APPLICATION FORM
PLEASURE FUND

To ensure comparability of all submitted outline applications, please prepare your application in English not exceeding 6 pages (DIN A4, at least 11 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm and single-spaced lines). The number of pages includes cited literature.

Further, letters of support only by patients, patient representative(s), patients' self-help group(s) or patient advocacy group(s) supporting the requested study are allowed in the appendix. These letters should best be written in English. If the study is supported by stakeholder and patient engagement groups provide a clear and detailed statement on how and by whom the study will be supported in its planning, conduct and result dissemination. Do not submit any other appendices (e.g. letter of intent / letter of support by other parties).

1. STUDY SYNOPSIS

APPLICANT/PRINCIPAL INVESTIGATOR	Name, address, telephone, e-mail
ANCRONYM / TITLE OF STUDY	Descriptive title identifying the study design and population (if applicable: interventions). In case of funding this title shall be quoted on the website of the company.
CONDITION	The condition being studied and how it is related to sexual pleasure and wellbeing
OBJECTIVE(S)	Which principal research questions are to be addressed? For confirmatory studies specify clearly the primary hypothesis that determines sample size calculation.
KEY INCLUSION AND EX-CLUSION CRITERIA	Key inclusion criteria: Key exclusion criteria:
INTERVENTION(S) *(optional, in case of clinical trials)*	*(optional)* *Description of the experimental and the control treatments or interventions as well as dose and mode of application.* Experimental intervention: Control intervention: Duration of intervention per patient: Follow-up per patient:
OUTCOME(S)	Primary endpoint: Key secondary endpoint(s): Assessment of safety:
STUDY TYPE	*e.g. survey, qualitative study, case-control study, randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over, …*
STATISTICAL ANALYSIS	Analyses of primary endpoints (for clinical trials efficacy): Analyses of secondary endpoints: Safety: *Please describe for clinical trials the strategy for assessment of safety issues in the study. Which are relevant safety variables?*
SAMPLE SIZE	To be analysed (n = ...) Optional for clinical trials: To be assessed for eligibility (n = ...) To be allocated to trial (n = ...)
STUDY DURATION	Time for preparation of the study/study (months): Recruitment period (months): First participant in to last participant out (months): Time for data clearance and analysis (months): Duration of the entire study (months):
PARTICIPATING CENTERS	To be involved (n): if applicable: How many centers will be involved?
DISSEMINATION OF RESULTS	Please indicate to which peer-reviewed journal you plan to submit the manuscript presenting the data derived by the research project. Which other community based publications do you consider to report on the results?

2. OTHER ONGOING APPLICATIONS TO FUND THIS STUDY

If applicable: Explain applications for grants from other funding sources.

3. RELEVANCE

Which problem is to be addressed related to sexual pleasure and wellbeing? Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations / starting hypotheses of the investigation planned.

3.1 FREQUENCY OF THE OCCURANCE OF THE CONDITION

Please state the prevalence, e.g. per 100,000 residents, incidence, e.g. per 100,000 residents per year or mortality (case fatality rate) of the disease, according to most reliable data.
In case of medical conditions: *prevalence, incidence, mortality.*

3.2 BURDEN OF CONDITION OR DISEASE

Please describe the burden of the condition and how the burden is related to a lack of sexual pleasure and wellbeing. Provide suitable indicators to assess the burden.

3.3 IMPACT OF THE STUDY

Novelty of findings: *Which therapy options are available for treatment of the disease? What is the novel aspect of the proposed study or what is novel aspects of knowledge added by the results of the study? Does the study challenge existing paradigms? Which evidence gap related to sexual pleasure is to be closed?*
Pleasure benefit: *Describe the possible real life benefit(s) for the sexual pleasure and wellbeing of the target population of the study. Detail the potential impact on relieving the burden of lack of sexual pleasure.*
In case of medical conditions clinical impact: *Provide information on the possible impact on the delivery of health care and on clinical practice related to sexual health.*
Socioeconomic impact: *Reflect on the socioeconomic impact of the study.*

