Standard Operating Procedures for IndiaCLEN
Version 2 : 2008

Introduction

IndiaCLEN offers a unique resource as a network of health professionals well trained in a range of disciplines who apply their understanding of efficacy, effectiveness and efficiency to improving health systems at different levels of health care in the country. Over the years collaborative research that addresses important practices and policies have been fostered and training and continuing education activities have been expanded. To maximize the likelihood that the network functions cohesively and follows a system of governance that is both democratic and transparent, a set of standard operating procedures have been developed. Rather than act as stumbling blocks to the efficient functioning of an organization, these guidelines, we believe, will lay down appropriate and acceptable norms that will facilitate efficient functioning. In addition it will help set up a system that will ensure that all the activities of the network follow set procedures which will help sustain the integrity of the network.

1. Operating Procedures for the IndiaCLEN Programme for Health Intervention Development and Evaluation (IPHIDE)-

The IPHIDE is a strategic plan for "Research Activities" to be taken up by IndiaCLEN in a phased manner during a specified period i.e. 1st October 2004 – 30th Sept 2008 (07) with funding from USAID, New Delhi. These research activities supported by USAID should have the potential for scaling up to a national /state health program which could impact on population health indices. A comprehensive document called the IPHIDE document has been developed describing the different research initiatives for which funding support is available. Here, the focus is on providing a standard operating procedure for the conduct of the IPHIDE.

1(a). Proposed Operating Procedures

Funds committed for an initiative are:

- For defined project(s)
- Cannot be released unless
  - Complete proposal is developed
  - IRB Clearance obtained
  - Approved by IEO
- Cannot be transferred from one defined activity to another
- Research projects listed in the document are not necessarily automatically assured of funds
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- Funds for "IndiaCLEN Program Support" (Office, CEU Core and IRB) indicated in the document can not be utilized until we start and complete the research projects out of which these funds allocations are made

1(b). Process of Developing Teams for Initiatives and Nomination of Coordinators

- The IndiaCLEN office will list the names of Investigators both IndiaCLEN and Non-IndiaCLEN Partners, who have interest, experience and expertise in the fields related to the initiative

- A nomination committee comprising the President, IPHIDE Coordinator and the Secretary will shortlist investigators (Core Team) willing to participate in the process of developing the research agenda and work as prime movers (n-10; 6-IndiaCLEN; 4-Non-IndiaCLEN)
- The nomination of the Coordinator of the initiative by the Core Team will be for one funding cycle only

1(c). Functions of Initiative Coordinator

The specific functions of an initiative coordinator are as follows:

- A facilitator and not Principal Investigator (PI) for every project
- Ensures that projects which have been approved in principle by the funding agency become operational without delay .{Encouraging PIs to proactively develop complete proposals, obtain relevant clearance (RSC-IRB) and submit to IEO for approval and release of funds}
- Utilization of funds allocated to the initiative: at least 25% in the first year and >75% in subsequent years. - If the Initiative fails to utilize the above stated levels of resources, the Core Team will nominate another Initiative Coordinator.

1(d). Process of Developing Research Agenda for the Initiative

- The Core Team under the leadership of Initiative Coordinator will identify, prioritize the research agenda and specific proposals, and suggest phasing of activities
- The IPHIDE Coordinator will facilitate the above process
- The IPHIDE Coordinator along with Initiative Coordinators will discuss the research agenda with the donor agency (viz. USAID) to identify specific proposals for funding during the current cycle
- Same process/iteration will be followed for all subsequent funding cycles

2. Operating Procedures for Governing Body Meetings

The Governing Body of IndiaCLEN must meet at least 2 times in a year one of which will take place during the annual meeting of IndiaCLEN. The secretary with the assistance of the IndiaCLEN Country Director will be responsible for organizing these meetings, finalizing and distributing the agenda, recording and compiling the minutes of each meeting, recording attendance and circulating the minutes after initial approval by the President. The minutes of each meeting must be compiled within four days of the conclusion of the meeting. This must then be sent out to the President by email who then gives his/her approval - which process must also be completed within one week after which it must be circulated by email to all the GBM members. If within a week no further modifications or comments are suggested by any of the GBM members, the minutes will be considered as approved. Fifty percent of the members must be present to fulfill the quorum.

3. IndiaCLEN Office

Country Director
Duties & Responsibilities

1. Will be a full time employee of IndiaCLEN with no other responsibilities
2. Liaison with INDIACLEN and USAID and other funding agencies
3. Fundraising and program development (new projects)

4. Market IndiaCLEN as a research organization and disseminate the IndiaCLEN work at different form
5. Ensure uninterrupted operations of science projects and capacity building activities of the network
6. Assist with meeting logistics for IRB and Program Monitoring Committee

Country Director will be located in Chennai with overall responsibility of the IndiaCLEN office and will report to the President and Governing Body. He/she will be authorized and responsible for maintaining contact with all PIs of science projects approved by USAID and other funding agencies and for assisting as required to maintain the approved project timeline. The CERTC located at Trivandrum and ICE, KGMU, Lucknow will be considered quasi-science project for the purpose of this document and will be monitored accordingly. The Country Director will provide brief project updates related to approved milestones achieved noting any potential difficulties that my result in project delays. These updates will include all ongoing projects and are to be circulated to the program committee every 60-90 days. He/she will evaluate, and suggest potential sources of core funding to the Program Monitoring Committee and the Governing Body. He/she will also be responsible for assisting the IndiaCLEN members with identifying potential science projects to ensure that five major multicentric projects of policy and program relevance are always running. New projects should be ready to launch as existing projects are completed.

Milestones

1. Program progress summary to Program Monitoring Committee every 60-90 days
2. Recommend and secure sufficient funding from non-USAID sources to offset 20% of core funding by the end of year two
3. Assist IndiaCLEN scientist with project identification and approval prior to the completion of an existing project to maintain 5 active multi-site science projects at any time

Finance and Administrative Officer
Duties & Responsibilities

1. Maintain proper accounting of all project and office funds
2. Liaise with external auditors
3. Prepare and coordinate all statutory reporting related to the IndiaCLEN organization and the projects. Prepare and/or coordinate all project financial reports to INDIACLEN.
4. Oversee the facilities, supervise the computer operator and administrative assistant
5. Coordinate all meeting functions for IndiaCLEN, IRB, and Program Monitoring Committee
6. Establish a credible and stable mechanism and capacity within IndiaCLEN to receive, manage and report national and international funding within next three years.

Computer Operator

1. Maintain all computer equipment
2. Perform all data entry
3. Maintain electronic filing system

Administrative Assistant

1. Prepare and file all correspondence as required by the IndiaCLEN staff, the IRB, and the Program Monitoring Committee
2. Assist the Finance and Administrative Officer with financial payments and filing as directed
3. Handle all incoming mail, electronic and postal
4. Maintain reporting calendar and files as directed

4. Program Monitoring Committee

1. IndiaCLEN President (Committee Chair)
2. Immediate Past President
3. President Elect
4. INDIACLEN Senior Program Consultant
5. External Expert from the Evaluation team

Duties:

1. Oversee the science of all IndiaCLEN projects (USAID and non-USAID)
2. Monitor and oversee the timely completion of all project milestones.
3. Assist Program Director and Project Coordinators with overcoming existing and predicted problems with science or milestone issues related to approved projects.
4. Report progress and problems directly to INDIACLEN within 15 days of each meeting. INDIACLEN shall communicate to either USAID or other funding agencies.
5. Follow-up mechanisms will be developed to evaluate the effectiveness of problem solving and reported every 30 days.

Program Monitoring Committee will meet every 60 – 90 days via face-to-face meeting and teleconference (4 times yearly) to review the materials and reports prepared by the IndiaCLEN Country Director specifically related to science projects funded by USAID and non-USAID sources and Capacity Building initiative. The objective of the Program Monitoring Committee will be to advance the approved projects and assist the IndiaCLEN Country Director with necessary advise/action directly related to maintaining quality science according to approved milestones.

