of the medical condition
	        None Medication Surgery Medication and Surgery
	        Other _____ **If Other then description required**
	                       If <> Other then description must be null
	
	    If "Medication" or "Medication and Surgery" then message prior final submission =
	    "Please complete the Medications form since you indicated that a medication was
	    prescribed."

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25 ==**BM3 (default)**: *Enter the resolution date for all conditions active at the time of enrollment or develop later that resolve*==
26 ==*during study.***End BM3**==
27

	RESOLUTION

MedCondResDt
MedCondResDtApprox
	1. **Date of resolution:** ___ ___/ __ __ __/__ __ __ __ *(dd/mmm/yyyy)*
	   ☐**Approximate**
	   If not null, must be <= today and:
	     >= onset date (where onset date is enroll date minus time in question 2a -
	   # of days between EnrollDt and Date of Resolution must be <= upper limit of
	   timeframe in MedCondPreStartCat(#2a.)
	     OR >= Date of Diagnosis
	     OR Diagnosis date must be unknown.

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30 **Comments**   **FormCmts**

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VALIDATIONS

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EXTRA INSTRUNCTIONS
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41   N/A
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45   ***REVIEW AND SUBMIT***
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48 **UPDATES TO DATABASE AND MESSAGES TO DISPLAY**
49 *Standard processing only*
50
51 **MESSAGE TEXT**
52 *None*
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54
55 **Created By:** Werner Sauer
56 **Developed By:** Werner Sauer
57 **Documentation Date:** 01/08/2010
58 **Task Description:** Data entry form for site to enter Medical Condition Form for a subject.
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60 **Website Menu:** Protocol ->Subject Dynamic Menu -> Medical Condition
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62 **Flow:**
63 *Standard processing based on tblForm configuration.*
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65 **Objects Used:**

Object Name	Selects	Inserts	Updates
tbl<Protocol>MedicalConditionDE		x	x
tbl<Protocol>MedicalCondition	x	x	
usp_JFE_Lookup_Auto_MedCondList	x		
ufn_GetPreStartCatDays	x		

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68 **Template Revisions** (Enter explanation when template filename changes)

Template File Name	Date Revised	Reason Revised
MedicalConditions_a_01	Initial	NA
MedicalConditions_a_01	8/18/2011	Redefined previous data list so that it is usable for SignOff

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Deleted: F:\user\Development\Study Apps -
Patient\RTS\Medical Condition\MedicalConditions_01.docx