

OVERVIEW OF PIL

MREC Ref: 07/MRE00/74
EudraCT No: 2006-005800-15

Protocol No: G0600329

Title: Randomised controlled trial of 6-Mercaptopurine versus placebo to prevent recurrence of Crohn's disease following surgical resection (TOPPIC)

Patient Information Sheet/Leaflet/Booklet

Version	Date	Amendment no.	Description
2	02 May 2007	Initial approval	Parts 1-4 Participant Information Sheet
3	November 2007	Amendment 1	Parts 1-4 Participant Information Leaflet
4	4 July 2008	Amendment 2	Part 1 of Patient Information Leaflet. Part 1 of Patient Information Booklet Part 1/Screening
4	16/06/2009	Amendment 5	Parts 2 and 4 Participant Information Sheet
5	16/06/2009	Amendment 5	Part 1 of Patient Information Sheet Part 1/Screening

Patient Information Sheet

Version	Date	Amendment no.	Description
1	November 2009	Amendment 7	Patient Information Sheet
2	01 August 2010	Amendment 10	Patient Information Sheet

OVERVIEW OF SCREENING CONSENT

Version	Date	Amendment no.	Description
1	01 Dec 2006	Initial approval	Participant Consent Form: Screening Samples
3	November 2007	Amendment 1	Consent for Screening Samples
4	July 2008	Non-substantial amendment approved 28/04/2009	Consent for Screening Samples
5	16 June 2009	Amendment 5	Consent Form for Screening
6	November 2009	Amendment 7	Participant Consent Form for Screening
7	30 September 2010	Non-substantial amendment approved 30/09/2010	Consent for Screening

OVERVIEW OF CONSENT TO TAKE SAMPLES

Version	Date	Amendment no.	Description
1	01 Dec 2006	Initial approval	Participant consent form: To Provide Samples
3	November 2007	Amendment 1	Consent to Provide samples
4	July 2008	Non-substantial amendment approved 28/04/2009	Consent to Provide samples
5	16 June 2009	Amendment 5	Consent for Samples

OVERVIEW OF PARTICIPATION CONSENT

Version	Date	Amendment no.	Description
1	01 Dec 2006	Initial approval	Participant Consent Form: To Take Part
3	November 2007	Amendment 1	Consent to Take Part
4	July 2008	Non-substantial amendment approved 28/04/2009	Consent to Take Part
5	16 June 2009	Amendment 5	Consent Form for Taking Part

1	01 November 2009	Amendment 7	Consent to Take Part
2	30 September 2010	Non-substantial amendment approved 30/09/2010	Consent to Take Part