5. Operating Procedures for IRB Meetings

5(a). Composition, Tenure and Mode of Selection of Members

The role and purpose of the IRB is to review research proposals being carried out by members of the network with a view to ensuring adherence to the principles of ethics in research. The IRB must meet at least three times in a year for the purpose of carrying out this review. It is composed of a total of 13 members including the Chairperson. While 7 of them are IndiaCLEN members whose names are nominated by the respective CEU directors, the remaining 6 comprise non-IndiaCLEN members. The latter are also suggested by the respective CEUs concerned and the IRB Chairperson in consultation with the President makes their selection to the IRB. One among these 6 has to be a representative from the legal profession and one other must be a lay person who would represent the community. The remaining 4 must be professionals with medical and non-medical backgrounds. The Chairperson must be a non-IndiaCLEN member, preferably with background in epidemiology, and will be selected by and from among the existing IRB members. A detailed reference manual on the composition and functioning of the IRB is available with the IndiaCLEN office.

5(b). Tenure of the Committee

The tenure of an IRB member including that of the chairperson will commence in the month of September and will last for two years. To ensure continuity as well as a smooth transition process, an overlapping rotational system was made operational. Under this arrangement, 50% of the members retired in September 2001 and were replaced. The

remaining 50% retired this year and were replaced in August 2002. A chairperson will have a two-year term and will be nominated from among the older 50% of the members who joined in September 2001. The process of nomination of a new chairperson as well as the replacement of the 50% members who step down should be finalized in the IRB meeting that takes place in the month of June before the September meeting. This will ensure that the new body along with chairperson is in place before the annual conference in September when the announcements will be made in the governing and general body meetings.

5(c). Operating Procedures

The IRB must meet once in three months for the purpose of reviewing research proposals. The IndiaCLEN office will handle the coordination and organization of the meetings. The IRB coordinator, who is the country director will be responsible for ensuring that each of the proposals have complied with the required IRB format before it is sent out to each of the IRB members for the purpose of review. Each meeting must be minuted and the minutes of each meeting must be compiled within four days of the conclusion of the meeting. This must then be sent out by email to the Chairperson who then gives his/her approval - which process must also be completed within 4 days – after which it must be circulated by email to all the IRB members. If within a week no further modifications or comments have been suggested by any of the IRB members, the minutes will be considered as approved. The IRB coordinator is responsible for communicating the specific comments of the IRB on their respective projects to the PIs concerned, to enable them to take appropriate action or make re-submissions based on the modifications suggested by the IRB. Upon completion of the project a copy of the report must be submitted to the office. Projects that have a duration of more than one year must obtain IRB re-approval at the end of one year. This needs to be done in the format provided ***(Please Refer to Appendix I for IRB guidelines)***

The IRB should confine itself to review of ethical issues only, in research proposals taken up by them. Proposals are in any case reviewed by the Research Sub-committee which is a technical body specifically set up to ensure that research projects are methodologically sound. The IRB members must be provided the necessary training to ensure that they have the expertise and capacity to carry out this mandate. The operating procedures for the IndiaCLEN IRB should be in conformance with both USAID and ICMR guidelines. It is of course, the duty of the IRB to assure that the proposal is scientifically sound, as otherwise it would be unethical to conduct the research. This in turn does not imply that the IRB should take the primary responsibility for scientific review. The research committee needs to provide good evidence to the IRB that the proposal has been appropriately reviewed and revised, and is scientifically sound.

6. Overall Financial Management Issues

The fiscal year for the IndiaCLEN network follows the USAID format, which is from the month of June to the month of July in the following year. Consequently, the annual auditing of accounts will take place from the month of August. ***(Refer to Appendix II for INDIACLEN Budgeting and Accounting Manual for USAID-Funded Projects)***

The authorized auditors for the network are Bansal and Co. who will be responsible for the auditing of the CEU core grants; USAID-INDIACLEN funded project grants; IRB and the IndiaCLEN office accounts which includes the sub-committee funds also, namely, RSC and CBS. Quarterly financial and technical reports on each of the above mentioned projects must also be submitted to IEO. With reference to multi-centric projects, the coordinating site is responsible for obtaining and submitting separate financial reports from each of the project sites and preparing a technical report. It must be noted that if separate budgets have been provided for site and coordinating centers then accordingly, separate financial statements need to be prepared also. These reports will then need to be submitted to the IndiaCLEN office where it will be compiled and finally submitted to IEO.

For INDIACLEN funded workshops, a revolving fund of US$ 500 and travel expenses of participants only will be transferred to the coordinating site. These funds will be routed through the office. IndiaCLEN will settle all other expenses directly by cheques.

6(a). Maintenance of Bills and Vouchers

All bills and vouchers supporting expenses incurred on that particular project/programme must be properly maintained, numbered and signed by the authorized person and must bear the “paid and cancelled” seal on the bill. All financial accounting must be computerized. Purchase of any item costing USD 500/- or more requires prior permission to be obtained from IEO and once approval for purchase has been obtained quotations from a minimum of three companies must be obtained and a copy sent to the IEO. A decision on which company’s equipment will be purchased is left to the discretion of the principal investigator but appropriate justifications behind choosing a certain company as well as the reasons for the purchase of the equipment concerned must be provided.

6(b). Overnight Stay and Taxi Travel Allowances

All overnight stay costs will be settled upon submission of relevant bills. With respect to use of taxi for travel as from Vellore to Chennai, if the member hires a taxi he/she will be reimbursed on submission of the taxi bill. If the member uses his/her institutional vehicle, he/ she will be reimbursed based on the amount indicated in the institutional bill. Alternatively, if the member uses his/her vehicle he/she will be reimbursed at the rate of Rs. 7 per kilometer. With respect to incidentals (includes food and refreshments) and local travel expenses incurred while on a visit, a flat rate Rs. 500/- per day has been set which members can claim. Overnight stay/ taxi travel allowance will be periodically revised in keeping with inflation rates As far as possible members are urged to submit all their bills of expenditure to enable accurate accounting and fulfill the USAID guidelines.

With respect to air and train travel arrangements and Hotel accommodation for attending meetings and workshops within the country, the PIs/Project coordinators are responsible

for arrangement and payment. 90% of the budgeted funds will be transferred to the PI/Project coordinator on receipt by the IndiaCLEN office. On completion, a financial statement and technical report must be submitted to the IndiaCLEN office after which the balance in funds will be transferred.

International travel and Hotel arrangements for the Global Meet will be organized by the IndiaCLEN office, unless a member specifically wishes to make his/her own arrangements.

6(c). Tax Deduction at Source (TDS)

Having obtained the Foreign Contribution Regulation Act (FCRA) registration number that enables IndiaCLEN to receive foreign money, financial returns have to be filed annually with the Ministry of Home Affairs as well as with the Government of Tamilnadu, the latter, as per the Societies Registration Act. According to the Govt. of India Income Tax rules any Honorarium/Professional time i.e. money paid to an individual for providing his/her professional expertise, that exceeds Rs. 20,000 per year has to be subject to Tax Deduction at Source (TDS). Currently, the percentage that would be deducted is 5.25%, which, however is not a constant percentage and may vary. At the end of the financial year (April – March) the TDS certificate will be provided to the respective individuals concerned by the IndiaCLEN office. This will apply to all individuals receiving honorarium/professional time from research projects and in their capacity as IRB members, that totals or exceeds Rs. 20,000 per year. On the advice of our auditors we will be implementing this rule from April 2002 onwards.

