Informed Consent And Subject Information Form ICH Checklist

Drug Code: _____ PROTOCOL NO.:_____

Informed Consent Version No./Date:_____

			COMMENTS
Correct Protocol Title and Study #	Yes ☐	No ☐	
Appropriate Signatures-	Yes ☐	No ☐	
Signature line for legal guardian or impartial witness (if applicable)	Yes ☐	No ☐	
Lines for Printed names	Yes ☐	No ☐	

REQUIRED ELEMENTS (ICH GUIDELINES) (According to ICH 4.8.10 a. to t.)	REVIEW	COMMENTS
1. That the trial involves research	Present ☐ Absent ☐	
2. The purpose of the trial	Present ☐ Absent ☐	
3. The trial treatment(s) and the probability for random assignment to each treatment	Present ☐ Absent ☐ N/A ☐	
4. The trial procedures to be followed, including all invasive procedures	Present ☐ Absent ☐	
5. The subject's responsibilities	Present ☐ Absent ☐	
6. Those aspects of the trial that are experimental	Present ☐ Absent ☐	
7. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant	Present ☐ Absent ☐	
8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this	Present ☐ Absent ☐	
9. The alternative procedure(s) or course(s) of treatment, that may be available to the subject, and their important potential benefits and risks	Present ☐ Absent ☐	
10. The compensation and/or treatment available to the subject in the event of trial-related injury	Present ☐ Absent ☐	
11.The anticipated prorated payment, if any, to the subject for participating in the trial	Present ☐ Absent ☐	
12.The anticipated expenses, if any, to the subject for participating in the trial	Present ☐ Absent ☐	
13. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.	Present ☐ Absent ☐	
14. That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulation and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.	Present ☐ Absent ☐	
15. That records identifying the subject will be kept confidential	Present ☐	

and to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.	Absent ☐	
16. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.	Present ☐ Absent ☐	
17. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contract in the event of trial-related injury.	Present ☐ Absent ☐	
18. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.	Present ☐ Absent ☐	
19. The expected duration of the subject's participation in the trial.	Present ☐ Absent ☐	
20. The approximate number of subjects involved in the trial.	Present ☐ Absent ☐	

Additional Elements for Inclusion in Informed Consent		
The subject must receive a copy of what he/she signed **ICH 4.8.11**	Present ☐ Absent ☐	
Transmission of the Data to other CPOs **EU Directive**	Present ☐ Absent ☐	
Comments/changes requested by the IRB/IEC/HA on *dd-Mmm-yy* have been properly addressed/implemented in current ICF & Patient information version.	Yes ☐ No ☐ NA ☐	

* Ensure also, local regulations are met

ICH Review Completed by:

Name: _____ **Function:** _____
Trial Organizer / Field Monitor/Clinical Trial Leader / Other, e.g. CPO Medical Advisor, CPE/TME

Signature: _____ **Date :** _____
(dd/mmm/yyy)

For ED trial, Medical Review Completed by:

Name: _____ **Function:** _____
CPE / TME / CPO Medical Advisor

Signature: _____ **Date :** _____
(dd/mmm/yyy)

Other comments:

_____

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_____

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Policy

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002
Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in

accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.[1]

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.[2]

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

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[1] **Note of clarification on paragraph 29 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

[2] **Note of clarification on paragraph 30 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

9.10.2004

Trial Drug:	ID	
Protocol:	Center No. ____ Subject No. ____ Subject's initials ____ (1. 2. fam.) Randomization Number ____	

SERIOUS ADVERSE EVENT REPORT

1. REPORT TYPE: ☐ Initial ☐ Follow-up | 2. Country: | 3. CASE ID:

I. ADVERSE EVENT INFORMATION

4. DATE OF BIRTH	5. AGE	6.RACE	7.SEX	8. HEIGHT	9. WEIGHT	10. ONSET OF FIRST SIGN/SYMPTOM OF SAE
day month year	yrs./mo.	☐ Caucasian ☐ Oriental ☐ Black ☐ Other	☐ Male ☐ Female	cm	kg	day month year

11. SERIOUS ADVERSE EVENT(S) IN MEDICAL TERMS (diagnosis, if possible)

Case description of the above SAE (include related signs/symptoms, treatment, course/outcome and suspected cause of the SAE) (continue on P.3 if more space is required):

Is the event due to lack of efficacy? ☐ No ☐ Yes

Is the event due to progression of underlying illness? ☐ No ☐ Yes

EXPEDITED REPORTING CRITERIA

12. CHECK ALL APPROPRIATE TO EVENT

☐ Patient died — day month year

☐ Involved or prolonged inpatient hospitalization

☐ Involved persistence of significant disability or incapacity

☐ Life-threatening

Other Seriousness Criteria:

☐ Congenital anomaly/birth defect

☐ Other significant medical events

II. TRIAL DRUG INFORMATION

13. TRIAL DRUG(S) AT OR BEFORE ONSET OF SAE (If blinded, provide drug package no.)

☐ Drug ☐ None

TRIAL DRUG PACKAGE NO.: N/A

Comments (Continue on P.3 if more space is required):

Drug Code Broken?

