CURRENT DOCUMENT LIST – Biologics for Children with Rheumatic Diseases (BCRD)

IRAS ID: 24269 Short Title: Safety and effectiveness of biologic treatments in children

	Document Description	***File Name***	***Version***	***Version Date***
1	Protocol	Extended Biologics Study Protocol v3.3_0107026_final	3.3	01/07/2026
2	Information sheet (under 6)	very_young_CHILDRENS_INFO_SHEET_V6_19052021	6	19/05/2021
3	Information sheet (6-10 years)	CHILDRENS_INFO_SHEET_V6_19052021	6	19/05/2021
4	Information sheet (11-15 years)	very_young_CHILDRENS_INFO_SHEET_V6_19052021	6	19/05/2021
5	Information sheet (16-18+ years)	INFO SHEET ADULT_V4.1_01092026	4.1	01/09/2026
6	Information sheet (Parent)	INFO SHEET PARENT_V7_01/07/2026	7	01/07/2026
7	Assent form (7-15 years)	ASSENT FORM_V6_19052021	6	19/05/2021
8	Consent form (16+ years)	CONSENT FORM_PARTICIPANT_V8_01092026	8	01/09/2026
9	Consent form (parent)	CONSENT FORM_PARENT_V7_01072026	7	01/07/2026
10	Invitation letter (participant 16+ years)	Invitation-Letter_for_participantOver16_V1_15102013	1	15/10/2013
11	Invitation letter (parent)	Invitation-Letter_V1_15092009	1	15/09/2009
12	GP letter	GP letter_Version1_15092009	1	15/09/2009
13	Participant diary	BCRD_diary_V1_12_08_2011	1	12/08/2011
14	Baseline registration questionnaire	Clinician_baseline V6_10/05/2022	6	10/05/2022
15	Follow-up questionnaire	Clinician follow up V6_10/05/2022	6	10/05/2022
16	Event of special interest pack (serious adverse event validation questionnaires)	ESI_pack_version3_06032025	3	06/03/2025
~~***17***~~	~~Joint assessment form~~	NO LONGER A STUDY DOCUMENT SINCE OCTOBER 2025	~~1~~	~~18/07/2011~~
18	Withdrawal, migration or death form	Withdraw_Migration or Death Report_15092009	1	15/09/2009
19	CHU-9D form (Age 4-7 parent to complete form. Age 7 years -15 years, child to complete)	CHU9D_v1_18012008	1	18/01/2008
20	Transition to adulthood questionnaire	BCRD_Transition to Adulthood Questionnaire v1 12062013	1	12/06/2013
21	Promotional poster	Biologic studies recruitment poster_v1_12092014	1	12/09/2014
22	Eligible but not recruited form	BCRD_eligible_but_not_recruited	1	01/03/2011
23	Blood sample collection letter	Sample collection letter V1.2 01032016	1.2	01/03/2016
24	Blood sample admin form	Sample collection_admin_form v1.4 06032025	1.4	06/03/2025
25	Saliva sample collection letter	Participant_Saliva_sample_COVER_LETTER_BCRD_V1.2_01032016	1.2	01/03/2016

26	Saliva sample collection letter	parent_Saliva_sample_COVER_LETTER_BCRD_V1.2_01032016	1.2	01/03/2016
27	Saliva sample admin form	SALIVA_Sample collection_admin_form v1.3_06032025	1.3	06/03/2025
28	Saliva sample collection instruction sheet	BCRDsaliva_saliva_sample_collection_instruction_sheet_04_10_2011	1	04/10/2011
29	Core data sheet	BCRD_Core_data_sheet_v1.1_01032016	1.1	01/03/2016
30	Symptom onset form	Symptom onset collection form 01032016	1	01/03/2016
31	*EQ-5D-Y Health Questionnaire Proxy (Guide age: 4-7 years)	BCRD_EQ-5D-Y_Proxy1 v1.2 (ID 54446)	1.2	
32	*EQ-5D-Y Health Questionnaire (Guide age: 8–18 years where appropriate)	BCRD_EQ-5D-Y_v1.0 (ID 25834)	1	
33	*EQ-5D-3L Health Questionnaire (Guide age: ≥11 years where appropriate)	BCRD_EQ-5D-3L_v1.0 (ID 23961)	1	
34	Communications Consent	Communications Consent_v1_20022018	1	20/02/2018
35	Transparency Sheet	IRAS ID 24269 – BCRD Transparency Information Sheet	1	24/05/2018
36	BCRD Remote Recruitment letter	BCRD_Remote_Recruitment_v1_01/07/2020	1	01/07/2020
37	BCRD Remote Reconsent letter	BCRD_Remote_Reconsent_v1_01/07/2020	1	01/07/2020

***The addition of quality of life questionnaire (EQ5D-Y and EQ5D) in Substantial Amendment 5**

The EQ5D (also known as the 'Euro-QoL') has been identified as an appropriate questionnaire to include, as there is a proxy version (EQ5D-Y PROXY 1) for parents/carers to complete in lieu of children 4-7 years old, a version for young people (EQ5D-Y) to be used in participants aged 8-11 years old, and a version used for participants over the age of 11 (EQ5D). The EQ5D team have advised that children up to the age of 18 can use the EQ5D-Y if this is deemed more appropriate by the research nurse/healthcare professional.

Age guidance:

•Age 0-3 = no form completed
•Age 4-7 = parent completes the EQ5D-Y PROXY 1
•Age 8-11 = participant should complete EQ5D-Y
•Age 11-18 = participant should complete either EQ5D-Y or EQ5D-3L, as deemed appropriate by the research nurse/study team at the hospital
•Age 18 and above = participant should complete EQ5D-3L