Some important issues and requirements of the Income Tax of India where the office was now regularly filing their returns. are as follows:

- Individual's salaries exceeding one lakh in a year (April-March) are subject to TDS
- The PI is responsible to deduct TDS
- To reduce/avoid tax ,consolidated salary should be avoided
- Detail of salary break-up could be discussed with auditors
- In case of non-deduction of TDS, PI is liable
- Individuals getting contractual/honorariums/consultancy exceeding Rs. 20,000 in a year are also subject to TDS
- IndiaCLEN office requires photocopy of TDS challan

The members were requested to furnish the following:

- In any financial report complete details of personnel employed and their monthly salaries to be provided
- In case of purchase of any assets such as equipment, furniture (non-consumables) photocopy of bill to be provided to the IndiaCLEN Office along with financial report
- Financial and technical reports sent to the IndiaCLEN Office have to be signed by the PI

The IndiaCLEN Office would in turn send out a format for this financial report along with each award letter so that members will know exactly in what form to submit their statements. With

respect to the issue of submission to FCRA, members wanted the office to clarify from our local auditors whether sub-contractors to IndiaCLEN grants also needed to obtain FCRA clearance.

6(d). Management of Financial Matters of Research Projects

- It is desirable that the financial management should be centralized within the respective CEUs or within the institution
- The PIs are responsible for submitting timely financial and technical reports.
- All half yearly reports (both technical and financial) need to be submitted no later than 15 days from the last date of the quarter, while the final report (both technical and financial) need to be submitted within 2 months of completion of the study.
- The specific type of disciplinary action for a particular kind of default is described in the table below.

Problem	Action(s)
Failure to submit 2 half yearly. Reports for project 2 years or more and 1 report for projects less than 2 years	Stoppage of funding until reports submission
Failure to submit final reports (after 2 months deadline, no request for extension)	No further funding for 1 year after resolution of the problem
Failure to return the balance of funds after completion of the project (after 1 month deadline) (provided no request for extension has been made)	No further funding for 1 year after resolution of the problem.

- These suggested actions are essentially to do with self-governance
- In cases of misappropriation of funds or fraudulent data an independent committee would be constituted by the governing body to verify the allegations and if found to be true, appropriate action including termination of membership would be taken

APPENDIX I

THE INTERNATIONAL CLINICAL EPIDEMIOLOGY NETWORK (INDIACLEN, Inc.)
INSTITUTIONAL REVIEW BOARD
COMMITTEE ON STUDIES INVOLVING HUMAN BEINGS

Guidelines for the Preparation of Protocols for Review

The Committee on Studies Involving Human Beings (name of IRB) has developed a checklist which will be used by the Committee members for reviewing all research protocols submitted to them (see next page). Please review this list when preparing your protocol to make sure the appropriate documentation has been included in your submission. We hope that by providing this additional outline, the required information is present, the selection of subjects is equitable, the necessary signatures have been obtained and the number of tabled protocols can be reduced. If your research study is to be conducted at more than one institution, you must submit the protocol to the Institutional Review Board (IRB) at each and forward one copy of the IRB approval letter from the cooperating facility.

HUMAN SUBJECT PROTOCOL CHECK LIST

I. Administrative
   a. Protocol "face sheet" filled out properly and thoroughly with appropriate signatures? One copy of the "face sheet" must be attached to each packet.
   b. There should be ten packets.
   c. **A protocol summary (2-3 pages) must be submitted. This information should abstract details from the larger protocol and summarize them**. One copy should be attached to each packet.

2. Scientific Aspects
   a. Is the hypothesis stated?
   b. Does the information to be collected provide a means to answer the hypothesis?
   c. Is a sample size calculation performed? If not, is it necessary?

3. Human Subject Issues
   a. Is the study population defined? Is there "equitable selection of subjects?" (If any subject population is excluded because of age, economic status, race or gender, there must be documentation regarding the reasons for exclusion).
   b. Are there any anticipated problems from using this study population? Is it appropriate for the hypothesis to be tested? Is how the subjects will be recruited documented? Will the study be advertised?
   c. Are the risks adequately defined?
   d. Are there extra procedures to be performed? What are they? Do they execute the usual level of care?
   e. Are the potential benefits clearly defined? To the patient? To society?
   f. Do the benefits outweigh the risks?
   g. Are there clearly documented eligibility and exclusionary criteria?
   h. Are there clear "stop-study" criteria?
   I. Do the procedures prevent subjects from receiving the usual or best care?

j. Are any costs to subjects or the institution defined?
k. Have advertisements for recruiting subjects been provided?

4. Consent Form
   a. Is the study title on each page with the investigator's name and telephone contact numbers on page one only? (Day and 24 Hour Emergency Numbers)
   b. Is there a clear description of the study goals, design and implementation?
   c. Is there a clear description of potential risks? Of side effects or toxicities of drugs? Of x-rays? Of phlebotomy?
   d. Is there a clear description of what is required of the subject? Extra visits? Extra tests? Duration of participation?
   e. Is there a clear description of alternative treatments?
   f. Are all of the standard INDIACLEN statements included confidentiality, withdrawal (by patient, by physician), injury/complications, subject rights, compensation provided (local currency amount), as outlined in Guidelines?
   g. Is the consent form readable and in clear easy to understand lay terms? Are there spelling, typographical or grammatical errors?
   h. One copy should accompany each packet.

PREPARING APPLICATIONS FOR REVIEW

Protocol Preparation

The protocol must be a summary of the research plan outlined according to factors which the Committee considers essential for its review. The protocol should be prepared according to the following outline:

1. Purpose: Summarize the purpose of the study, the hypotheses which are to be tested and a statistical analysis section.
2. Duration: Provide an estimate of the duration of the entire study.
   Please note that Committee approval is required at such intervals as designated by the Committee after final review.
3. Subject recruitment and selection: Provide the numbers of subjects to be invited to participate and specify those to be included as control subjects. If subjects are excluded because of age, gender, economic status, or race, the reasons for the exclusion must be documented. Describe any inducements which will be offered to subjects, e.g., cash payments, free hospitalization, medication, clinical testing, etc. Summarize the process of obtaining potential subjects. All advertisements to recruit research subjects must be submitted for approval. Include copies of all letters to subjects and intermediaries. Indicate all special categories of subjects to be included, e.g., mentally retarded or disabled, minors, pregnant women, prisoners, etc. Please note that administrative or researcher convenience is generally not a justification for use of special groups with limited capacity to give consent if alternative groups are available.
4. Location: Provide the specific name of the hospital, inpatient service or outpatient clinic, school, business or other agency from which subjects will be recruited and when documentation must be submitted that supervisory personnel are aware of the project.
5. Background: Describe succinctly and clearly the past findings which led to the plan for this project. A summary of the relevant literature in the area of interest and reports of previous studies can be included.

6. Research design: Prepare an orderly scientific description of the intended procedures as they directly affect the subject. Include the number and estimated length of hospitalizations, length of time for various procedures (e.g., interviews, completing questionnaires, etc.) and frequency of repetition; randomization; any manipulation which may cause discomfort or inconvenience; doses and routes of administration of drugs; total amount of blood to be withdrawn; and plans for follow-up. If there is a point at which the study procedures may be discontinued, state how it will be monitored and identified. Include measures which will be taken to treat side effects or to handle or refer problems identified during the study. Include three(3) copies of questionnaires or rating scales to be used. If the questionnaires, etc., are standard ones, you need only list the names of those to be administered. If drugs or devices are administered or used, the following questions must be answered. What is the name of the drug or device company? If the drug or device is marketed, is it approved at the dose level you plan, for this purpose, or by this means of administration or use?

7. Potential risks: Describe and assess any potential risks--physical, psychological, social, economic, monetary, legal or other--and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

8. Consent procedures: Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained.

9. Protection of subjects: Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks, and assessment of their likely effectiveness.

10. Potential benefits: Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

11. The Risk/Benefit ratio: Analyze the ratio of the benefit to be obtained from the study relative to the risks involved. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests. All proposals should include a risk/benefit statement.