☐ No ☐ Yes ☒ N/A

14. LAST VISIT/WEEK BEFORE ONSET OF SAE

VISIT NO.: WEEK NO.:

15. DOSES AT OR BEFORE ONSET OF SAE (total daily dose or specify if other - Add additional pages)	16. ROUTE OF ADMINISTRATION	17. THERAPY DATES (from / to)
		day month year — day month year

18. TRIAL INDICATION	19. THERAPY DURATION UNTIL ONSET OF FIRST SIGNS/SYMPTOM OF SAE	20. TIME ELAPSED BETWEEN LAST DRUG ADMINISTRATION AND ONSET OF FIRST SIGNS/SYMPTOM OF SAE
Advanced Prostate Cancer	hrs/days/months	mins/hrs/days/months

III. HISTORY

21. PATIENT'S PAST MEDICAL HISTORY (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

IV. MANUFACTURER INFORMATION (FOR INTERNAL USE ONLY)

22. DATE MANUFACTURER NOTIFIED OF SAE day month year

23. DATE OF THIS REPORT day month year

24. NAME AND ADDRESS OF REPORTING MANUFACTURER

PLEASE FAX FORM TO LOCAL CS&E FAX NO. ____

Trial Drug:	ID	
Protocol:	Center No. / Subject No. Subject's initials 1. 2. fam. Randomization Number	

SERIOUS ADVERSE EVENT REPORT

1. REPORT TYPE: ☐ Initial ☐ Follow-up | 3. CASE ID:

25. CONCOMITANT DRUGS RELEVANT TO THE SAE (exclude therapy to treat SAE)

DRUG NAME(S)	DOSE / ROUTE	UNIT / SCHEDULE	DATE STARTED day month year	CONT. 0=No 1=Yes	DATE DISCONTINUED day month year	REASON FOR USE

26. COMMENTS (If adverse event is considered to be caused by a comedication, please note it here)

27. ACTION TAKEN (mark all as appropriate)

☐ No Action Taken
☐ Trial drug permanently discontinued due to this adverse event
☐ Concomitant medication taken
☐ Trial Drug dosage adjusted/temporarily interrupted *
☐ Non-drug therapy given **
☐ Hospitalization/prolonged hospitalization

* If ticked, enter new dosage information in field 11
** If ticked, provide therapeutic measures in field 11

28. TEST / LABORATORY FINDINGS (enter only those findings necessary for SAE diagnosis or course description)

TEST/ LAB NAME	UNIT	DATE day month year	VALUE	DATE day month year	VALUE	DATE day month year	VALUE

29. COMMENTS ON TEST/LABORATORY FINDINGS (Provide normal ranges on Pg. 3 if not already provided.) (If the SAE is a laboratory abnormality, enter comments on clinical findings and/or treatment in field 11.)

30. OUTCOME OF THE PATIENT/SAE

☐ Completely Recovered — Date of recovery: Day Month Year
☐ Recovered with sequelae
☐ Condition improving
☐ Condition still present and unchanged
☐ Condition deteriorated
☐ Death — Autopsy: ☐ No ☐ Yes

31. ASSESSMENT OF CAUSALITY

Relationship to study drug ☐ Not suspected ☐ Suspected

V. INFORMATION SOURCE

32. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR

Signature:

32. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT

day month year

PLEASE FAX FORM TO LOCAL CS&E FAX NO.

Trial Drug: Zometa (Zoledronic Acid) Protocol: CZOL446E2432	ID Center No. Subject No. Subject's initials 1. 2. fam. Randomization Number	

SERIOUS ADVERSE EVENT REPORT

1. REPORT TYPE: ☐ Initial ☐ Follow-up	3. CASE ID:

FOR ADDITIONAL INFORMATION:

V. INFORMATION SOURCE

32. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR	32. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT
Signature:	day month year

PLEASE FAX FORM TO LOCAL CS&E FAX NO.