Grant Agreement
Between
The Partnership for Transparency Fund, Inc.
And
Jananeethi

1. **Jananeethi** has requested financial support of The Partnership for Transparency Fund, Inc. (PTF) to implement a program for **Save Clinical Drug Trials Ethically Sound and Corruption-Free (State-wide campaign for the ethical standards in clinical drug trials on human participants through RESEARCH)**. The program will be called "**Save Clinical Drug Trials Ethically Sound and Corruption-Free**" and will commence from **01st March 2011** and is expected to be completed by **31st August 2012.** The Grant is being made under the under the Citizens Against Corruption (CAC) program in South Asia that is being implemented by PTF and its partner Public Affairs Center (hereafter called PAC), Bangalore, India in South Asia.

2. **Jananeethi** has submitted the attached Project Proposal dated 17th January 2011, which includes background information on **Jananeethi**, an operational plan for the project, and a detailed breakdown of costs.

3. On the basis of this information, PTF has approved a grant of **US $ 35,000 (Thirty five thousand US Dollars)** to be disbursed in three tranches, each for the purposes spelled out in the attached document. The tranches will be disbursed as follows:

a) First tranche of **US$ 10,500 (Ten thousand and five hundred US Dollars)** to be disbursed on signature of this Grant Agreement.

b) Second tranche of **US$ 21,000 (Twenty one thousand US Dollars)** to be disbursed six months after the start of the project, and upon receipt by PTF of a certified statement of expenditure showing the itemized use made of the first tranche funds and satisfactorily progress in **completion of Activities 3, 6 and 12 as** deemed to be satisfactory by PAC and PTF. If there is a need for reallocation of the budget, this must be reported, and mutual agreement on the proposed changes obtained from PAC and PTF for this.

c) Third tranche of **US$ 3,500 (Three thousand and five hundred US Dollars)** to be disbursed on receipt from **Jananeethi** of a satisfactory, as deemed by PTF and PAC, project completion report that describes and assesses the project achievements, including an assessment of the project's impact and a final certified statement of project expenditures.

4. **Jananeethi** on its part commits to provide counterpart support equivalent to **US $ 8,300 (Eight thousand and three hundred US Dollars)** to make up the balance of the US$ 43,300 **(Fourty three thousand and three hundred US Dollars)** estimated total cost of the project, and any additional balances needed to complete the project.

5. The PTF grant will be made available to **Jananeethi** on the following conditions:

    a) The grant will be used only for the purposes described in the attached Project Proposal. Any material changes in the use of project funds or project design shall be made only with the prior agreement of the PTF.

    b) If PTF finds that the its grant was not used/is not being used for the purposes or in the manner described in the Project Proposal or the conditions have changed such that the project is not likely to achieve its objectives, PTF has the right to cancel the remaining tranches of its grant. In case PTF finds that its grant funds were willfully misused by **Jananeethi**, PTF reserves the right to require the full refund of its grant.

    c) Any funds disbursed by PTF remaining unutilized at the end of the project shall be returned by **Jananeethi** to the PTF.

    d) **Jananeethi** shall keep a record of all expenditures incurred under the project and will provide PTF a full certified accounting of these expenditures, with relevant documentation, [1] following expenditure of the first tranche funds, and [2] on completion of the project. These expenditures will also be subject to the regular auditing requirements of **Jananeethi**, and **Jananeethi** will furnish PTF and PAC with a copy of the relevant audit if so requested.

    e) **Jananeethi** will make brief monthly reports on the implementation of the project accompanied by a statement of expenditure showing the use of PTF funds and, on project completion, a detailed final report summarizing the implementation of the project and its outcome and assessing the impact of the project on reducing corruption, its likely sustainability and the lessons learned, together with a certified final itemized statement of expenditure. The latter report will be sent within two months of the completion of the project, together with a copy of any other reports prepared under the project.

    f) Following project completion, the PTF and PAC may make their own independent ex post evaluation of the implementation, outcome and impact of the project. **Jananeethi** will furnish the person appointed to undertake this task all possible assistance and access to all relevant documents and personnel.

    g) **Jananeethi** will post this Grant Agreement, the Project Proposal, the final project report, and the statement of expenditures on **Jananeethi's** website, and PTF and PAC shall have the right to post on its website such documents

and any other reports received from **Jananeethi** or from its independent evaluation of the project.