Consent Form:

The consent form should be a succinct statement (preferably one-four pages) which gives reasonable information about the study, its purpose, procedures, benefits, risks, duration and alternate therapy to enable the subject to make a meaningful decision about participation. It should be entitled Consent Form and sub-titled with the name of the study. The name(s) of the responsible investigator(s) should appear at the top right of page one of the document and the study title should be carried over to the top of each page as well. It is a good idea to date the document and any revisions so that a currently approved form will be used during the study. The consent form should be written in clear, understandable local language which explains the purpose of the study and precisely what will be done to the subject. It must provide adequate information for the subject to decide whether or not to participate. Each adult subject or patient

advocate and each parent/guardian who signs consent for a minor subject must receive a copy of the signed document. The principal investigator must retain in his/her confidential files copies of consent forms signed by each subject in the study for at least 3 years after completion of the research or such longer period as may be specified by program requirements.

I. THE FOLLOWING POINTS MUST BE COVERED IN THE CONSENT FORM:

It is recommended that all consent forms be written in the same person (pronoun) throughout, scientific terminology defined for layman understanding and documents edited for spelling and typographical errors.

a. Purpose: The purpose of the study should be expressed in lay terms and should clearly state the nature of the research project. The subject should be told that he/she is being asked to participate in a research study.

b. Selection of Subjects: The subject must be informed of the reason why he/she has been invited to participate in this study. This may be because of a specific disease or condition which the subject or one of his/her relatives has, or because he/she is believed to be free of a specific disease -- a healthy control.

c. Procedures: The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization, types of medication, placebo administration, types and numbers of tests, total amount of blood to be withdrawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons), randomization, questionnaires, video-taping, diets, withholding of standard treatment, follow-up studies, etc. If a test article is involved, the consent form should explain that:

1) It is routinely used for the proposed purposes of the study.

d. Risks: It must be clearly stated that participation in this study may bear some known or unforeseeable hazards, discomforts, or inconveniences. These may include side effects of drugs, procedural hazards, withholding of therapeutic regimen of proved value, or time involved. The disclosure of risks must also include the implications of randomization of subjects and of placebo administration. If double-blind studies are involved, it should be made clear to the subjects that neither the investigator nor the subject will know which medication the subject is receiving during the study. Special implications of crossover studies should be explained (e.g., the subject who has a beneficial response to the experimental drug may have to do without it for the placebo phase). For any double-blind drug study, the subject must be informed that the code will be broken in the event of an emergency. The name and telephone number of the responsible investigator(s) must appear at the top right on page one of the consent document.

e. Benefits: The benefits to the subject, if any, are to be explained. If there are no benefits for subjects, this too should be clearly stated.

f. Costs: Subjects should be told specifically what charges they are responsible for and which will be paid for by the sponsor. If subjects are to be paid for participation, the schedule of payment and the local currency amount must be documented with specificity. If they won't be paid, this fact must be recorded.

g. Alternatives: In therapeutic studies, alternatives should be described. The description would include other accepted treatment regimens, as well as a brief description of the benefits and risks of each alternative. If the only alternative is not to participate in the study, this fact must be recorded.

h. Confidentiality: In studies involving acquisition or use of sensitive information, the subject must be informed of the steps that will be taken to assure confidentiality, particularly when personally identifiable information is to be recorded. Coding of data, maintaining separate files for identifying information and limiting access to investigators only, as well as eventual disposal of recordings are means of assuring confidentiality and should be described. In some cases, instructions concerning who may be contacted for answers to pertinent questions and/or who will receive information derived from the study should be addressed.

I. Disclaimer/Withdrawal: The subject must be informed that he/she is free to decide whether or not to participate in the study and is free to withdraw from the study at any time. The subject should be assured that non-participation or withdrawal from the project will not affect the standard of care or other services he/she will receive. There must also be assurance that a decision not to participate will not prejudice future interactions with the institution particularly if any potentially coercive relationship exists between the investigator and subject, such as physician-patient, employer-employee, faculty-student, etc.

j. Injury/Complications: Prospective subjects should be advised as to the availability or non-availability of medical treatment or compensation for injury incurred as a result of participating in biomedical or behavioral research. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

l) Studies where no threat of injury exists, no additional statement is necessary.

2) The usual human study involving healthy volunteers or patients in whom complications of the research are expected to be identifiable, the consent form should state:
"I understand that in the event of injury resulting from the research procedures, medical treatment will be provided without cost to me, but financial compensation is not available."
(NOTE: This statement is the one which should be included in most consent forms.)

3) There are a number of disease processes in which complications are particularly severe, frequent, and/or various. e.g., some types of cancer, organ failure, or massive infection. For some categories of investigation in such patients, it may be unrealistic to provide assurances that distinguish complications of research and those of the natural history of the disease. In these special circumstances, it is suggested that the consent form contain a statement such as:

"I understand that complications may arise during the course of therapy either due to my disease or due to the treatment. I have been advised that therapy for any such complications will be carried out by my doctors. I have been advised that no compensation will be provided to me as a result of my participation in this study."

This alternative statement should only be employed when the natural history of the disease and the likely complications of the research are not expected to be separately identifiable.

k. Subject Rights: The following statement regarding the rights of research subjects must appear in all consent forms:

"I understand that if I wish further information regarding my rights as a research subject, I may contact the hospital where the study is taking place."

l. Questions: The subject should be encouraged to ask questions. The consent form should include a statement that the subject has been given the opportunity to ask questions and has had them answered to their satisfaction. If the proposed procedures are complex or hazardous, subjects should be encouraged to discuss them with their own physician or other respected person before making a decision. If the experiment involves a considerable degree of risk, the subject must be briefed twice with at least two days intervening between briefings. If it is anticipated that the second briefing may have to be waived in some circumstances, the investigator should include information to this effect in his protocol for approval by the Committee. Prior to signing the consent form, the subject should be asked to reply, in his or her own words, and without immediate reference to the consent form, to the following questions: (Do not include these questions in the consent form)

a) What is the purpose of this study?

b) What will be done?

c) What risks and discomforts may occur from participating in this study?

d) What benefits may accrue to subjects from participating in this study?

A person may participate in an experiment only if his/her answers demonstrate an educated understanding of it.

m. Conclusion and Signatures: The last statements in the consent document should read, "I have understand and received a copy of the consent form. I agree to participate in this research study. With reference to the requirements above and to document the fact that informed consent has been obtained, the consent form must be signed by appropriate individuals. The subject must sign a statement that he/she agrees to participate in the project. If the subject is a minor, space should be provided for the relative/guardian to give consent, indicating the relationship. A separate assent form must be developed for minors aged 7-18. In the case of subjects whose capacity or competence to give consent is limited for any reason, the signature of the required "patient advocate" or "legally authorized representative" must be obtained. Also, space should be provided on the form for the signature of the investigator and for a witness.

Special Consent Procedures

Oral Consent: In most cases written consent is required. However, on rare occasions, oral consent may be considered more appropriate as per 22 CFR 225.117(c). For such studies the investigator must submit in writing to the Committee the information he plans to present to the subject orally, an explanation of why oral consent is considered more appropriate and a request for a waiver of the requirement for written consent. This will be the case only if:

1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subjects wishes will govern.

2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Departmental Review and Submission to Committee

After preparation of the protocol, the investigator must then submit it to his/her department chairperson for approval. For projects involving personnel from more than one department, investigators must submit the protocol to the chairperson of each department. Students, fellows, doctoral candidates, etc., must also submit the protocol to a faculty sponsor or dissertation advisor. The signature of the department chairperson, (and faculty sponsor or advisor, if appropriate) must appear on the protocol Face Sheet.

