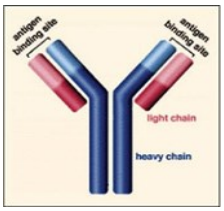

OPTIMAL

Oxford University Hospitals NHS
NHS Trust

Optimising Renal outcome in Myeloma Renal Failure

CASE REPORT FORMS

Patient Initials	Date of Birth	Site Number	Trial Number
	d d - m m - y y y y	0	0

Clinical Trial Coordinator

Late Phase Haematology Research Team

Blue Portacabin

Churchill Drive

Churchill Hospital

Headington

Oxford, OX3 7LE

Telephone: 01865 223353

Fax: 01865 572035

Email: optimal.trial@nhs.net

Version	Date	Author	Reason for Revision
1	13.06.2014	TG	Initial Document
2	24.09.2014	LW & SP	Grammar corrections and inclusion of timeline
3	30.10.2014	LW & SP	1) Added correct address 2) Added note about additional information sheet (CRF 17) 3) Amended "Withdrawal of Consent" section 4) "Amended schedule of forms" table 5) Added patient treatment diary cards
4	12.11.2014	LW & SP	Amended patient detail capture boxes, reference to CFR 17 for additional information, addition of treatment diary cards to CRF schedule.

General instructions for completing Case Report Forms (CRFs)

Completing Forms:

- Ensure all entries are clear, legible and written in black ink.
- Avoid the use of abbreviations and acronyms.
- The CRF should be completed as soon as possible after the scheduled visit.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF.
- CRFs may only be completed by an individual delegated as responsible by the PI.
- CRF Footer section:
    - The “completed by” name should be legible and CRFs should only be completed by individuals on the site signature and delegation log.
    - Each CRF should be signed and dated by the person completing the form.
    - Do not complete the *For Office Use only* section.
- The original CRF should be sent to the Clinical Trial Coordinator with a copy retained at site (ensure when photocopying the page that the copy is added to the CRF booklet in the same place where the original was stored).
- Serious Adverse Events (SAEs) must be sent within 1 business day of the site being aware of the event to the Clinical Trial Coordinator either by fax or email.
- If you have any queries or require clarification about completing a CRF, please contact a member of the Trial Team using the contact details below.
- Completed ORIGINAL CRFs should be sent within 30 days of the scheduled visit to the address below:

Clinical Trial Coordinator
Late Phase Haematology Research Team
Blue Portacabin
Churchill Drive
Churchill Hospital
Headington
Oxford, OX3 7LE
Tele: 01865 223353
Fax: 01865 572035
Email: optimal.trial@nhs.net

Correction to entries:

- If an error is made draw a single line through the entry, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.
- **Do NOT:**
    - Obscure the original entry by scribbling it out.
    - Try to correct/modify the original entry.
    - Use Tippex or other correction fluid.

Additional Information:

- If you run out of space on any CRF please continue on an Additional Information form, CRF 17.

General instructions for completing Case Report Forms (CRFs)

Provision of CRFs:

- All CRFs can be downloaded from the OPTIMAL website: *http://nssg.oxford-haematology.org.uk/myeloma/optimal.html.* When a new version of a CRF is released it will be circulated to centres via email and uploaded onto the OPTIMAL website.

Review of CRFs:

Before sending the CRF to the Trial Coordinator please review it by:

- Checking the legibility of the form entries.
- Checking all corrections have been appropriately made.
- Checking that all appropriate fields have been updated.
    - If a test has not been performed or a measure not taken enter ND (Not Done), if applicable state the reason.
    - If a measure is not required enter NA (Not Applicable).
    - If data is unknown enter NK (Not Known). This should only be used once every effort to obtain the data has been exhausted.

CRF Queries:

- When the form is received at the Optimal Trial Office it will be checked and data entered into a trial database by data management staff.
- Query sheets may be generated which will detail a description of the data being queried, there will be a section to comment on the query.
- A query may require an update to a CRF or just a clarification on the query sheet.
- The query sheet must be signed and dated and the original sent to the Trial Coordinator with a copy retained with the patients CRF.
- Data that are likely to be queried include missing values, ambiguous entries, illogical data and out of range values.