3.4 PATIENT AND STAKEHOLDER INVOLVEMENT

Patient and stakeholder engagement is highly recommended. Patient involvement can be implemented in different stages of the study and to a different extent. Please justify why your concept is adequate for the planned study[1,2].
Who? *Which representative(s), self-help or advocacy group(s) or other relevant stakeholders were involved in the planning, who is planned to be involved during the conduct of the ongoing study and dissemination of the results?*
How? *E.g. developing the main question, developing the study design, defining endpoints, accompanying the ongoing study, communicating study results? Is engagement at specific time points or continuous engagement (including feedback loops) planned?*

4. EVIDENCE

Set your study into perspective. *This section should detail the background of the starting hypotheses of the study and the need for the study (including operationalisation of a patient-relevant endpoints and feasibility). How does this study inform a subsequent research, technical developments and/or community based actions.*
Provide a narrative summary: *Which studies have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and / or pilot studies, feasibility studies, relevant previous / ongoing studies, case reports / series. State what your study adds to the existing body of evidence.*

5. JUSTIFICATION OF DESIGN ASPECTS

[1] Consider this briefing by the British National Institute for Health Research, NHS „Briefing note for Researchers“: https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371
[2] Consider GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research” for reporting of patient and public involvement. https://www.equator-network.org/reporting-guidelines/gripp2-reporting-checklists-tools-to-improve-reporting-of-patient-and-public-involvement-in-research/

Please provide justifications on different design aspects and explain how they inform the design of the subsequent confirmatory study. Do not only list the respective information.

5.1 INCLUSION / EXCLUSION CRITERIA

List the defined inclusion and exclusion criteria. Justify the population to be studied, include reflections on generalisability and representativeness.

5.2 CONTROL(S) / COMPARATOR(S)

Justify the choice of control(s) / comparison(s).

For clinical trials: Is placebo acceptable? Which studies establish efficacy and safety of the chosen control regimen?

5.2.2. INTERVENTION (only for clinical trials)

Justify the choice of your planned intervention(s). Illustrate your intervention scheme graphically in the appendix.

5.3 OUTCOME MEASURES

Justify the endpoints chosen. Have the measures been validated? Are there other studies that have utilized the primary endpoint? Are there any guidelines proposing this endpoint / these endpoints?

Discuss the relevance of the outcome measures for the target population. Justify appropriateness and limitations of composite / surrogate endpoints, if applicable.

5.4 METHODS AGAINST BIAS

What are the proposed practical arrangements for allocating participants to study groups? How will aspects of gender and diversity will be reflected in the recruitment and the data analysis?

Only for clinical trials: *Justify the randomisation scheme. Which prognostic factors need to be regarded in the randomisation scheme and the analysis? Will trial-site effects be considered in randomization? It is expected that the study is randomised. No randomisation must be justified and may only be acceptable if the subsequent confirmatory trial is single-armed. This needs to be justified. Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome).*

5.5 PROPOSED SAMPLE SIZE, POWER CALCULATIONS AND STATISTICAL ANALYSIS OF PRIMARY AND SONDARY ENDPOINTS

What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations, statistical analysis of primary and secondary endpoints and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates/means/medians and the software used for sample size calculation and statistical analysis as appropriate.

If applicable: Justify the size of difference that the trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial is powered to exclude. It is important that the sample size calculations take into account anticipated rates of non-compliance and losses to follow up.

If the proposed sample size is not based on statistical calculation, please justify why another approach has been chosen and why the proposed sample size will be adequate to answer the objective of the study.

Please note: various approaches may be eligible to justify sample size calculation. In exploratory studies, sample size calculation must relate to the chosen endpoint (but not necessarily to a clinical endpoint).

5.6 FEASIBILITY

What is the evidence that the intended recruitment rate is achievable (e.g. pilot study)? Describe from how you assessed the potential for recruiting the required number of suitable subjects and the time for recruitment.
What are the risks in recruitment, conductance and dissemination of results?