The original and three (3) copies of the protocol must be delivered to the Institutional Review Board, for scheduling the review, which will normally be three to four weeks after receipt. Ten copies of the "face sheet", protocol summary and consent form must be

provided as individual packets. While every effort will be made to review protocols in a timely manner, no guarantees can be made as to when a particular protocol will be scheduled. Only a limited number of protocols can be placed on the agenda for a Committee meeting and they are assigned on a first-come-first-served basis. Investigators are urged to submit their studies as far in advance of a deadline date as possible in order to insure timely review. INDIACLEN policy mandates that documentation for human subject review must be submitted at least by the time an application for funding is forwarded to the Institutional Review Board for processing.

Action by the Committee

Copies of each protocol are sent to all Committee members for study. Two members of the Committee are assigned as primary reviewers of the protocol. At the Committee meeting each protocol is discussed by the entire Committee, but, it is the responsibility of the primary reviewers to lead the discussion. In assessing the risks and benefits, the Committee decides whether to a) approve the protocol as submitted; b) approve the protocol contingent on specific revisions; c) table the protocol for substantive change and resubmission to the Committee, or d) disapprove the protocol. The IRB Secretariat will notify the investigator in writing of the action as soon as possible after the meeting.

a) Approval as submitted: The investigator will be sent an approval notice including a statement of his/her responsibility to report adverse reactions and request Committee review of modifications or revisions to the protocol. The investigator will also be informed of his/her responsibility to submit a summary of the project every twelve months for expedited continuing review or more often if requested by the Committee.

b) Withheld approval contingent upon specific revisions: The investigator will be sent a memo describing the revisions requested. After revising the protocol and/or consent form, the investigator will return one copy with the revisions underlined or highlighted to the IRB Secretariat who will forward the revisions to members of the IRBs. If they are satisfactory an approval notice will be sent to the investigator. If the investigator disagrees with requested revisions, he/she may document their reasons for disagreement to the IRB Secretariat. The Chairperson will review this response and if necessary request the investigator to appear at the next Committee meeting to answer questions and explain relevant matters. The investigator will be notified in writing of the Committee's decision.

c) Tabled for substantive change: The investigator will be sent a memo describing the reason for tabling and outlining revisions or clarifications necessary for reconsideration. For some studies one or more members of the Committee may be appointed to discuss the reasons with the investigator (or the Committee may request the investigator to attend the next Committee meeting to answer questions or clarify certain procedures). The investigator must submit 10 copies of the response to the IRB Secretariat for distribution to and re-review by the Committee.

d) Disapproval: The investigator will be sent a memo describing the reasons for disapproving the protocol. Disapproval of the protocol usually occurs when the Committee determines that the risk of the procedures outweighs any benefit to be gained. The investigator may discuss the Committee's review with the

Chairperson or designee. A revised protocol (10 copies) must be submitted for re-review.

16. Institutional Endorsement

Many agencies which fund research require certification by an authorized official of the institution that research involving human subjects as described in the application has been approved by an Institutional Review Board (The Committee). The IRB Secretariat will provide the sponsor with appropriate documentation of the Committee's approval.

17. Re-approval Process

INDIACLEN policy requires that all research studies involving human subjects be reviewed at least every twelve months as long as the project is continued. Dependent on the risks associated with some protocols, it may be necessary to have more frequent reviews than annually. The investigator will be notified via the final approval letter for a specific study when a more frequent review is necessary. Investigators will be sent an annual request for re-approval form approximately two months prior to the anniversary of approval. These forms must be completed and requested materials returned will in advance of the re-approval date to assure uninterrupted activity.

18. Protocol Changes

If the investigator plans to make changes in the research protocol, the requested change must be communicated promptly in writing to the IRB Secretariat, including the exact title of the protocol and a complete description of all changes to be made. If the proposed changes necessitate a change in the consent form, then a revised consent form should also be attached. Approval will be on the advice of the Chairperson. A change in principal investigator must also be submitted to the IRB Secretariat.

19. Adverse Reactions or Other Complications

If any adverse reaction or complication develops in the course of the research to a human subject, the investigator must notify the IRB Secretariat immediately. A written report should be submitted in duplicate to the Committee within five (5) working days of the event.

20. Termination

Investigators must notify the Committee through the IRB Secretariat when a project is terminated.

APPENDIX A

Date:_____ Protocol #

(**For Committee Use Only**)

INDIACLEN, Inc.

IRB PROTOCOL "FACE SHEET"

Submit 15 copies of the protocol for full review or for exempted/expedited review to the IRB Secretariat prior to the initiation of any work involving human subjects or human material. Please limit the title to 2 lines of 50 characters each if possible and answer all items below.

Project Title:

Funding Agency or Sponsor:_____Grant #:

Address:

_____

Principal Investigator, Title & Department:

_____

Mailing Address: Telephone:

E-Mail Address: _____

Other Investigators:

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. __YES__NO This project is to be undertaken as part of a previously approved Program grant. Grant Number, Project Title, and Director:

_____

2. __YES__NO Does the project involve the administration of personality tests, inventories, or questionnaires? If YES, provide the name of the standard tests or questionnaire or 3 copies of the proposed tests.

3. __YES__NO Does the project involve the use or drawing of human blood, blood products, tissues or body fluids?

4. __YES__NO Does the project involve administration of ionizing radiation to subjects for other than clinical purposes?

5. __YES__NO Does the project involve the testing of investigational drugs or devices? If YES, provide: Name of Drug or Device:_____
Name of Manufacturer:_____
If this protocol involves the administration of medications to humans for research purposes (not part of general clinical practice), you must obtain an authorization.

6. Human Subjects would be involved in the proposed activity as either:
__None of the following, or including:__minors,__fetuses,__abortuses, pregnant women,__prisoners,__mentally retarded,__mentally disabled, HIV-Positive subjects.

Signatures: Principal Investigator:

*Department Chairperson:_____ Department:

Department Chairperson: _____ Department:

Faculty Sponsor (if required):

*The signature of each department chairperson with faculty involved is required.

A Dean's signature must be obtained if the investigator is also the chairperson.

INDIACLEN SAMPLE CONSENT FORM

P.I. Name & Department
Telephone Number(s)
Co-P.I. Name(s)
Day Telephone Number(s)

PATIENT INFORMATION SHEET

(Title of Study) (must be at the top of each page)

INVITATION TO PARTICIPATE: I am being asked to participate in a research study because, etc.

PURPOSE: The purpose of the study should be expressed in lay language and should clearly state the nature of the research project.

PROCEDURES: The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization, types of medication, placebo administration, types and number of tests, total amount of blood to be drawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons), randomization, questionnaires, video-taping, diets, withholding of standard treatment, follow-up studies, etc. If a test article is involved, the consent form should explain that:

l. It is routinely used for the proposed purposes of the study.

2. It is experimental and not approved for general use in the India but has been approved for the use in this study.

RISKS: Describe in lay language any potential side effects due to the procedures being performed and/or due to test articles being utilized in this study.

BENEFITS: Direct or to society. If there is no direct benefit to the subject, a statement reflecting this fact must be recorded.

The following statement (as is or amended as appropriate) must be included in the informed consent only if the study drug/device could effect woman of child-bearing age, the unborn fetus or a women breast-feeding a child.

PREGNANCY ISSUES: Due to the effect of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if I am pregnant, I will inform you and understand I will not be included in the study. If I am still capable of becoming pregnant, I will be given a serum pregnancy test prior to entry into the study. I also understand that I will practice a medically approved method of birth control during my participation in the study. Further, I understand that while I am taking this drug/device I should not become pregnant, and if I do become pregnant, I must discontinue

the drug/device and consider termination of the pregnancy. If male contraception methods or warnings are warranted, the appropriate information must be provided in this section.

ALTERNATIVES: Describe in lay language how the patient would be treated if not otherwise in a research study and any potential adverse effects from the alternatives. If there are no alternatives other than not to participate in this study, this fact should be documented.