Discontinuation of Treatment:

- If a patient prematurely discontinues treatment, please complete the One Month Follow-Up Form approximately 30 days after discontinuation of treatment, and the 12 Month Follow-Up Form 12 months after randomisation, unless the participant or clinician has requested otherwise.

Withdrawal of Consent

- If a patient withdraws consent to trial treatment whilst on treatment but is happy to complete all follow-up trial assessments, Q of L and sampling, please complete the Withdrawal and Lost to Follow-Up Form, and continue to follow–up the patient as per the trial protocol.
- If a patient withdraws consent to follow-up please complete the Withdrawal and Lost to Follow-Up Form, specifying whether or not the patient would be happy for the trial to collect follow-up information on their status long-term.
- If a patient withdraws consent to trial treatment whilst on treatment and also withdraws consent to follow-up; please complete both the One Month Follow-Up Form and Withdrawal and Lost to Follow-Up Forms, specifying whether or not the patient would be happy for the trial to follow-up information on their status long-term.

Patient Death

- If a patient dies at any point after randomisation please complete the notification of Death Form.

Schedule of Forms

The Schedule of Forms (below) is designed to help you track patient visits. (This form does not need to be sent to the Clinical Trial Coordinator).

FORM No.	CRF Name	Date CRF due (DD/MM/YYYY)	Date Completed (DD/MM/YYYY)	Date Sent (DD/MM/YYYY)
Screening and Randomisation				
1	Screening Form			
2	Eligibility Check List Form			
3	Randomisation Form			
Treatment				
4	OPTIMAL Treatment Form cycle 1			
5	OPTIMAL Treatment Form cycle 2			
6	OPTIMAL Treatment Form cycle 3			
7	OPTIMAL Treatment Form cycle 4			
8	OPTIMAL Treatment Form cycle 5			
9	OPTIMAL Treatment Form cycle 6			
Follow-Ups				
10	One Month Follow-Up (≥ 30 days post final treatment)			
11	12 Month Follow-up Form (12 months post randomisation)			
Event reporting (*these may not be required*)				
12	Serious Adverse Event Reporting Form			
13	Transfer Form			
14	Withdrawal & Lost to Follow-Up Form			
15	Pregnancy Form			
16	Death Form			
Continuation Form (*this may not be required*)				
17	Additional Information Form			
Central Samples				
18	Oxford Sample Request Form	Due at: • Screening & • One Month Follow-Up		
19	Birmingham Immunology Sample Request Form	Due at: • Screening, • End of weeks 1, 2, 3, 4, 5, 6, 9 &12 on treatment & • One Month Follow-Up		

OPTIMAL CRF Completion Timelines

Please ensure that you complete CRFs in the following order:

Screening Form **after consent, before randomisation.**

↓

Oxford Sample Request Form **at screening and at One Month Follow-up post treatment.**

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Birmingham Immunology Sample Analysis Request Form **at screening, at the end of weeks 1, 2, 3, 4, 5, 6, 9 and 12 on treatment; and at One Month Follow-Up post treatment.**

↓

Eligibility Form **complete before randomisation.**

↓

Randomisation Form **before you call to randomise patient.**

↓

Treatment Forms **for cycles 1-4 or cycles 1-6.**

↓

One Month Follow-Up Form **30 days after final treatment (or discontinuation of treatment).**

↓

12 Month Follow-Up Form **at 12 months from randomisation.**

↓

SAE Reporting Form **ASAP within 24 hours of knowledge of SAE (include SAE continuation form to provide additional information if needed).**

↓

Transfer Form **on transfer of patient to another hospital for any reason.**

↓

Withdrawal and Lost to Follow-Up Form **if a patient withdraws from the trial or is lost to follow-up.**

↓

Pregnancy Form A **ASAP within 24 hours of knowledge of pregnancy.**

↓

Pregnancy Form B **ASAP within 24 hours of knowledge of pregnancy outcome.**

↓

Death Form **on death of patient.**

Quality of Life - The EQ-5D questionnaire: **Day 1 of cycles 1-4 & at One Month Follow-Up.**

Original copies of completed Quality of Life Questionnaires should be sent to the OPTIMAL Trial Office. Please do not keep copies at site.

Patient Treatment Diary Cards: **Cycles 1- 4 or cycles 1- 6.**

Original copies of completed Treatment Diary Cards should be sent to the OPTIMAL Trial Office.