6. Public Affairs Centre (PAC), Bangalore are authorized to administer this project, track the implementation of the use of the grant by the Grant Applicant and to initiate necessary action with regard to the project. The Grant Applicant will respond to enquiries and directions on all matters pertaining to this project from PAC, and from PTF, during the course of the project. The Grant Applicant is also expected to contribute to common learning events and activities designed and conducted by PAC and PTF in furtherance of the objectives of the Citizens Against Corruption program from time to time.

7. **Jananeethi** will be responsible for securing all necessary government approvals of the grant, if any, and any necessary government filings and will be responsible for paying any tax liability arising from the grant. **Jananeethi** shall compensate PTF in the event that PTF suffers any liability or expense as a result of **Jananeethi's** failure to obtain any such required approvals or to pay any such tax liability

8. The signed copy of this Grant Agreement and the request for the subsequent tranche releases may be sent by email to the PTF Secretary at: **danielgritchie@gmail.com.** The two original copies of the Grant Agreement should be mailed to Daniel Ritchie, Secretary, PTF, at 1875 Connecticut Avenue, N.W., Suite 1210, Washington, D.C. 20009.

9. The responsible PTF Project Advisor in respect of this project **is Mr.Jagdish Upadhay and his e-mail ID is jupadhyay@gmail.com** or such other Project Advisor as PTF may subsequently notify to **Jananeethi**. Such Project Advisor shall be **Jananeethi's** principal point of contact in respect of the project.

10. The responsible **Jananeethi** project director in respect of this project **Advocate George Pulikuthiyil and his email ID is george@jananeethi.org, pulikuthiyil@gmail.com** or such other project director as **Jananeethi** may subsequently notify to PTF. Such project director shall be PTF's principal point of contact in respect of the project.

11. Each of PTF and **Jananeethi** represents and warrants, for the benefit of the other party, that:

a. it is a legal entity recognized under the laws of the jurisdiction of its formation or in which its principal activities are conducted; and

b. this Grant Agreement constitutes its legal, valid and binding obligation, enforceable in accordance with its terms.

In addition, **Jananeethi** represents and warrants, for the benefit of PTF and PAC that the information set forth in the Project Proposal does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.

12. This Grant Agreement shall be governed by the laws of the District of Columbia in the United States of America, the jurisdiction in which PTF is organized as a not-for-profit corporation and in which its principal executive offices are located. In the event of any dispute between the parties in respect of the Grant Agreement, the parties shall act in good faith to resolve such dispute through discussions and negotiation, and they may seek the assistance of a third party mediator to assist them in the resolution of such dispute. In the absence of a mutually acceptable resolution, such dispute shall be resolved by arbitration in accordance with the UNCITRAL Arbitration Rules in effect on the date of this Agreement. Any such arbitration shall be conducted in the English language before an impartial single arbitrator sitting in Washington, D.C., appointed by the American Arbitration Association as appointing authority.

Dated:

For
The Partnership for Transparency Fund, Inc.

Executive Secretary

For **Jananeethi** and [Name and designation of officers signing the agreement]

1. George Pulikuthiyil,
   Executive Director, Jananeethi.

2. N.N. Gokuldas
   Director, Jananeethi.

JANANEETHI
Tel.: 0487-2373479
ജനനീതി
Fax: 0487-2373281
P.B. No.8, Mannuthy P.O., Thrissur-680651

Dated: 22nd February 2011

Address for Notices:
[CSO NAME,office and mailing address Phone numbers and and email contact address]

JANANEETHI
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Thrissur District, Kerala State, India.
Tel: 0487-2373479 Fax: 0487-2373281
E-mail: gpneethi@sancharnet.in
Web: www.jananeethi.org

Attachments: Project Proposal, detailed budget, logframe and PPM.

