Study synopsis

Title of the project Subtitle **Comparison of the Freiburg Visual Acuity Test (FrACT) with the EDTRS– and Landoltring Charts** Assessment of the inter–test agreement and the test–retest reliability	**Name of researcher in charge:** xxxxx **Acronym:** FEL_Reli **Date / Version:** 2018-04-19 / V1

1. Aims of this project	
1.1. Main purpose **→ Primary objective** What goals shall be achieved at the end of this project – which results shall be achieved?	To compare 1.1.1. Visual acuity of $FrACT_k$ and $FrACT_h$ 1.1.2. Inter-Test-Agreement between $FrACT_k$ and $FrACT_h$ 1.1.3. Retest-reliability of $FrACT_k$ and $FrACT_h$
1.2. Null Hypothesis for primary objective	1.2.1. Visual acuity results, obtained with $FrACT_k$ and $FrACT_h$ are identical 1.2.2. Retest-reliabilities of $FrACT_k$ and $FrACT_h$ are identical
1.3. Other purpose(s) **→ Secondary objective(s)**	To compare 1.3.1. Visual acuity of $FrACT_k$, $FrACT_h$, ETDRS- and Landoltring Charts 1.3.2. Inter-Test-Agreement between all tests mentioned at 1.3.1 1.3.3. Retest-reliabilities of all tests mentioned at 1.3.1
1.4. Null Hypothesis/es for secondary objective/s	1.4.1. Visual acuity results, obtained with all tests mentioned at 1.3.1 are identical 1.4.2. Retest-reliabilities of all tests mentioned at 1.3.1 are identical
1.5. Specify relevant/critical effect size Please differentiate carefully from statistical significant result!	A difference of more than 2 lines (visual acuity) is specified as relevant
2. Project organization	
2.1. Technical requirements	2.1.1. FrACT (internet version 3.8.1) haptic Landoltring device ($FrACT_h$) and Landoltring-Keypad ($FrACT_k$) 2.1.2. ETDRS Visual Acuity Tester (Steinbeis-Transferzentrum Biomedizinische Optik, Tübingen / Germany) luminance level 237 cd/m^2, surround luminance level 85 cd/m^2 2.1.3. Landoltring-Chart (Visus GmbH, Stuttgart / Germany) luminance level 236 cd/m^2, surround luminance level 84 cd/m^2 2.1.4. VISUCAT monitor with single optotype display (numbers; argus individuell optic GmbH, Putzbrunn / Germany) luminance level 380 cd/m^2, surround luminance level 70 cd/m^2 2.1.5. Laptopdisplay (TravelMate, Acer, 8372 Taipeh / China): luminance level 151 cd/m^2, surround luminance level 75 cd/m^2 2.1.6. Room illuminance level: 250 lx, assessed with digital luxmeter (Peak Tech 5025, Peak Tech Prüf- und Messtechnik GmbH, Ahrensburg / Germany) 2.1.7. Stopwatch (Apple iPhone 4S, Cupertino, CA, USA) 2.1.8. Laser Rangefinder (GLM 80 Professional, Bosch GmbH, Stuttgart / Germany) 2.1.9. luminance meter (used for 2.1.2 – 2.1.5) Minolta Spotmeter (IS-110, Minolta, Tokyo / Japan)

2.2. Tasks	**Name**	**Comments**
1. supervisor	Prof. Dr. med. Ulrich Schiefer	
2. supervisor	xxxxx	
Examiner	xxxxx	
Study group	Vision Research	
2.3. Quality management Contact, meetings, supervision	2.3.1. Continuous e-mail contact between 1. supervisor and the examiner 2.3.2. Regular meetings (1. supervisor and the examiner) in biweekly sequence	

2.4. Time frame	Min. duration (planned): 4 months, after max. 6 months the project has to be finished
2.5. Scheduled launch of the project	April 1st, 2018
2.6. End of the project	July 31st, 2018
3. Project related issues	
3.1. Study design	Pilot study / explorative study
3.2.1. Sample size **3.2.2. Estimation of sample size** needed?	3.2.1. 5 3.2.2. no
3.3. In- and Exclusion criteria? *further specification depending on project* **3.3.1. Inclusion criteria** **3.3.2. Exclusion criteria**	3.3.1. age ≥ 18 years 3.3.2. min. distant visual acuity (with/without correction): 0.2 As long as min. distant visual acuity limits are exceeded, test runs without optical corrections are preferred in order to enhance the spectrum/variety of tested visual acuity values 3.3.3. Ametropia: max. myopia: sph -8,00 dpt, max. hyperopia: sph +5,50 dpt max. astigmatism: cyl 2,50 dpt 3.3.4. no medication that extend reaction time 3.3.5. informed consent
3.4. Recruitment of patients	Aalen university students (except students of ophthalmic optics, terms 2 – 7)
3.5. Randomization	Randomization with respect to the leading eye (see also clause 3.7.5.)
3.6. Data analysis / Statistics	3.6.1. Bland-Altman plots with regard to the evaluation of inter-test agreement and retest-reliability, respectively 3.6.2. Statistical software: GNU R, version 3.1.0 (2014-04-10), Platform: i386-w64-mingw32/i386 (32-bit) combined with Notepad++ version 6.5.5 (2014-03-07)
3.7. Methodology course of the project	3.7.1. Determination oft he leading eye (Rosenbach sighting test) 3.7.2. Randomization of examinations with regard tot he leading eye 3.7.3. For assessment of the visual acuity as an in- and exclusion criterion, the first session of the VISUCAT test with single optotype number charts will be used 3.7.4. Examinees will pass each visual acuity test twice (excluding VISUCAT) 3.7.5. (Balanced) randomization of the sequence of the visual acuity tests (with exception of the initial VISUCAT session) is maintained by a pre-specified randomization list. All examinees will be briefed with respect to each visual acuity test 3.7.6. A forced-choice procedure without feedback regarding correct / false responses will be applied for each acuity test
4. Resources and Costs	
4.1. What **Costs** arise? What **Resources** are needed? *Personnel/Staff, Material costs, Equipment, Space/Rooms*	4.1.1. Ethics committee approval 4.1.2. Staff: 1. and 2. supervisor, further persons in charge 4.1.3. Pre-examination by ophthalmologist 4.1.4. Examination rooms (for ophthalmological examinations) and laboratories
4.2. Insurance needed? **4.2.1. Travel accident insurance** **4.2.2. Subject´s insurance**	4.2.1. yes 4.2.2. no
4.3. Institutional review board / Ethics committee approval needed?	yes

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Date, Signature of the Chief Executor

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Date, Signature of the Co-Operating Research Group(s)

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Date, Signature of the Co-Operating Research Group(s)