

Time 15.8.2012 klo 13:00-14:55

Place Biomedicum Helsinki 1, Bottom floor, Meeting room 4

Participants

	Name	Task	Time	Further information
PRESENT	Tilvis Reijo	Chairman	13:00-14:55	
		prof		
	Lauhio Anneli	Vice chairman	13:00-14:55	
		Assistant prof		
	Tammilehto Lauri	Vice chairman	13:00-14:55	
		Assistant prof		
	Atula Sari	Member	13:00-14:55	
	Eriksson Ulla	Member	13:00-14:55	
		Nursing science representative		
	Sipponen Taina	Member, MD	13:00-14:55	
	Toivonen Lauri	Member	13:00-14:55	
		Assistant prof		
ABSENT	Ylikarjula Simo	Layperson	13:00-14:55	
	Lindgren Briitta	Layperson	13:00-14:55	
	Sorsa Pirjo	Member		
		Management law specialist		
	Pohja Marjatta	Deputy member		
	Vuorinen Riitta	Deputy member, Nursing science representative		
	Ristola Matti	Deputy member, Assistant prof		
	Yki-Järvinen Hannele	Deputy member, Prof		
OTHER	Roine Risto P.	Deputy member, Assistant prof		
	Sovijärvi Anssi	Deputy member, Prof		
	Hippi Monica	Secretary	13:00-14:55	

#### STATEMENT OF THE LEGITIMACY AND QUORUM

The meeting was found legitimate and with quorum present.

#### ACCEPTANCE OF AGENDA

The agenda was accepted.

#### REVIEWING OF THE RECORD

It was agreed that the record will be copied for the next meeting in order to be reviewed.

#### ACCEPTANCE OF RECORD FROM THE PREVIOUS MEETING

The record from the meeting 9/2012, 27.6.2012 was accepted with the remark, that the legal incompetence of Lauri Toivonen had been recorded incorrectly on the cover. Should be §§ 104 and 142.

#### NEXT MEETING

The next meeting is to be held on the 5<sup>th</sup> of September at 13:00, Biomedicum 1, meeting room 4, P-floor.

251/13/03/01/12 NEW RESERCAH PLAN

251/13/03/01/2012

TMK11 § 161

Publicity	Confidential (JulkL 621/199, 24 §)
Study name	IBS.2: Effect of probiotic supplement in alleviating functional gastrointestinal symptoms
Description	The review board has received for review a new single centre clinical trial study.
Principal investigator	MD PhD Lea Veijola, Herttoniemi Hospital
Investigators	At a private clinic in Helsinki: -MD PhD Lea Veijola, MD Janne Rajala, MD PhD Markku Hillilä
Study sponsor and conductor	Danisco Sweeteners Oy, Sokeritehtaantie 20, 02460 Kantvik
Delivered documents	<ol style="list-style-type: none"><li>1. Cover letter, version 1, 5.7.2012</li><li>2. Application for the ethical board, 5.7.2012</li><li>3. Study protocol in English, version 1 / 040712</li><li>4. Summary of the study protocol in Finnish, version 1, 4.7.2012</li><li>5. Subject information leaflet and Subject information leaflet/Additional study, version 1/040712</li><li>6. Consent form and Consent form/Additional study, version 1 / 040712</li><li>7. Description of study registry for clinical trial, 5.7.2012</li><li>8. Anamnesis form, version 1, 050712</li><li>9. Sample donation and delivery instructions, version 1, 050712</li><li>10. Questionnaire 1 (IBS-SSS), version 1</li><li>11. Questionnaire 2 (AR), version 1</li><li>12. Questionnaire 3 (IBS-QoL), version 9, 12.1.2012</li><li>13. Questionnaire 4 (Bristol) , version 1</li><li>14. Questionnaire 5 (HADS), version 1</li><li>15. Principal investigators statement on the ethics of the study, Lea Veijola, 5.7.2012</li><li>16. CV Lea Veijola</li><li>17. Clarification on financing and investigators' compensations, version 1, 4.7.2012</li><li>18. Newspaper advertisement, version 1, 4.7.2012</li><li>19. List of products to avoid, version 1, 5.7.2012</li><li>20. Product liability insurance</li></ol>
Draft resolution	<p>The Ethical Committee decides</p> <ol style="list-style-type: none"><li>1. on the matter during meeting proceedings,</li><li>2. collects a statement fee of 2 200 euros (STM act 46/2012, 1 § 1 mom. 2-article)</li></ol>

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Statement	<p>The Ethics Committee sees, that the study protocol and its attachments abide the regulations implemented by the laws (488/99 and latter modifications) and acts (986/99 and latter modifications) on medical research, on confidentiality, and international regulations on clinical trials and concerning clinical trial subjects that apply to medical research on humans.</p> <p>The Ethical Committee considers the study protocol ethically acceptable and decides to</p> <ol style="list-style-type: none"><li>1. give a favorable statement.</li></ol> <p>Any issues concerning the statement will be responded to by the chairman.</p> <ol style="list-style-type: none"><li>2. collect a statement fee according to the draft resolution.</li></ol> <p>The statement of the Ethical Committee is not subject to appeal. If the ethical approval is denied, the applicant may apply for an approval again. If the applicant requests, the local Ethical Committee must present a statement from the national Ethical Committee before giving a new statement (Research law 488/1999 and latter modifications).</p> <p>Liability to pay may be appealed against, if the fee has been incorrectly designated. Instructions for appeal are attached.</p>
Additional information	<p>Chairman Reijo Tilvis, Tel. 050 428 6480</p> <p>Committee secretary Monica Hippi, Tel. 050 427 9345, 09 471 71607.</p> <p>The record extract from the non-reviewed record is certified by</p> <p>Helsinki, 17.8.2012</p> <p>(signature)</p> <p>Monica Hippi</p> <p>secretary</p>
Sent for information	17.8.2012
Attachment	Instructions for appeal
Distribution	Anna Lyra, Danisco Sweeteners Oy, Sokeritehtaank. 20, 02460, Kantvik MD PhD Lea Veijola, Herttoniemi Hospital, Kettutie 8 I, 00800 Helsinki

Verification of an unofficial translation of the Ethical Committee record extract 10/2012 on the IBS.2: Effect of probiotic supplement in alleviating functional gastrointestinal symptoms –study ethical approval statement.



Julia Tennilä

Scientist

DuPont Nutrition and Health



Päivi Nurminen

H&N Platform Manager

DuPont Nutrition and Health