R representation, to respective Govt. bodies, institutions/departments
E engagements, of various stake holders and decision makers
S sensitization, among medical and para-medical students and health workers
E enabling, the society to form a critical mass
A advocacy, for appropriate legislations and regulations
R reaching out, to the public through display boards, IEC materials
C consortium of community organizations for collaboration and networking
H help desk at Jananeethi to ensure social and legal reparation, and guidance.

1. **Name and Address of CSO**:

JANANEETHI
Jananeethi Campus, Mannuthy Post,
Thrissur 680651, Kerala, India.
Tel: +0487-2373479/2373281
Email: gpneethi@sancharnet.in; jananeethi@jananeethi.org

2. **Lessons/Results learned in Phase 1:**

1. Researchers, medical practitioners and institutions widely and rampantly violate ethical guidelines and mandatory norms in Clinical Drug Trials. The present legal system on clinical drug trials in India requires that every institutions, officials and authorities are bound to follow the following guidelines during its conduction -

   a. Ethical Guidelines for Bio Medical Research on human participants issued by Indian Council of Medical Research (2006)

   b. Drug and Cosmetics Act-1940 Schedule Y as amended in 2005.

   c. Helsinki Declaration by World Medical Association as amended in 2008

   d. International Guidelines for Bio Medical Research involving human subjects, jointly declared by WHO and CIOMS (Council of International Organizations for Medical Sciences) 1993

   e. Universal Declaration on Bio Ethics and Human Rights by UNESCO, 2005

   The above-mentioned Guidelines govern the clinical drug trials in India. But the major issue related to this system is the absence of specific legislation on clinical drug trials. The present guidelines though it is to be mandatorily followed during clinical drug trials if not observed, are not followed by any punitive action. We emphasis and advocate for a specific law on this subject defining the rights of human participants, duties, powers and responsibilities of institutions and officials including the ethics committees and most importantly specify the offences and appropriate punishments for its violations. We from our experience found that these guidelines are not stringent enough to combat the existing flaws in the drug trial system. The Indian Government has proposed to enact a

specific legislation and drafted a bill named Bio-Medical Research on human participants (promotion and regulation) bill, but it is pending since 2005.

2. Majority of members of Ethical Committees, hospital managements, human participants, other concerned departments and offices are ignorant of the mandatory norms and regulations in a clinical drug trial.
3. Medical community by and large are opposed to discuss in open the issues of Drug trials and to subject themselves to reforms.
4. Absence of specific laws and rules makes implementation of guidelines rather difficult, if not impossible.
5. Confidentiality in matters of clinical drug trials has grossly been misused and manipulated by researchers/medical practitioners not to get exposed of their unethical practices and violations of statutory norms.
6. As the problem of unethical clinical trials are endemic, several organizations from Mumbai, Hyderabad, and Bangalore have come forward to support and associate with any step initiated against the corrupt practices.
7. Individual doctors from private and public sectors have offered assistance in the process and they are pretty sure of the social maladies involved in clinical drug trials.
8. Thrissur Government Medical College, on our intervention, has decided to incorporate ethical standards in clinical drug trials in their course curriculum, and Jubilee Mission Medical College, Thrissur has offered opportunities to address their academic community over the issue. It is possible to enhance this sort of good will among other stakeholders through appropriate interventions.
9. Invariably, all the five human participants in a clinical trial in Thrissur did not prefer to put up a complaint against the doctor, though they were quite aware of the unethical and illegal nature of the clinical trial involving them without their clear mandate. This was also true with regard to the surviving family members of the diseased participants in clinical drug trial in 2002 at Regional Cancer Centre, Thriruvananthapuram.
10. Cancellation of a scheduled clinical drug trial for Migraine in adolescent children proposed by a clinical research organization involving huge amounts (Around Six Million) in a leading private hospital in Thrissur district.

Phase 1 and 2 are very much interlinked. The activities and programmes in Phase 2 are visualized and designed to address predominantly the issues and challenges emerged in Phase 1. Therefore, Phase 2 is only the continuation of phase 1 and is mutually complementary.

3. **Project Goals:**

1. The global standards and best practices in Clinical Drug Trials on human participants are respected and strictly complied with in hospitals and research institutions in Kerala State.

