freiburger
ethik-kommission
founded 1980
international

Review Request Form

clinical study

Version 30.06.2003

Mozartstr. 21
D-79104 Freiburg
Telephone: +49 (0)761 32007
Fax.: +49 (0)761 23313
e-mail: graf@feki.com

Study Title

Study Code or Study Number

Code 1	Code 2

see: Guideline for the review request form clinical study *Version 30.06.2003*
(the guideline should not be submitted with the rewiew request form)

1. Data on the Persons in Charge

1.1 Party Requesting Review		*1.2 Principal Investigator*	
Name/ Titel		**Name/ Titel**	
Company / Institute / Clinic		**Company / Institute / Clinic**	
Qualification / Position		**Qualification / Position**	
Street / Zip Code / City / Country		**Street / Zip Code / City / Country**	
Phone:	**Fax:**	**Phone:**	**Fax:**
e-mail:		**e-mail:**	

1.3 Sponsor		*1.4 Invoice Recipient*	
Name/ Titel		**Name/ Titel**	
Company / Institute / Clinic		**Company / Institute / Clinic**	
Street / Zip Code / City / Country		**Street / Zip Code / City / Country**	
Phone:	**Fax:**	**Phone:**	**Fax:**
e-mail:		**e-mail:**	

Study Code or Study Number

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2. The following required documents were submitted as listed below:

(each document can be sent alternatively by e-mail and / or fax and / or post)
(please mark the appropriate box e-mail, fax, post with a cross, if the document was submitted; if not, leave empty)

Document	*Version / Number / Date*	*e-mail*	*fax*	*post*
2.1 Informal Covering Letter		☐	☐	☐
2.2 Review Request Form clinical study	Version 30.06.2003	☐	☐	☐
2.3 Study Protocol (Protokol-synopsis should be included in the protocol)		☐	☐	☐
2.4 Informed Consent (both in the national language and in German)		☐	☐	☐
2.5 Investigator's Brochure Produkt Information		☐	☐	☐
2.6 Verification of Insurance Policy Covering Test Subjects (copy)		☐	☐	☐
2.7 Principal Investigator's CV		☐	☐	☐
2.8 Confidentiality Statement (if required)		☐	☐	☐
2.9 Copy of CE Certificate (if available) (applicable only for Medical Devices)		☐	☐	☐
2.10 Case Report Form (CRF)		☐	☐	☐
2.11 Information Concerning Test Subject / Patient Recruitment		☐	☐	☐
2.12 Information Concerning the Qualification of the Study Center		☐	☐	☐
2.13 Further Documents (if required) (please add accordingly)		☐	☐	☐
2.14		☐	☐	☐
2.15		☐	☐	☐
2.16		☐	☐	☐
2.17		☐	☐	☐

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3. Details Concerning Test Substance and / or Test Product

3.1 Indication or Name of Test Substance and / or Test Product

3.1.1 Medical Device: Designation according to UMDNS (Universal Medical Device Nomenclature System)
3.1.2 Drug: Scientific abbreviation according to INN, Names of all active ingredients, trade name, if known)
3.1.3 Other: no drug and no medical device (e.g.: cosmetics, nutritional supplements, ...)

3.2 Brief Description and Function of Test Substance and / or Test Product

4. Details Concerning the Clinical Study

(please mark the appropriate box with a cross)

4.1 single center ☐	**4.2 multicenter** ☐	**4.3 multicountry** ☐

(please enter the appropriate date and/or duration (in days oder months oder years))

4.4 expected start of the study: (day / month / year) mm.dd.yy	**4.5 expected end of the study:** (day / month / year) mm.dd.yy	**4.6 expected duration of the study:** ☐ day(s)

(please enter the expected duration (in days or months or years) for the individual test subject / patient in the study, if different from the duration of the whole study)

4.7 expected duration for the individual test subject / patient participating in the study:	☐ day(s)

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5. Details Concerning Study Centers

(please register, if already known at the time of application)

Name / Titel of Investigator	*Company / Institute / Clinic*	*City / Country*
5.1		
5.2		
5.3		
5.4		
5.5		
5.6		

6. List of Existing Votes from Other Ethics Commissions

(please register, if already known at the time of application)
(please submit the vote if already available by e-mail and / or fax and / or post)

Name of Ethics Commissions	*Date of Vote*	*e-mail*	*fax*	*post*
6.1		☐	☐	☐
6.2		☐	☐	☐

7. Further Informal Commentary

(please add, if required)

☐

Place, Date	*Signature of Party Requesting Review*

Study Code or Study Number

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