NHS
Health Research Authority
Yorkshire & The Humber - Leeds East Research Ethics Committee
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09 June 2016

Professor Janet Brown
University of Sheffield
Weston Park Hospital, Whitham Road
Sheffield
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Dear Professor Brown

Study title:	**The role of ZOLedronic acid and MENOpausal status on the tumour and bone microenvironment in patients with early breast cancer: a single centre, randomised, proof of concept clinical study.**
REC reference:	**16/YH/0151**
Protocol number:	**STH19171**
EudraCT number:	**2015-005713-67**
IRAS project ID:	**197918**

Thank you for your letter of 7th June. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 13 May 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
IRAS Checklist XML [Checklist_07062016]		07 June 2016
Participant consent form [ZOLMENO Consent Form]	1.1	19 May 2016
REC Application Form [REC_Form_07062016]		07 June 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters [GP Letter Group A]	1.0	11 March 2016
IRAS Checklist XML [Checklist_30032016]		30 March 2016
IRAS Checklist XML [Checklist_07062016]		07 June 2016
Other [GP Letter Group B]	1.0	11 March 2016
Other [Student CV]		28 January 2016
Participant consent form [ZOLMENO Consent Form]	1.0	11 March 2016
Participant consent form [ZOLMENO Consent Form]	1.1	19 May 2016
Participant information sheet (PIS) [ZOLMENO Participant Information Sheet]	1.0	11 March 2016
REC Application Form [REC_Form_21032016]		21 March 2016
REC Application Form [REC_Form_07062016]		07 June 2016
Research protocol or project proposal [ZOLMENO protocol]	1.0	11 March 2016
Summary CV for Chief Investigator (CI) [Chief Investigator CV (JEB)]	1.0	11 March 2016
Summary of product characteristics (SmPC) [SPC Zoledronic Acid]	1.0	11 March 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/YH/0151 **Please quote this number on all correspondence**

Yours sincerely

Katy Cassidy

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Copy to: Dr Erica Wallis, Sheffield Teaching Hospitals NHS Foundation Trust