2. There are strict and specific rules and regulations in the State with respect to clinical drug trials on human participants, and any one who violates them is liable to be prosecuted and victims of such unethical practices are adequately compensated as per norms prescribed.

3. A critical mass is created in Kerala Society with respect to the ethical standards of clinical drug trials on human participants.

4. Project Objectives:

Phase II is only the continuation of Phase I. Activities 9,10, 11, 12, 13,14 and 15 of Phase I were not completed since they were initially designed for two years. Those activities will be carried forward to Phase II. The budget allotments in Phase I for those activities shall be spent on those activities in phase II. Hence they do not come under the budget allocations of Phase II.

The following objectives for Phase II will decide upon the extent of activities to be followed in Phase II, in addition to those incomplete activities carried forward from Phase I to Phase II. These objectives are SMART when read with corresponding activities.

Objective 1: Awareness Building
Objective 2: Advocacy
Objective 3: Monitoring
Objective 4: Alliance Building

5. Project Strategies:

1. Make **representations** to respective Government Departments and local bodies and such other institutions so that appropriate orders / directions / notifications are issued for promulgating best practices in clinical drug trials.

2. Strengthen constructive **engagements** of various stakeholders and decision makers to effectively implement the national and international guidelines and best practices in clinical trials.

3. Organize **sensitization** workshops and awareness generation programmes for medical practitioners, researchers, hospital managements, para-medicals, members of institutional review committees and such other bodies on the mandatory provisions of ethical standards in clinical trials.

4. Arrange radio/channel discussions **enabling** the society to create a critical mass with respect to Ethical Standards in clinical drug trials

5. Initiate **advocacy** among members of Parliament and Legislative Assembly for specific legislations to control, monitor and regulate clinical drug trials consistent with the universal norms and standards.

6. Arrange display boards, hand outs, IEC materials for **reaching out** to the general public with respect to the mandatory standards in clinical drug trials

7. Build a **consortium** of community organizations in Kerala for wider and deeper understanding of the issues involved, and for sustainable outcome.

8. Start a **Help Desk** at Jananeethi to monitor and keep vigil on clinical drug trials in the State that would also address grievances of victims of unethical and corrupt practices in the area of clinical drug trials.

6. Project Activities: (corresponding to objectives)

OBJECTIVES	ACTIVITIES
Objective 1: **Awareness Building**	**Activity-1:** Weekly sensitization programmes on areas of public concern in clinical drug trials for medical and para-medical students and staff, community workers, elected representatives to local bodies, civil society organizations, media personnel, service providers etc. **Activity-2:** Quarterly workshops for medical practitioners, researchers, hospital managements and members of ethical (review) committees on best practices in clinical drug trials. **Activity –3:** Prepare an 'information kit' in the first quarter of the Phase II with - respect to basic information regarding ethical standards and best practices in clinical drug trials. This will be in Malayalam and will be distributed among participants of sensitization programmes and training sessions. The information kit will contain guidelines of clinical trials, rights of the human participants, services provided by the Help Desk of Jananeethi, contact details and few case studies. **Activity-4:** Prepare badges/stickers and banners on good practices in the second quarter of the project and distribute among student participants of sensitization programmes in schools and educational institutions. **Activity-5:** Devote one page of Jananeethi monthly journal (in Malayalam) to appraise its readers the corrupt practices in clinical drug trials and universally accepted best practices and ethical standards in such clinical trials. This will be done from first month of phase II. **Activity-5a:** Preparation of Charter of Rights of Human Participants. (Carry forwarded from Phase I)

Objective 2: **Advocacy**	**Activity-6:** Make representations in the second quarter of the project to both the Union and State Governments for the enactment of specific legislations on clinical drug trials. **Activity-7:** Meet Secretary of Health in Government, Director of Medical Research and Education, and Heads of medical colleges in the first quarter to ensure their full support and cooperation in checking unethical practices in clinical drug trials. **Activity-8:** Quarterly meetings of heads of Institutional Ethics Committees / Review Committees to apprise, assess and evaluate the various steps taken to enforce best practices. **Activity-9:** Arrange in association with the All India Radio, Private Cable Network, FM radio stations and other main stream television channels monthly programmes on the rights of human participants in clinical drug trials and the statutory norms thereon. **Activity-10**: Publish at least one article in three months in a popular news paper/news magazine regarding the mandatory norms and best practices in clinical drug trials. **Activity-11:** Create a blog that publishes all our findings and relevant information connected with drug trials and link with similar activities in India and abroad. **Activity-12:** Organize one appraisal meeting in Delhi for Members of Parliament, and 2 meetings in Thiruvananthapuram for Members of State Assembly on the need of specific legislations for checking and regulating clinical trials on human subjects. **Activity-13:** Talk to the Secretary of Ministry for Local Self Government in the second quarter of the project to include best clinical practices into the curriculum of KILA for newly elected people's

	representatives. (KILA - Kerala Institute of Local Administration). **Activity-14:** Give talks to the top brass of *Kudumbasree*, Self Help Groups, ICDS network etc at their monthly gatherings regarding norms to be followed in clinical trials. **Activity-14a:** Filing Public Interest Litigations in the Kerala High Court for the inclusion of the Guide Line in the course curriculum of medical students. (Carry forwarded from Phase I)
Objective 3: **Monitoring**	**Activity-15:** Commence Help Desk at Jananeethi from first month of phase II to provide correct information to people with regard to clinical drug trials, and to investigate and act upon complaints regarding unethical practices and corruption in the area of clinical drug trials. **Activity-16:** Establish Kerala Health Watch from second quarter of phase II linking individuals and civil society groups in all the districts of Kerala to monitor clinical drug trials on human persons and to report malpractice, if any.
Objective 4: **Alliance Building**	**Activity-17**: Build up institutional contacts and networking with organizations and institutions in India and abroad for the promotion of best practices in clinical drug trials on human participants, from second quarter of phase II. **Activity-18:** Organize a consortium of NGOs/CBOs in Kerala that work for the ethical standards in medical research and clinical practices. Organize its meeting once in six months to appraise situations in Kerala and outside with respect to new trends and challenges.

6 A. Activities carried forward from Phase I to Phase II (budget already allocated in Phase I)

Activity 9 & 10: campaigning for formation of Institutional Ethics Committees as per best practices as envisaged in ICMR guidelines;

Activity 11: Public Interest Litigation in the Kerala High Court for appropriate direction to Director of Medical Education in the State for inclusion of the Guidelines in the course curriculum for medical students;

Activity 12: Fixing up hoardings / display boards in the premises of medical colleges on the ethical guidelines for clinical drug trials;

Activity 13: Media appraisal and interface through visual media on ethical standards in clinical drug trials;

Activity 14: Preparation of Charter of Rights of Human Participants in drug trials;

Activity 15: Campaign for introduction of ID cards to human participants in clinical drug trials.

(**These activities will be completed in the first 2 quarters of phase II)**

7. **Expected Results and Targets (Please explain how the Phase 1 and 2 are linked and what will be the incremental results from Phase 2 and the cumulative results when Phase 1 and 2 are completed. Please use the following table format:**

Outcome	**Indicator**	**Baseline from Phase I**	**End of Phase I actual (also serve as baseline for Phase II)**	**Targeted end of Phase II value**	**Data sources**
1. Issues and problems are brought to the notice of all concerned. Importance of the mater discussed.	1. Number of participants in each training session and their active involvements in the discussions held.	1. Unaware of the problem; were not concerned of the Ethical standards	1. Started listening and discussing though with reluctance	1. Get full involvement of these offices and authorities in cleaning up clinical trials.	1. Written responses and subsequent actions taken.
2. Appropriate orders by Directorate of Medical Education.	2. Written order issued, and steps taken for implementation.	2. Reluctant and unwilling to appreciate or accept our complaints.	2. There is willingness to listen.	2. Authorities take decisions to issue orders to improve clinical trials.	2. Documentary evidence.
3. Hoardings and Display boards erected in campuses.	3. Photographs of the boards	3. N.A.	3. We have more data to convince them.	3. Large number of patients and their families come to know about the implications of clinical trials.	3. Photographs.
4. Focused Groups and General public become better conversant with rights of human participants.	4. List of participants in programs and their responses.	4. Ignorance and indifference.	4. Discussions held for focused groups; however general public yet remain unaware of.	4. Clinical trials and related topics become a matter in the public domain.	4. A feed back will be taken from random groups of common people.
5. Society at large becomes increasingly aware of ethical standards in trials.	5. Feed backs will be collected from AIR, media houses.	5. Not concerned of.	5. Not as their priority. Never thought about.	5. AIR, Visual Media, Publishing Houses become aware of problems connected with trials and hence common man becomes aware of.	5. List of programmes and published materials.

