CURRENT DOCUMENT LIST – British Society for Paediatric and Adolescent Rheumatology Etanercept Study (BSPAR ETN)

IRAS ID: IRAS 42118

	Document Description	*File Name*	*Version*	*Version Date*
1	Protocol	BSPAR ECS Protocol_V10_01072026	10	01/07/2026
2	PIS – parents	BSPAR_ETN_INFO SHEET PARENT_V7 01072026_CLINIC	7	01/07/2026
3	PIS – adult patients (16-18)	BSPAR_ETN_INFO SHEET ADULT_V3.1 01092026_CLINIC	3.1	01/09/2026
4	PIS – adolescents	BSPAR_ETN_INFO SHEET YOUNG PERSON_V5 10042018	5	10/04/2018
5	PIS – children	BSPAR_ETN_INFO SHEET CHILDREN_V5 10042018	5	10/04/2018
6	PIS – very young children	BSPAR_ETN_INFO SHEET VERY YOUNG CHILDREN_V2 10042018	2	10/04/2018
7	Consent form – participant	BSPAR_ETN_CONSENT FORM_PARTICIPANT_V8 01092026_CLINIC	8	01/09/2026
8	Consent form – parents	BSPAR_ETN_CONSENT FORM_PARENT_V7 01072026_CLINIC	7	01/07/2026
9	Assent form – children	BSPAR_ETN_ASSENT FORM_V6 10/04/2018	6	10/04/2018
10	Telephone invitation letter	BSPAR_ECS_Telephone Invitation Letter_V2_16052012	2	16/05/2012
11	Telephone PIS – parents	BSPAR_ETN_TELEPHONE INFO SHEET PARENT_V6_01072026	6	01/07/2026
12	Telephone PIS – adult patients (16-18)	BSPAR_ETN_TELEPHONE INFO SHEET ADULT_V3.1_01092026	3.1	01/09/2026
13	Telephone PIS – adolescents	BSPAR_ETN_TELEPHONE INFO SHEET YOUNG PERSON_V4 10/04/2018	4	10/04/2018
14	Telephone PIS – children	BSPAR_ETN_TELEPHONE INFO SHEET CHILDREN_V4 10042018	4	10/04/2018
15	Telephone PIS – very young children	BSPAR_ETN_TELEPHONE INFO SHEET VERY YOUNG CHILDREN_V2_10042018	2	10/04/2018
16	Telephone Consent form – young adults	BSPAR_ETN_TELEPHONE CONSENT PARTICIPANT_V7_01092026	7	01/09/2026
17	Telephone Consent form – parents	BSPAR_ETN_TELEPHONE CONSENT PARENT _V6_01072026	6	01/07/2026
18	Telephone assent form – children	BSPAR_ETN_TELEPHONE ASSENT YOUNG PERSON_V5_10042018	5	10/04/2018
19	Invitation letter	BSPAR_ECS_Invitation-Letter_V2_12022012	2	12/02/2012
20	Invitation letter >16 years	Invitation-Letter_for_participantOver16_V1_14072014	1	14/07/2014
21	Retrospective blood collection information sheet	BSPAR_ECS_Retro_sample_Collection_Info_Sheet_V1_21032012	1	21/03/2012
22	Retrospective blood collection consent form	BSPAR_ECS_Retro_sample_Collection_Consent_V2_14082012	2	14/08/2012
23	Migration / withdrawal / death form	BSPAR_ECS_Withdrawal_Migration or Death Report_21032012	3	21/03/2012
24	Baseline questionnaire	Clinician_baseline V7.1_16032022	7.1	16/03/2022
25	~~Joint assessment form~~	~~BSPAR ECS_JointAssessment_V_1_09022012~~	~~1~~	~~09/02/2012~~
26	ESI pack	ESI Final Pack Version 1 21032012	1	21/03/2012

27	Uveitis ESI updated	BSPAR ECS_Uveitis ESI_V2 09102014_FINAL	2	09/10/2014
28	Follow-up questionnaire	Clinician follow up V8.1_16032022	8.1	16/03/2022
29	Participant diary	BSPAR ECS diary_V1_09022012	1	09/02/2012
30	Retrospective follow-up questionnaire	Clinician Retrospective follow up V1 16042012	1	16/04/2012
31	Transition to Adulthood Questionnaire	BSPAR ECS_Transition to Adulthood Questionnaire v1 12062013	1	12/06/2013
32	GP letter	BSPAR_ECS_GP letter_Version2_12022012	2	12/02/2012
33	Sample collection form	BSPAR_ETN_BLOOD SAMPLE COLLECTION FORM v1.2 01032016	1.2	01/03/2016
43	GP Sample Collection Letter	BSPAR_ETN_GP SAMPLE COLLECTION LETTER V1.2 01032016	1.2	01/03/2016
35	Saliva Collection form	BSPAR_ETN_SALIVA SAMPLE COLLECTION FORM v1.2 01032016	1.2	01/03/2016
36	Saliva collection cover letter – parents	BSPAR_ETN_SALIVA SAMPLE COVER LETTER V1 01032016	1	01/03/2016
37	Saliva collection cover letter – adult patients (16-18)	BSPAR_ETN_SALIVA SAMPLE COVER LETTER ADULT PARTICIPANT V1 01032016	1	01/03/2016
38	Core data sheet	BSPAR ETN_CORE DATA COLLECTION FORM_v1.1_01032016	1.1	01/03/2016
39	Symptom onset collection form	Symptom onset collection form 01032016	1	01/03/2016
40	CHU9D	CHU9D_v1_18012008	1	18/01/2008
41	*EQ5D – 3L	BSPAR ETN_EQ-5D-3L_v1.0 (ID 23961)	1	N/A
42	*EQ5D – Y	BSPAR ETN_EQ-5D-Y_v1.0 (ID 25834)	1	N/A
43	*EQ5D – Y - Proxy	BSPAR ETN_EQ-5D-Y_Proxy1 v1.2 (ID 54446)	1.2	N/A
44	Promotional poster for clinics	Biologic studies recruitment poster_v1_12092014	1	12/09/2014
45	Eligible but not included form	BSPAR ECS_eligible_but_not_recruited	1.1	10/04/2018
46	Communication consent form	BSPAR EN_Communications Consent_v1_10042018	1	10/04/2018
47	Transparency Information Sheet	IRAS ID 42118 - BSPAREN Transparency Information Sheet v1 240518	1	24/05/2018
48	Macrophage Activation Syndrome ESI pre bio	ESI_MAS pre biologic v1.0	1	10/01/2020
49	Macrophage Activation Syndrome ESI after bio	ESI_MAS on biologic v1.0	1	10/01/2020

***The addition of a quality of life questionnaire (EQ5D-Y and EQ5D) in Amendment 7**

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