COMPENSATION: Describe any fees (local currency amount) to be paid to the subject for participation, describe partial payment or no payment for early termination or bonus for completion. Or a statement that there will be no financial compensation for participation.

CONFIDENTIALITY: There are two standard statements of confidentiality, one of which needs to be included this section.

I understand that my records may undergo review and inspection by the United States Agency for International Development (USAID), or any donor supporting this activity.

For non-clinical trial studies:

I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. If any publication results from this research, I will not be identified by name.

ADDITIONAL INFORMATION: A statement that any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation will be provided to the subject. (The investigator must provide the subject and the IRB with a written statement concerning any significant finding(s) that may potentially influence a subject's decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent.

For Clinical Trials involving investigational medications:

I understand that there is no guarantee that I may continue receiving the medication at the end of this study.

DISCLAIMER/WITHDRAWAL: There are two standard statements of disclaimer/withdrawal, one of which needs to be included this section.

PATIENT CONSENT FORM

I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my present or future care. I also understand that should my physician find it necessary, and/or in my best interest, he/she may withdraw me from the study.

I understand that in the event of an injury resulting from the research procedures, medical treatment will be provided without cost to me, but financial compensation is not available.

I understand that complications may arise during the course of therapy either due to my disease or due to the treatment. I have been advised that therapy for any such complications will be carried out by my doctors. I have been advised that no compensation will be provided to me as a result of my participation in this study.

I understand that if I wish further information regarding my rights as a research subject, I may contact the Hospital Administration.

I also understand that if I have any questions pertaining to my participation in this research study, I may contact the physician by calling the telephone number(s) listed at the top of page one.

I have been given the opportunity to ask questions and have had them answered to my satisfaction.

I have read and/or understand the consent form. I agree to participate in this research study. Upon signing below, I will receive a copy of the consent form.

_____

Name of Subject Signature of Subject Date

_____

Name of Investigator Signature of Investigator Date

_____

Name of Witness Signature of Witness Date

APPENDIX II

INDIACLEN BUDGETING AND Accounting Manual for USAID-funded Projects

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INDIACLEN - ACCOUNTING MANUAL FOR PROJECTS

I. INDIACLEN PROJECT TERMS AND CONDITIONS FOR FUNDING

All CEU project directors, principal investigators and their accounting staff should have a clear understanding of their grant's Terms and Conditions. This manual summarizes the requirements and obligations that impact directly on project operations. We advise you to refer to the Terms and Conditions attached to your grant award for full information.

INDIACLEN Terms and Conditions apply to all INDIACLEN funded projects. By depositing INDIACLEN funds, your institution/organization agrees to follow and comply with all the requirements contained therein. No INDIACLEN funds should be utilized until your institution/organization has secured all relevant institutional/governmental authorizations as applicable.

Although the funds come from the INDIACLEN Philadelphia Office (IPO) their original source is USAID. All rules and regulations as stipulated in the agreement between USAID / India and the Government of India remain in force regarding the requirements for source and origin of equipment, allowable items for reimbursement, etc.

Several of the criteria relate to the financial and administrative management of grant funds, equipment and supplies. We present these financial and administrative-related Terms and Conditions here with a discussion of the implications for the management of your project.

BUDGETING REQUIREMENTS

2.1 Letter of Request

INDIACLEN grants are made to institutions. An official letter of request must clearly reflect that the request for grant support is being made by the respective institution. A grant will not be made to an institution on the basis of a request from a staff member. An official letter requesting a grant from the institution must:

- Be signed by an appropriate sponsor or dean, co-signed by the CEU director and where applicable, the principal investigator.
- Name the project for which funds are requested specify the amount being requested from INDIACLEN, and give the time period during which funds would be expended.
- Detail any special payment instructions.

Budget requests must be accompanied by the overall research plan (for new proposals) and one-year workplans including expected outputs (for yearly renewals). See Annexure IV for example of a workplan.

1.2 Budgeting and USAID Categories

All budgets for INDIACLEN/USAID projects are to be submitted by the CEU Director of Primary Investigator with the following CATEGORY HEADINGS. The Category Headings include the following items:

Personnel - Salary support for the following persons: Coordinator, Administrator, Microbiologists, Research Associates, Senior Researcher (PI), Data Entry, Data Analysis, Lab Assistant, Interviewers/Field Workers, Administrative Support/Unit, Partner Organization Administrative Support, Time Protection for PIs/Co-PIs, etc.

Travel - All travel and meeting costs including international and local travel, international, local and field per diem or room and board. Travel costs for IRB and IndiaCLEN meetings and Global Meeting are also included here.

Equipment - All equipment for office, lab, units, and projects including fax machines, copiers, computers, printers, laser printers, software, maintenance contracts, lab equipment (air conditioner, incubator, refrigerator, deep freezer, safety cab., specialized and miscellaneous lab equipment).
Please note: If a sales tax waiver is available by/from an institution, it must be obtained and used. Sales tax will be a disallowed cost in circumstances where sales tax waivers are available.

Supplies - General supplies for office, lab, and units including paper, stationery, pens, pencils, and various other office supplies.

Contractual -Payment for consultants for various projects.

Other - All other budget items including: Honoraria for IRB Members; Communication expenses (fax, phone, postage, e-mail, Medline, etc); Data Dissemination (monographs, edit assistants, workshops, manuals); Training (short courses, lab training, master's level training- national and international); Project evaluation and institutional fees.

Budget requests must be signed by the CEU Director and the Chief Financial Officer of the respective institution. A comprehensive workplan/project proposal must be submitted along with the budget delineating how the project will use the funds to attain its stated goals and objects. A suggested format for a proposed workplan is enclosed as Annexure IV.

1.3 Budget Justifications

Relate each item in your proposed budget from the list above to a fact, circumstance, or explanation, which is to be shown as a just, right or reasonable cost.

2.4 Budget Formats

Refer to Annexure V for a budget example. The following items should be considered when preparing a budget:

- Include unit costs for salaries/month, hotel rates, etc. which will help eliminate mistakes in calculating total amounts
- Budget costs /figures should be listed in local currency
- INDIACLEN will provide information on prevailing US$ exchange rates periodically. Inquiries regarding exchange rates should be directed to the IPO.
- When budgeting for equipment and/or supplies in general, you may use estimated costs from one supplier. If the budget is approved, three price quotations for each item must be provided to the IPO before purchase is made
- Budget proposals should be submitted in Excel or some other financial management tool. This is to minimize errors in calculations; submissions in other formats may delay approval.

2.5. Budget Revisions

When reviewing workplans for the coming year, there may be revisions, changes and/or justifications from the previous year. There should be columns that show the total budget for the project and expenditures for the previous year or years. Balance from the total budget per budget item should be included. For proposed budgets for the coming year, explanations or justifications for changes in the total budget should be included, if any.

II. REPORTING REQUIREMENTS

3.1 Reports

INDIACLEN requires that all projects submit quarterly technical progress and financial reports (every three months). You will find a complete set of Report Forms and instructions attached (Annexure III). Failure to submit Reports on a timely basis will adversely effect continued funding of the grant/project. This also applies to incomplete or improperly prepared reports. All reports must be submitted in the proper format. Refer to Annexure IV for workplans and Annexure V for progress reports.

3.2 Report Schedule

The project report schedule is provided below:

Reporting Periods for INDIACLEN/USAID Grant

Report Period	Report Due
June 16 – September 15	September 25
September 16 - December 15	December 28
December 16 - March 15	March 25
March 16 - June 15	June 25

3.3 Submission of Reports

Reports should be forwarded to the attention of Ms. Tina Heiler, Development and Grants Officer, at:

INDIACLEN Philadelphia Office Fax: 215 222 7741
3600 Market Street, Suite 380 E-mail: <heiler@INDIACLEN.org>
Philadelphia, PA 19104-2644, USA.