6. Legislators in Parliament and Assembly become part of the campaign.	6. The number of sessions with them and their responses.	6. No involvement No concern	6. Are aware of but have no involvement, no initiative taken.	6. Get support and help from Members of Parliament and Assembly.	6. Number of visits and meetings held. Actions followed.
7. People have something to take home and refer back. Becomes a talk in the family.	7. Number of kits delivered and feed backs.	7. Not heard of. Was never a matter of concern.	7. Little bit of information; but are not aware of the problem.	7. Larger sections of people become aware of the problems and actions to be taken.	7. Feed backs.
8. Rights of patients and human participants become matter of common concern and part of good governance.	8. Approved as part of syllabus for trainings at KILA.	8. Completely unaware of corrupt practices in drug trials.	8. It was never a major concern in local bodies and among common people, only because of ignorance.	8. Ethical concerns and rights of human participants in drug trials become a major concern in Panchayaths and local communities.	8. Number of programs and feed backs collected from participants.
9. Global sensitivity and international monitoring over clinical drug trials. Our problems are brought to the notice of international community.	9. Our news and case studies as get published and debated upon in the West.	9. International Community was not adequately appraised and hence was unaware of.	9. International Community is unaware of the unethical practices and colossal rights violations.	9. There is regular exchange of news and views among organizations working on these issues and violations of best practices could be taken up at the very source for remedial action.	9. From reports from overseas and international publications.

8. Geographical Area of work & Time frame:

Phase I was originally focused on Five Medical Colleges in districts of Ernakulam, Thrissur and Calicut in Kerala State. The geographical area was later extended to Thiruvananthapuram towards the South in consideration of non-availability of human participants in clinical trials. However, Phase II will be having the whole of the State as its geographical area since we intend to reach out to larger population. In the second phase of the project we are concentrating mainly on the advocacy and awareness programmes based on the learning's and experiences from the phase I, hence specific institutions are not mentioned.

The following is the time-bound activity schedule of the project:

Time Frame of Project Activities	MONTHS																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Activity 1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 2			x			x			x			x			x			x
Activity 3	x	x	x															
Activity 4				x	x	x	x	x	x	x	x	x	x	x	x			
Activity 5	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 5a	x	x	x	x	x	x												
Activity 6				x	x	x												
Activity 7	x	x	x															
Activity 8			x			x			x			x			x			x
Activity 9	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 10			x			x			x			x			x			x
Activity 11						x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 12					x						x						x	
Activity 13				x	x	x												
Activity 14	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 14a	x	x	x	x	x	x												
Activity 15	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 16	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 17					x	x	x	x	x	x	x	x	x	x	x	x	x	x
Activity 18									x						x			

9. Monitoring and Evaluation:

Regular monitoring and evaluation shall be conducted by the project director to oversee the progress of the project. A monitoring committee shall be formed that shall include external consultants who are experts in various health as well as non-health areas. Mid term evaluation shall be conducted in the ninth month of the phase II and final evaluation shall be conducted in eighteenth month. M & E shall be conducted using well defined research tools for impact assessment. Monthly reports, event reports, media reports etc shall supplement the M&E process.

