ICONIC Patient Information Version History

Name of Trial: ICONIC
Name of Chief Investigator: Dr Sandra Strauss

Table 1: Current versions

then:
Table 2: superseded versions

1. Adult consent
2. Parent/guardian consent
3. Adult PIS
4. Parent/Guardian PIS
5. 13-15 yrs PIS
6. 10-12 yrs PIS
7. 06-09 yrs PIS
8. Consultee Declaration Sheet
9. Consultee PIS
10. GP letter
11. SAM questionnaire
12. ED pathway patient questionnaire
13. ED pathway GP questionnaire
14. ED pathway GP information Sheet
15. Patient leaflet or poster
16. Patient case study: broad questions.

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Name of Chief Investigator: Dr Sandra Strauss

ICONIC
IMPROVING OUTCOMES THROUGH COLLABORATION IN OSTEOSARCOMA
A BONE CANCER RESEARCH TRUST FUNDED PROJECT

Table 1: current ICONIC pt information versions:

	Document*	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
Current	Adult consent form	6	17/03/23	• Administrative changes for clarification, reordering, rewording • Addition of names of blood samples and whether patient consents to having these taken outside of standard of care samples for obligatory and optional samples • Addition of details of PMBC samples (for UCLH patients only) • Addition of research samples to consent to all samples being stored for use in future ethically and scientifically approved research in the UK or abroad, including genetic studies.	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	Parent consent form	9	20/06/2023	• Amendment of date and version no. for accompanying PIS.	n/a: non Substantial Amendment	22/06/2023	06/07/2023
Current	Adult PIS	4	17/03/2023	• Administrative changes for clarification, reordering, rewording • Change of target recruitment to at least 350 patients • Change of recruitment time from 4 to 2 years • Deletion of 'it is also possible that you may not have any treatment' • Addition of definitions of each samples type to clarify consent form • Addition of details of PMBC samples (for UCLH patients only)"	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	Parent PIS	6	24/05/2023	• Statement 'We will aim to take a minimum of 5ml for each sample if possible.' Added for Blood Samples. • This will total a minimum of 60ml rather than 200ml.	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	13 – 15 PIS	5	24/05/2023	• Simplification of wording describing blood tests in section 3 and elsewhere • Section 11: . 'Who has checked that the study is safe?' Changed to 'Who has reviewed the study?'	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	10-12 yrs PIS	1	07/03/19	• n/a	10/05/19	16/08/2019	Start of trial
Current	06-09 yrs PIS	1	07/03/19	• n/a	10/05/19	16/08/2019	Start of trial

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Table 1: current ICONIC pt information versions:

	Document*	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
Current	Consultee Declaration Sheet	3	17/03/2023	• Administrative changes for clarification, reordering, rewording • Addition of names of blood samples for obligatory and optional samples • Addition of details of PMBC samples (for UCLH patients only) • Addition of research samples to consent to all samples being stored for use in future ethically and scientifically approved research in the UK or abroad, including genetic studies."	REC: 20/06/2023 HRA: 20/06/2023	22/06/2023	06/07/2023
Current	Consultee PIS	3	17/03/2023	• Administrative changes for clarification, reordering, rewording • Change of target recruitment to at least 350 patients • Change of recruitment time from 4 to 2 years • Deletion of 'it is also possible that you may not have any treatment' • Addition of definitions of each samples type to clarify consent form • Addition of details of PMBC samples (for UCLH patients only)"	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	GP Letter	3	17/03/2023	• Administrative changes: reordering, clarifications, rewording, correction of typos/formatting errors • Change of target recruitment no. from 160 to 350 patients"	REC: 20/06/2023 HRA 20/06/2023	22/06/2023	06/07/2023
Current	SAM Quest/nnaire	3	03/08/2023	• Amended to include missing assessment points (1-4) in section 2 for Question 27 on page 5.	n/a: non Substantial Amendment	04/08/2023	04/08/2023
Current	ED p/way pt quest/nnaire	1	07/03/19	• n/a	10/05/19	16/08/19	Start of trial
Current	ED p/way GP quest/nnaire	2	23/01/2020	• Updated to enable completion of GP ED questionnaire electronically	25/03/2020	08/04/2020	30/04/2020
Current	ED p/way GP info sheet	2	07/06/2019	• Update on use of information on request of HRA.	25/03/2020	16/08/19	Start of trial

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Table 2: superseded patient information documents

no	Document	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
1	Adult consent form	2	22/07/21	• addition of consultee declaration to allow AWI patients to come into Study (see v1 below) updated to v2, 22/08/21 • [English and Welsh sites only, NOT implemented in Scotland.]	REC: 28/07/21 HRA: 31/07/21	02-3/08/21 [English and Welsh sites only, NOT implemented in Scotland.]	06/09/21 [English and Welsh sites only, NOT implemented in Scotland.]
1	Consent form – patient	5	25/06/21	• Amended to current UCL CTC template.	REC: 28/07/21 HRA: 31/07/21	02-3/08/21	06/09/21
1	Consent form – patient	4	25/03/2020	• Aligned with parents ICF: • Option for patient to refuse collection of research samples if they can't be taken at same time as routine bloods • Clarification that patient understands risk of having research biopsy	25/03/2020	08/04/2020	30/04/2020
1	*Consent form – patient*	*3*	*17/02/2020*	• *ICF split into separate patient & parent ICFs at request of REC*	*Not approved*	*Not released, not approved by REC*	
1-2	*Consent form - (combined patient & parent)*	*2*	*23/01/2020*	• *Clarification on which sections are mandatory and which optional* • *'my child' added where applicable*	*Not approved*	*Not released, not approved by REC*	
1-2	Consent form - (combined patient & parent)	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
2	Parent consent form	8	17/03/2023	• Administrative changes for clarification, reordering, rewording • Addition of names of blood samples and whether patient consents to having these taken outside of standard of care samples for obligatory and optional samples • Addition of details of PMBC samples (for UCLH patients only)	*Not approved*	*Not released, not approved by REC*	