Send your reports within two weeks of the close of the three-month period, electronically by e-mail and a copy by fax or regular mail. Please also forward an electronic copy to Dr. Mary Ann Lansang, Executive Director <mlansang@INDIACLENtrust.org> and to Dr. Rodolfo Dennis, Senior Program Consultant <rdennis@javeriana.edu.co>.

III. AGREEMENT AWARD MANAGEMENT

4.1 Cost Reimbursable Agreement

This is a cost reimbursable agreement. This means that INDIACLEN will reimburse, upon submission and review of properly completed progress and financial reports, allowable expenditures up to but not exceeding, the total US Dollar amount specified in the grant award. Small advances in partial payment of the grant award may be approved upon submission and approval of a project description and budget. The balance will be made available in accordance with our approved disbursement schedule and/or properly completed progress and financial reports. In no case may your organization/institution exceed the total US Dollar agreement budget paid out of non-INDIACLEN funds without prior written approval from INDIACLEN.

4.2 Allowable Costs

INDIACLEN will pay/reimburse the recipient for costs incurred in carrying out the grant as described in the approved Project Description and Budget. All costs will be determined by INDIACLEN to be reasonable, allocable, and allowable as defined herein, and be in accordance with the terms and conditions of the grant.

Reasonable Costs are those which are generally recognized as ordinary and necessary and would be incurred by a prudent person carrying out normal business.

In determining the reasonableness of a given cost, consideration shall be given to:

- Whether the cost is of a type generally recognized as ordinary and necessary for the operation of the organization or the performance of the award.
- The restraints or requirements imposed by such factors as generally accepted sound business practices and terms and conditions of the award.
- Whether the individuals concerned acted with prudence in the circumstances, considering their responsibilities to the organization, its members, employees, and clients, the public at large, and INDIACLEN.
- Significant deviations from the established practices of the organization, which may unjustifiably increase the award, costs.

Allocable Costs are those that are allocable to a particular cost objective, such as a grant, contract, project, service, or other activity, in accordance with the relative benefits received. A cost is allocable to a grant award if it is treated consistently with other costs incurred for the same purpose in like circumstances and if the cost:

- Is incurred specifically for the award,
- Benefits both the award and other work and can be distributed in reasonable proportion to the benefits received, or
- Is necessary to the overall operation of the organization, although a direct relationship to any particular cost objective cannot be shown.

Any cost allocable to a particular award or other cost objective under these principles may not be shifted to other INDIACLEN awards to overcome funding deficiencies, or to avoid restrictions imposed by law or by the terms of the award.

Allowable Costs are those costs, which conform to any limitations in the grant or must conform to the approved grant budget. Allowable costs should:

- Be reasonable for the performance of the award and be allocable under these principles.
- Conform to any limitations or exclusions set forth in these principles or in the award as to types or amount of cost items.
- Be consistent with policies and procedures that apply uniformly to both INDIACLEN-financed and other activities of the organization.
- Be accorded consistent treatment.
- Be determined in accordance with generally accepted accounting principles.
- Be adequately documented.

The engagement of sub-grant agreements with other organizations or individuals and the provisions of such sub-grant agreements require the prior written approval of INDIACLEN if they are to be funded within grant award, unless they are already approved in the Project Description and Budget.

Funds may not be loaned or otherwise made available to any other organization or individual; nor can these funds be used to pay for any of the organization's other expenses. Personal accounts are not allowable under INDIACLEN grant awards.

It is INDIACLEN policy that no funds shall be paid as profit or fee to a recipient under any grant or sub-grant. This restriction does not apply to contractual relationship under grant awards or honoraria for review board members.

4.2 Unallowable Costs

Unallowable costs include:

- Advertising and public relations costs
  (Certain public relations costs for the purpose of communicating specific activities related to the sponsored programs to the public or the press are allowable costs. When they are necessary for program outreach effort as required by sponsored programs, public relations costs are allowable. Costs of advertising and public relations incurred solely to promote the organization are unallowable.)
- Entertainment costs (e.g., dinners, parties, alcoholic beverages etc.)
- Contingencies (do not use "contingency costs" in budgets or proposals. This is not an allowable INDIACLEN / USAID cost)
- Professional service costs incurred in connection with litigation against INDIACLEN. Also, defense and prosecution of criminal and civil proceeding, claims, appeals and patent infringements
- Bad debts
- Fines and penalties
- Interest expense
- Losses on other awards
- Taxes, if exemption available
- First class air fare (See also Section 3.13)
- Overhead as a percentage of other costs
- Depreciation
- See also Section 3.11, ineligible and restricted goods (page 9)

If you have a question regarding a specific or unique cost, contact INDIACLEN for a written determination as to its allowability prior to incurring said costs or procurement of an item. Otherwise, if INDIACLEN determines that the grantee has procured goods or services, which per these Terms and Conditions are unallowable or fall into a questionable category, INDIACLEN will require you to refund the disallowed/questioned costs.

4.4 Payment Schedule

INDIACLEN shall, upon receipt of the grant award letter, provide the grantee with an initial advance payment. Subsequent payments will be made upon receipt of satisfactorily completed quarterly Technical Progress and Financial Reports or in response to an established disbursement schedule.

4.5 Project Bank Accounts

For each new project, the grantee must open in a local bank an interest-bearing checking account for the deposit and disbursement of funds provided under the award.

If the project cannot obtain an interest- bearing checking account, the grantee still must ensure that it maintains a separate checking account, restricted only to grant funds. Keep INDIACLEN grant funds for a specific project separate from any other funds. You may not loan or otherwise make available to any other organization or individual the funds provided under the INDIACLEN grant award.

Upon acceptance of grant funds please provide specific information on the bank account including the bank name and branch, address of actual branch depository, account number, interest rate and name(s) of signatories. For those wishing to receive wire transfers, please also provide the Swift Code Number.

We stress again the importance of control over and segregation of project cash from various projects within your CEU and/or Institution.

4.6 Acknowledgment of Receipt of Payments

INDIACLEN's Terms and Conditions require acknowledgement, on a timely basis, of all funds received by the project. Thus, your organization/institution must notify INDIACLEN immediately upon receipt of all INDIACLEN payments. Complete and return promptly the Letter of Acknowledgement sent to you by INDIACLEN. Please attach a copy of the bank statement indicating the amount of local currency received, any commissions or fees deducted, and the exchange rate on the day of receipt. You may fax this information.

Acknowledging receipt of funds plays an important role, as INDIACLEN will not disburse funds if it has no record of receipt of prior disbursements. Maintain copies of these documents as part of the permanent accounting records of the project.

4.7 Interest Earned on Funds

All interest earned on INDIACLEN funds must be reported to INDIACLEN and credited to the respective grant award. Interest earned may be used to offset bank charges or will be refunded to INDIACLEN by a debit of the grant award.

4.8 Program Income

INDIACLEN Terms and Conditions state that if the project generates income of any kind, the full amount generated each period must be reported to INDIACLEN. Also, this program income must be listed and explained in the quarterly financial report.

In general, the project must utilize its income to support project activities as defined in the project description. You must obtain INDIACLEN's authorization to spend any funds earned. If the project identifies and implements unplanned income-producing opportunities during the project period, advise INDIACLEN in writing of the activities, fees, prices, and description of activities concerning the income generation. Additional income must be deposited into either the project's account or another separate account, not mixed with other organizational funds.

4.9 Unexpended Funds and Refunds

Any unexpended funds remaining after the expiration of the approved grant period will revert to INDIACLEN. Unexpended funds should be promptly reported to INDIACLEN.

Any funds that are held by the grantee at the time the grant ends must be refunded to INDIACLEN unless other written instructions regarding disposal of such funds are received from INDIACLEN.

Funds obligated by INDIACLEN for a specific grant, but not yet advanced and/or reimbursed to the grantee at the time the grant ends or is terminated, will not be disbursed to the grantee except for funds obligated by the grantee by a legally binding transaction to be completed within three months and applicable to the award.