10. Organizational Team and Roles:

i. **Advocate George Pulikuthiyil**: He will be the project holder and Project Director. He will be responsible for the successful completion of the project. Will be accountable to PAC and the donor agency. Will closely monitor every step in the implementation of the project. Will organize monitoring and evaluation at relevant time and will coordinate the project staff and the committees of consultants and experts.

ii. **Advocate P. Sunilkumar**: Will be the Project Coordinator. He will be the principal actor in the project implementation. Will coordinate all the activities as envisaged in the project proposal. Will prepare timely reports and will report to the project director on the progress made. Will convene meetings and apprise to the media and supporting organizations. Will represent the implementing organization at all seminars/workshops organized by PAC/PTF combine.

iii. **Advoate Ms. Faritha Ansari**, Project Officer (Help Desk): Will look into the legal dimension of the issues and human rights violations. Will take care of the psycho-legal counseling of the victims of corruption and unethical practices; further their family members and dependants. Will attend wherever and whenever legal intervention is required.

iv. **Project Officer** (Field): Will work closely with the project coordinator. Will visit institutions and organizations to fix up programmes. Will keep live contacts with all stake holders, beneficiaries and partner organizations. Will help the coordinator in preparing the reports and will document them.

v. **Mr. M.N. Suresh Babu,** Project Officer (Accounts): Will be responsible for management of accounts, auditing, data entry and processing. Will work closely with the communication officer. Will assist monitoring and evaluation and periodical project assessment.

vi. **Ms. E. Jayashree,** Project Officer (Communication & Documentation): Will work closely with the project coordinator and project officer (Help Desk). Will assist the accounts manager for book keeping and data collection. Will organize meetings of the victims and will coordinate their psycho-legal counseling in consultation with the project officer (help desk).

11. Community Organizations and their role:

Several civil society groups and community organizations, including local civil bodies, self help groups and neighbourhood groups, across the State of Kerala are keen in associating with Jananeethi in the implementation of the project. Their participation and involvement in the project are streamlined in the advocacy and monitoring stages. The following groups / organizations / network groups will have extensive roles in the process. They are –

i. *Kudumbasreee* units (neighbourhood groups of women of low income families),
ii. Self Help Groups (SHGs), ICDS (integrated child development scheme),
iii. District Panchayat Council of Thrissur District,
iv. Thrissur Municipal Corporation,
v. *Sahayi*, Thiruvananthapuram;
vi. *Bhoomika,* Kottayam;
vii. *Neethivedhi*, Kalpetta, Wayanad;
viii. Centre for Public Policy and Research, Kochi and
ix. *Anweshi* Women's Advocacy and Resouces Centre, Kozhikode.

12. Activities to promote Peer Learning:

Other CAC partners under PAC/PTF joint initiative are dealing with different issues and hence they may not have much to contribute to Jananeethi in the given project implementation. However, there are other civil society groups/community organizations in other parts of the country whose experiences and learning shall surely be of great value to Jananeethi. Therefore, there shall be half yearly meeting of partner organizations to benefit out of their profound experiences in addressing similar concerns.

13. Initiatives for Sustainability:

One of the major features of phase II is constructive engagements with local self government and stake holders. Maintaining global ethical standards and best practices in clinical drug trials should remain basic responsibility of concerned institutions. Hence we involve them in the deliberations so that they take effective steps to ensure the standards in clinical trials. Under the Panchayati Raj Act, it shall remain the responsibility of Panchayati Raj Institutions (PRIs) to monitor and watch if the norms and regulations are complied with.

14. Risks and Assumptions:

Public education and awareness building have less risks than identifying victims / participants of clinical trials and investigating the matter for legal reparations. However, education and awareness building among the public will naturally have to expose the unethical practices for unlawful gains. As this will affect the business prospects of concerned persons/institutions, we do expect, they will resist and will navigate defensive steps intending to dissuade / discourage us from the project activities. We consider it a natural reaction of interested groups.

