

Participant Study No

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Trial Consent Form

Copy 1
Participant's copy to keep

I have:

- Discussed the study with

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Yes No

- Been given the Information Leaflets about the study
- Received satisfactory answers to my questions.
- Been given satisfactory information about the study.

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

I understand that:

- I have chosen to be randomly allocated to either receiving symptomatic treatment for my Paget's Disease or intensive bisphosphonate therapy.
- I will be asked to fill out questionnaires at specified time intervals after starting the study.
- I may be approached to find out how I am, for some years after starting the study.
- My General Practitioner will be notified that I am taking part in the study.
- My participation is voluntary and that I am free to withdraw from the study at any time without having to give a reason. If I withdraw, this will not affect my future medical care or legal rights.

I agree that:

- information related to my treatment for Paget's Disease may be collected from my hospital or other NHS notes by authorised individuals

I agree to take part in the study

Signature of participant

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Name (in block capitals)

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Date

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I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature of researcher

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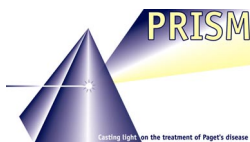
Date

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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I have:

PRISM Trial Office, Health Services Research Unit
Tel: 01224 551106 F

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Participant Study No

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Trial Consent Form

Copy 2

To be returned to the PRISM Trial Office

- Discussed the study with

- | | Yes | No |
|--|--------------------------|--------------------------|
| • Been given the Information Leaflets about the study (Version 2, Aug 2001). | <input type="checkbox"/> | <input type="checkbox"/> |
| • Received satisfactory answers to my questions. | <input type="checkbox"/> | <input type="checkbox"/> |
| • Been given satisfactory information about the study. | <input type="checkbox"/> | <input type="checkbox"/> |

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I agree to take part in the study

Signature of participant

Name (in block capitals)

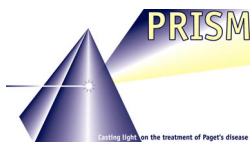
Date

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature of researcher

Date

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Participant Study No

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Trial Consent Form

Copy 3
To be placed in the Patient's Notes

I have:

- Discussed the study with

- | | Yes | No |
|--|--------------------------|--------------------------|
| • Been given the Information Leaflets about the study (Version 2, Aug 2001). | <input type="checkbox"/> | <input type="checkbox"/> |
| • Received satisfactory answers to my questions. | <input type="checkbox"/> | <input type="checkbox"/> |
| • Been given satisfactory information about the study. | <input type="checkbox"/> | <input type="checkbox"/> |

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- I may be approached to find out how I am, for some years after starting the study.
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I agree that:

- information related to my treatment for Paget's Disease may be collected from my hospital or other NHS notes by authorised individuals

I agree to take part in the study

Signature of participant

Name (in block capitals)

Date

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature of researcher

Date

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