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

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

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|  | ***Document Description*** | ***File Name*** | ***Version*** | ***Version Date*** |
| ***1*** | Protocol | Extended Biologics Study Protocol v3.1\_28/11/2023 | 3.1 | 28/11/2023 |
| ***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\_V3\_19052021 | 3 | 19/05/2021 |
| ***6*** | Information sheet (Parent) | INFO SHEET PARENT\_V6\_19052021 | 6 | 19/05/2021 |
| ***7*** | Assent form (7-15 years) | ASSENT FORM\_V6\_19052021 | 6 | 19/05/2021 |
| ***8*** | Consent form (16+ years) | CONSENT FORM\_PARTICIPANT\_V6\_19052021 | 6 | 19/05/2021 |
| ***9*** | Consent form (parent) | CONSENT FORM\_PARENT\_V6\_19052021 | 6 | 19/05/2021 |
| ***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\_version2\_03102014 | 2 | 03/10/2014 |
| ***17*** | Joint assessment form | BCRD\_JointAssessment\_V1\_18072011 | 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 v1.3 05062018 | 1.3 | 05/06/2018 |
| ***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 v1.201032016 | 1.2 | 01/03/2016 |
| ***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*** | Macrophage Activation Syndrome ESI pre bio | ESI\_MAS pre biologic v1.0\_BCRD | 1 | 14/01/2020 |
| ***37*** | Macrophage Activation Syndrome ESI after bio | ESI\_MAS on biologic v1.0\_BCRD | 1 | 14/01/2020 |
| ***38*** | BCRD Remote Recruitment letter | BCRD\_Remote\_Recruitment\_v1\_01/07/2020 | 1 | 01/07/2020 |
| ***39*** | BCRD Remote Reconsent letter | BCRD\_Remote\_Reconsent\_v1\_01/07/2020 | 1 | 01/07/2020 |
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**\*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