Please provide
- *Gantt-chart (figure)*
- *Milestones (table)*

5.7 RECRUITMENT
What is the evidence that the intended recruitment rate is achievable (e.g. pilot study)? Describe from how you assessed the potential for recruiting the required number of suitable subjects and the time for recruitment.

5.7 ETHICAL CONSIDERATIONS
Are there risks or burden for participants caused by taking part in the study? Which actions are taken to reduce risks of participants?

5.7 DATA PROTECTION
Please list kind of personal data collected and processed regarding both, study participants and patients (including location of data subjects and countries to which personal data is transferred). Explain which data protection law(s) is/are applicable and how compliance is ensured (including consent requirements). Confirm that you will only share data with WOW Tech Europe GmbH and the Advisory Board in compliance with data protection law.

9. STUDY MANAGEMENT

9.1 MAJOR PARTICIPANTS
Please indicate persons responsible for design, management and analysis of the study.

#	**Name**	**Affiliation**	**Responsibility/Role**
			Principal Investigator
			Study Statistician

9.2 EXPERTISE
Please indicate expertise of all above-mentioned participants by citing relevant publications and / or specifying major role in ongoing study(s) (to be identified; max. 5 publications of the last 5 years per person). Ensure that the team of investigators has the necessary expertise to carry out the study.

9.3 STUDY-SUPPORTING FACILITIES
Which study-specific facilities and other resources are available for conducting the study?

10. FINANCIAL SUMMARY
Please give a detail estimation of the costs that will be covered by this grant for the total duration of the study.

#	**Item** e.g.	**Costs (€)** Total trial duration
	Project Management	
	If applicable case Payment	
	Materials	
	Case Payment	
	Patient Involvement (e.g. Workshops, Focus Groups, Questionnaires)	
	Data management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management)	
	Biostatistics	
	TOTAL (without overhead)	

Please give a detail estimation of the costs required for aspects relevant to the study that will NOT be covered by this grant. Please provide the information if the costs can be covered and how.

#	**Item** e.g.	**Costs (€)** Total trial duration	**Coverage**
	Project Management		
	If applicable case Payment		
	Materials		
	Case Payment		
	Patient Involvement (e.g. Workshops, Focus Groups, Questionnaires)		
	Data management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management)		
	Biostatistics		
	TOTAL (without overhead)		

Please note that the following costs cannot be funded by this grant (please also see Terms and Conditions):

1) Indirect costs
2) Estate costs
3) University tuition fees
4) Rent of a laboratory or clinical space
5) Part or full salary or time of staff who have permanent contracts
6) Time of student supervisors
7) Sub-contractor fees
8) Consultancy fees
9) Membership fees to learned societies including ESSM
10) Application fees to ethics committees or regulatory bodies
11) Stationary, office costs or secretarial assistance unless directly incurred by the project
12) Prescription costs
13) Publication costs
14) Costs of managing, protecting and exploiting the intellectual property
15) Maternity/paternity leave/cover

16) Sick leave
17) Local taxes
18) Employer's contribution to national insurance or pension scheme
19) Any indemnity or insurance costs

Indicate the overhead requested by your institution. Or if no overhead will be requested.

Only for pharmacological interventions: trial drug under patent protection
□ No
□ Yes, until Date:

For interventions with medical devices: device is CE-certified
□ No
□ Yes

Please indicate any other certification:

References:
For your references please use the Vancouver style (the full title of the publication must be displayed; please find further information here: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

SIGNATURES:

I have read and understood the Pleasure Fund Terms and Conditions and agree that if my application is successful, I will abide by them. I shall be actively engaged in, and in day-to-day control of, this project. I confirm that the content of this application is true, accurate and comprehensive.

Principal Investigator

Name, surname:

Signature:

Date:

With the signature the representative(s) of the Lead Organisation and the Administrative Authority confirm that (s)he/they have read this application and that, if granted, the work will be accommodated and administered in this Department/Institution in accordance with the Pleasure Fund Terms and Conditions. The representative(s) confirm that the resources necessary to support this research are available within the Department/Institution.

Lead Organisation

Name, surname:
Position:

Signature:

Date:

Administrative Authority:

Name, surname:
Position:

Signature:

Date: