Consent Checklist

1.	Has the participant received an oral explanation of the proposed research project?
2.	Has the participant received the information sheets?
3.	Have you told the participant that he/ she will be kept informed of all relevant information which becomes available during the course of the study?

Did your oral explanation to the participant include:

4.	that this is a research project?
5.	participation is voluntary?
6.	the aims of the project?
7.	the likely duration of the participant's involvement? (3 years although there is a possibility that follow-up may continue for some time after that. We will get further permission if this happens)
8.	the expected benefits to the participant and others?
9.	the nature of the intervention ?
10.	the procedures which will be involved in participation? (bone scan, X-ray, blood tests, questionnaires, audiogram in some cases)
11.	that the participant may instead receive a symptomatic treatment?
12.	what risks, GI side effects, inconvenience, discomfort or distress may reasonably be anticipated for this participant: the level and likelihood
13.	that a refusal to participate may be given without reasons and will not affect the care which will be given to the participant?
14.	that the participant may be withdrawn from the study if the investigating physician considers this is necessary in the best interests of the participant?
15.	that personal information may be scrutinised during audit by competent authorities (e.g. Ethical Committees) and properly authorised people, but all personal information will be treated as strictly confidential and will not be made publicly available? That there is a trial office in Aberdeen (with 3 staff).
16.	that information generated by the study may be published but that no details will be divulged from which the participant could be identified?
17.	that some such information will be retained for a period after the end of the trial?
18.	what compensation arrangements are available?(normal NHS complaint and indemnity arrangements)
19.	whom to contact in an emergency and how? (information leaflet Part 3)

20.	Is or has the participant been involved in other research studies? (excluded if Yes)
21.	Is or has the participant recently been taking, or does he/she intend to take, any other medicines or preparations?
22.	Have you allowed the participant sufficient time to consider the matter on his/her own, to discuss with others if wished, or ask you questions?
23.	In your opinion, has the participant understood and consented to take part in this research?