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no	Document	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
				• Addition of research samples to consent to all samples being stored for use in future ethically and scientifically approved research in the UK or abroad, including genetic studies.			
2	Consent form – parent/local guardian	7	22/07/21	• Amended to current UCL CTC template. (see v6 below) • Typo: change to #my child's health at point 4	REC: 28/07/21 HRA: 31/07/21	02-3/08/21	06/09/21
2	*Consent form – parent/local guardian*	*6*	*25/06/21*	• *Amended to current UCL CTC template.*	*Not approved*	*n/a*	*n/a*
2	Consent form – parent/local guardian	5	23/03/2020	• 'research' added to risk of child having biopsy	25/03/2020	08/04/2020	30/04/2020
2	*Consent form – parent*	*4*	*19/03/2020*	• *Option for parent to refuse collection of research samples from child if they can't be taken at same time as routine bloods* • *Clarification that parent understands risk of child having biopsy*	*Not approved*	*Not released, not approved by REC*	
2	*Consent form – parent*	*3*	*17/02/2020*	• *ICF split into separate patient & parent ICFs at request of REC (NB no version 2 of parent ICF, as aligned with patient ICF version number)*	*Not approved*	*Not released, not approved by REC*	
3	Adult PIS	3	25/06/21	• Clarification that SAM taken at least 6 monthly	REC: 28/07/21 HRA: 31/07/21	02-3/08/21	06/09/21
3	Adult PIS	2	23/01/2020	• Clarification on collection timelines for ctDNA blood samples • Clarification that research samples may leave UK (to align with ICF)	25/03/2020	08/04/2020	30/04/2020
3	Adult PIS	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
3	Parent PIS	5	17/03/2023	• Administrative changes for clarification, reordering, rewording • Change of target recruitment to at least 350 patients	*Not approved*	*not approved by REC*	

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no	Document	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
				• Change of recruitment time from 4 to 2 years • Deletion of 'it is also possible that you may not have any treatment' • Addition of definitions of each samples type to clarify consent form • Addition of details of PMBC samples (for UCLH patients only)"			
3	Parents PIS	4	22/07/21	• Clarification that SAM taken at least 6 monthly (see v3 below) • Page 1: Typo: Deletion of word 'child' from request to complete PROMs for patients ≤13yrs, requested by REC	REC: 28/07/21 HRA: 31/07/21	02/08/21	06/09/21
4	Parents PIS	3	25/06/21	• Clarification that SAM taken at least 6 monthly	Not approved	n/a	n/a
4	Parents PIS	2	23/01/2020	• Clarification on collection timelines for ctDNA blood samples • Completion of ED questionnaire by parent for patients <13 years • Clarification that research samples may leave UK (to align with ICF)	25/03/2020	08/04/2020	30/04/2020
4	Parent PIS	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
5	13 – 15 PIS	4	17/03/2023	• Administrative changes for clarification, reordering, rewording • Change of target recruitment to at least 350 patients • Change of recruitment time from 4 to 2 years • Deletion of 'it is also possible that you may not have any treatment' • Addition of definitions of each samples type to clarify consent form • Addition of details of PMBC samples (for UCLH patients only)"	*Not approved*	*not approved by REC*	

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no	Document	Vn	Date	Main changes	REC approval date	Date of distribution to sites	Final implementation date
5	13-15 yrs PIS	3	25/06/21	• Clarification that SAM taken at least 6 monthly	REC: 28/07/21 HRA: 31/07/21	02-3/08/21	06/09/21
5	13-15 yrs PIS	2	23/01/2020	• Clarification on collection timelines for ctDNA blood samples • Clarification that research samples may leave UK (to align with ICF)	25/03/2020	08/04/2020	30/04/2020
5	13-15 yrs PIS	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
6	GP letter	2	23/01/2020	• Updated to acknowledge inclusion of GP ED information sheet	25/03/2020	08/04/2020	30/04/2020
6	GP letter	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
7	SAM questionnaire	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
7	SAM Questionnaire	2	17/03/2023	• Administrative changes for clarification, reordering, rewording • Addition of new questions on worries, returning to work/education, treatment from friends/family, intimacy and emotion, pain, painkillers, extremity sarcomas and prosthesis."	REC: 20/06/2023 HRA: 20/06/2023	22/06/2023	06/07/2023
9	ED pathway GP questionnaire	1	07/03/19	n/a	10/05/19	16/08/19	Start of trial
9	ED pathway GP Info sheet	1	07/03/19	n/a, superseded (not sent to sites)	10/05/19	n/a	
10	Pt leaflet or poster	1	07/03/2019	n/a	10/05/19	16/08/19	Start of trial
11	Patient case study – broad questions	n/a	23/01/2020	n/a	25/03/2020	n/a for BCRT use only	Start of trial