15. Revised LOGICAL FRAME WORK:

Narrative Summary	Verifiable Indicators	Baseline values (actual)	End project (targets)	Means of Verification	Important Assumptions
Goal: Global standards and best practices in clinical drug trials are respected and complied with in the State of Kerala, and there are strict rules and regulations as norms to be followed in drug trials violation of which shall be actionable offence, and that a critical mass in Kerala with respect to standards of clinical drug trials are concerned..	i. Statutory norms and policies are prescribed by government with respect to functioning of Ethical Committees and drug trials, and ii. Appropriate legislations are made with provisions for legal reparation, and iii. Number of awareness programmes conducted for general public.	The society in general and institutions in particular were not concerned or were totally unaware of the ethical standards and statutory norms with respect to clinical drug trials.	There were significant changes in the attitudes of institutions and medical practitioners with regard to rights of human participants in drug trials. However, the general public remains ignorant of the mandatory norms and best practices.	In the case of public, we will take their feed backs in the beginning and end of every session regarding norms and standards of clinical trials. In the case of institutions, we will collect copies of notifications/ directives passed by appropriate authorities.	There is indifference and insensitivity in individuals and institutions regarding concerns raised. However, changes are possible if proper awareness is given to different segments of society.
Purpose: Create awareness among various sections of society regarding the mandatory norms and standards in clinical drug trials, and create a critical mass in society who will demand for best practices and will seek legal reparations in the event of causalities.	The number of participants and institutions represented will speak for the success of the purposes. The general awakening of society will reflect in media in the form of articles talk shows, panel discussions etc.	The general public remain either ignorant or indifferent result of which is cause for rampant breech of laws and wide spread corruptions.	Institutions are moderately informed of the problems but general public are still unconcerned of the damages being caused.	Committee for M & E will make periodic reports with regard to success made. Feed back sheets will be collected from participants of training sessions and it will indicate to the changes brought in the participants of training sessions.	Consistent efforts are required to break the silence of the general public regarding unethical practices. Changes are possible if only pressure from top is applied in the form of strict measures and penalties.
Outputs: The society in general and the institutions in particular become better aware of the	The awareness level of participants can be assessed and verified using a	There has not been any specific effort from any quarter regarding	Due to the phase I interventions, there are expression of willingness	Increased number of participants in the succeeding training	Health is a common concern of all people of all times in all communities.

unethical and corrupt practices existing in society in the form of clinical drug trials. Consequently they become a critical mass watching and monitoring the activities of such institutions.	feedback questionnaire among the participants. In the case of institutions, any improvement they initiate in the system is an indication.	the best practices and ethical norms till Jananeethi intervened in the scenario.	among certain institutions in the form of amendments made in the curriculum. However, the public yet remains in the dark with respect to the norms and ethical standards.	sessions will be one method of verifications. The more the matter is discussed in public media, the larger will be the response of the public. People seeking the help from the Help Desk at Jananeethi will be another strong indication of the output of our programmes.	Hence we hope strong responses will be there to this project from the public.

16. Budget Break-up (for 18 months):

	Budget Category	Budget (Currency INR)	Source of Funding used		
			PTF		CSO
			INR	USD	INR
A.	**Human Resource Cost:**				
	1. Project Director	Free Service			
	2. Project Co-ordinator	216000	174960	3888	41040
	3. Project Officer (Field)	180000	145800	3240	34200
	4. Project Officer (Help Desk)	180000	145800	3240	34200
	5. Project Officer (Communication)	162000	131220	2916	30780
	6. Project Officer - Accounts (Part time)	144000	116640	2592	27360
		882000	**714420**	**15876**	**167580**
B.	**Office Expenses:**				
	1. Electricity + Telephone charges	81000	65610	1458	15390
	2. Postage, Xerox & Stationery	18000	14580	324	3420
	3. Audit charge	2500	2025	45	475
		101500	**82215**	**1827**	**19285**
C.	**Project Activities:**				
	1. Activities 1 - 5	535000	433350	9630	101650
	2. Activities 6 - 14	280000	226800	5040	53200
	3. Activities 15 & 16	90000	72900	1620	17100
	4. Activities 17 & 18	35000	28350	630	6650
		940000	**761400**	**16920**	**178600**
D	PAC Peer Review Charge	25000	20250	450	**4750**
	Grant Total	**1948500**	**1578285**	**35073**	**370215**

Total Project Cost	**INR**	**1948500.00**
Institutional Cost Sharing (19%)	**INR**	**370215.00**
Fund Requested from PTF	**INR**	**1578285.00**
(1USD = INR 45.00)	**USD**	**35073.00**

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