

Annex No. 4
to the Regulation on the Organization and Functioning
of the Scientific Research Ethics Committee

INFORMED CONSENT FORM

MODEL

PROJECT TITLE:	EFFECT OF NATURAL COMPOUNDS ON BACTERIAL PLAQUE
Purpose of the Study	<p>This research is conducted by Dr. Ioana Lile from "Vasile Goldiș" Western University of Arad. You are invited to participate in this research project because you present gingival inflammation.</p> <p>The purpose of this research project is to compare the effects of commercial mouthwashes and herbal infusions on oral health, particularly in reducing dental plaque, gingival inflammation, and improving breath freshness. The study aims to investigate the effectiveness and acceptability of these types of substances in order to determine which of them may provide more significant benefits for participants' oral health.</p> <p>Study Duration: 6 months</p> <p>The results of this project will be used for publication in scientific journals.</p>
Procedures	<p>Intervention:</p> <ul style="list-style-type: none">- Participants will use the mouthwashes according to specific instructions. These instructions will include frequency and duration of use (typically twice a day for 28 days).- Correct and consistent use throughout the study period will be monitored. <p>Monitoring Evaluations:</p> <ul style="list-style-type: none">- After 7, 14 and 28 days of using the mouthwash, participants will be re-evaluated to check the effects of the products on oral health. <p>The evaluations will include:</p> <ul style="list-style-type: none">- Measurement of dental plaque and gingival inflammation.- Assessment of breath freshness.- Completion of a satisfaction questionnaire to evaluate product acceptability (taste, sensation, ease of use, etc.).
Potential Risks and	<p>Participation in this project may involve certain potential risks or degrees of discomfort during or after the study, such as:</p> <ul style="list-style-type: none">• Allergic Reactions:

Discomforts	<ul style="list-style-type: none"> - There is a risk of allergic reactions to components in the mouthwashes, especially if the participant has previously unidentified sensitivities. - Safety Measures: Participants will be screened prior to the start of the study to identify any known allergies. They will also be monitored for any adverse reactions during the study. <ul style="list-style-type: none"> • Oral Mucosal Irritation: <ul style="list-style-type: none"> - Mouthwashes, regardless of type, may cause temporary irritation of the oral mucosa, gums, or tongue, especially if used improperly or if there is individual sensitivity. - Safety Measures: Participants will be instructed on the correct use of the mouthwash and monitored for any signs of irritation. • Discomfort or Temporary Taste Changes: <ul style="list-style-type: none"> - Some participants may experience unpleasant taste, dryness, or other unusual sensations after using the rinses, which may affect their overall experience. - Safety Measures: Participants will be informed about the possibility of these effects and encouraged to report any discomfort.
Possible Benefits	<p>There are no direct benefits for participants. However, potential benefits may include:</p> <ul style="list-style-type: none"> - Participants using the mouthwashes included in the study might notice an improvement in their oral health, including a reduction in plaque, gingivitis, and other gum issues, depending on the efficacy of the tested products. - This may lead to a reduced risk of dental caries, gingival inflammation, and other oral problems. We hope that, in the future, others may benefit from this study through improved understanding of oral hygiene and plaque control.
Confidentiality	<p>Any potential disclosure of confidential data will be minimized by storing data in a secure location, such as a locked office or cabinet, or on a protected computer, and retained for a duration in accordance with current legislation. Stored data will be destroyed after the legal retention period.</p> <p>If we write a report or article about this research project, your identity will be protected to the greatest extent possible. Your information may be shared with representatives of "Vasile Goldiș" Western University of Arad or with government authorities if you or someone else may be in danger or if the law requires it.</p>

Medical Treatment	The university does not provide medical insurance, hospitalization, or other insurance rights to participants in this study, nor any medical treatment or compensation for any injury resulting from participation in the study, except as provided by law.	
Participant Rights to Withdraw and Ask Questions	<p>Your participation in this research is entirely voluntary. You may decide not to participate at all. If you do choose to participate, you can withdraw at any time. In either case (choosing not to participate or withdrawing later), you will not be penalized in any way and will not lose any benefits you are entitled to.</p> <p>If you decide to withdraw from the study, if you have questions, concerns, complaints, or if you wish to report an injury or abuse related to the research, please contact the principal investigator: Dr. Ioana Lile +40 745 305 221 drileioana@yahoo.com</p>	
Participant Rights	<p>If you have questions regarding your rights as a research participant or wish to report a research-related injury, please contact:</p> <p>"Vasile Goldiș" Western University of Arad Scientific Research Ethics Committee Address: Bd. Revoluției, No. 94, Arad Email: eticacercetarii@uvvg.ro</p>	
Consent Declaration	<p>Your signature indicates that you are an adult (at least 18 years old), that you have read or been read this informed consent form, that your questions have been answered satisfactorily, and that you voluntarily agree to participate in this research. You will receive a signed copy of this informed consent form.</p> <p>If you agree to participate, please sign below:</p>	
Date and Signature	Participant's Name:	
	Participant's Signature:	
	Date:	