If, at any time during the life of the award or as a result of audit, it is determined by INDIACLEN that expenditures have been incurred that are not in accordance with the Project Terms and Conditions; the grantee shall refund such amount to INDIACLEN.

4.10 Extension to Grant Period

Upon written request, INDIACLEN will consider an extension of the grant period to permit completion of the project. A grant extension may be granted upon receipt of an interim accounting and progress report for funds spent to date, justification of extension request, a projected budget, and a timetable for completion of project and further expenditures.

4.11 Procurement - Supplies and Equipment

There are strict rules on procurement of goods and services. Precedence for procurement of items remains with the USA for all USAID contracts.

As specified in INDIACLEN's agreement with USAID, INDIACLEN's geographic code is 000 (US). This means that where possible, all equipment and supplies should be manufactured and purchased in the USA. All items for procurement must be documented and submitted to the contracts officer in Washington, DC (coursed through the IPO) for approval. The IPO will then submit this request for purchase to USAID-Washington, DC for approval before purchase. Exempt from this list to be purchased in the host country are the following:

- utilities (heat, water, electricity etc.)
- communication,
- rent,
- oil for cars, and
- printed materials.

These items should be listed under the budget category "other".

USAID requires INDIACLEN to obtain approval for procurement of <u>all</u> supplies and equipment. Therefore, INDIACLEN must approve all items over Rs. 2,250

(US$ 50) prior to purchase. If a manufacturer were the sole distributor of a specific item, an approval from INDIACLEN would still be required.

If an item to be purchased exceeds $5,000 per transaction, the item may NOT be purchased locally without a waiver from USAID Washington, DC. Unfortunately, the USAID Mission in India is unable to assist the IPO or IndiaCLEN in securing approvals or waivers. This process is solely the responsibility of USAID Washington, DC for all USAID contracts and grant.

Please allow sufficient amount of time to allow for review of all requests for procurement submitted to USAID Washington, DC. The IPO will submit requests for supplies and equipment purchases to USAID Washington, DC biannually on September 25 and March 25. Therefore new requests for purchase of equipment should be submitted to the IPO on or before September 1 and March 1 respectively. All requests for procurement must be accompanied by three price quotations per item to be included in the IPO's biannual submission to USAID. Your request must include the following information for consideration: item to be purchased, quantity, model no., brand, name and address of distributor, and price per item. Other requests for purchases will be considered only in emergency situations.

With the purchase of any equipment or office equipment the project must follow these guidelines:

1. Items to be purchased locally or regionally or in the US over US $50 require prior written approval from INDIACLEN. Include 3 price quotes per item from different suppliers with each request.
2. Items to be purchased locally over US $5,000 require a prior written waiver authorization from USAID Washington, DC.
3. Items to be purchased in the US over US $100,000 require a prior written waiver authorization from USAID Washington, DC

All procurement transactions (Goods and Services) should demonstrate open and free competition. The project must establish procurement procedures and policies that ensure against unnecessary or duplicate purchases. Each purchase should have the necessary documentation to show some form of price or cost analysis, which includes obtaining three price quotes for the same item from three separate suppliers for any item exceeding $50, and a record of the price and comparison of the quantity and quality. Normally the project should select the lowest price for purchase, but can choose the higher price item with justification and documentation. Procurement records for purchases in excess of $50 must include a statement as to the basis for contractor selection, justification for lack of competition if competitive bids not obtained, and the basis for award cost or price.

The project must keep inventory records. All equipment and furniture funded by INDIACLEN must carry labels numbered with the name of the project and the name of INDIACLEN to match the inventory records. In addition, all items must display USAID stickers.

Remember that INDIACLEN retains ownership of all property furnished to your organization’s project or purchased with INDIACLEN funds. You cannot dispose of goods purchased with INDIACLEN funds of US $1,000 value or more without written approval of INDIACLEN.

Expenditures from INDIACLEN funds are to meet allowable costs in the approved budget and which agree with the Project Terms and Conditions. If INDIACLEN discovers any purchases without supporting documents, according to the Project Terms and Conditions the project must refund INDIACLEN within 60 days from INDIACLEN's determination and written request.

Ineligible goods and services (These items without exception may not be purchased): Military, surveillance, weather modification and gambling equipment, police and law enforcement commodities and services, luxury goods, and abortion equipment and services.

Restricted goods (These items require a series of approvals before purchase is made): Agricultural commodities, motor vehicles, pesticides, used equipment, US Government excess property, fertilizer, and PHARMACEUTICALS. Please be advised that under no circumstances may pharmaceuticals be purchased without specific approval from the USAID Washington, DC office, coursed through the IPO.

Restricted Countries (Purchase of items from the listing below is not allowed): Iraq, China, Afghanistan, North Korea, and Sudan.

Waivers:

Any purchased of equipment and supplies over US $50 requires prior written approval from INDIACLEN. Please include 3 quotes from different suppliers for each item requested before purchase is made. A waiver for purchase of equipment and supplies is needed in the following situations.

1. When procurement of goods exceeds $5,000 per transaction in host country, a waiver must be obtained. In other words, any transaction over $5,000 each will require a waiver from USAID Washington, DC if not purchased from a US-based, US-Business. Prior approval from the Contract Officer in Washington, DC must be secured (coursed through the IPO) before any purchase is made for all equipment and supplies.

2. Any non-US professional services to be granted after the total project expenditures reach $250,000 for all contract services (US+non-US) over life of the project require written permission.

Waivers	US limit	Non-US limit
Equipment & Supplies #	Over $100,000	Over $5,000
Contracts	Total contracts over life of project exceeds $250,000	

3. One of the following situations must exist in order to secure a waiver from USAID Washington, DC for local purchases over $5,000:
   - emergency situations,
   - price differential exceeding 50%,
   - compelling local political situation,
   - goods and services not available in US,
   - procurement locally would be to promote the objectives of the foreign assistance program.

Note: These are calculated per transaction. "Per transaction" means per invoice for goods.

4.12 Salaries and Benefits

INDIACLEN will allow budgeting for a percentage of time per month of the salary of the investigator multiplied by the length of time of the project (% time per month x # of months of project = charge for personnel). This rate may be adjusted for seniority.

The Terms and Conditions state the project's responsibility to comply with the implementing organization/institution's policies and procedures, as well as with the laws and regulations of the country in which the project operates. The project must comply with local labor laws and withhold and remit all legally-required payroll taxes. In addition, where applicable the project may have to remit its share of payroll or benefits taxes as well. When the grantee must pay taxes and benefits, include them in the project budget. INDIACLEN will not reimburse or pay for any tax liabilities resulting from project noncompliance with local tax laws and regulations.

With regard to salaries, the project must maintain time and attendance records for all personnel who receive salaries or incentives, either fully or partially paid from project funds. These time and attendance records should indicate the number of hours worked by date for each part time or full time project staff person. The grantee's management shall verify that the project maintains these records, signed by the individual project staff person, certified as accurate by the project director, and retained with the financial records of the project.

4.13 Travel Standards

Air Travel

INDIACLEN is bound by the "Fly America Act". This means the following:

- All international travel must be secured with a US carrier, wherever a US carrier flies the specified route. A less expensive ticket on a non-US carrier is not considered a better option. INDIACLEN must approve all travel tickets before purchase.
- Flights on local carriers are allowed for domestic travel.
- All travel must be fully documented by providing INDIACLEN with a copy of the air ticket and an invoice from a travel agent before funds are disbursed.
- Applicable donor regulations, including prior donor authorizations or notifications, are to be respected. When travelling on project funds, travelers are also responsible for limiting their travel costs to the amounts budgeted and allowed under INDIACLEN policy.
- Staff members are expected to use low cost, reasonable means of travel and to exercise the same restraint that a prudent person of moderate means would exercise if travelling on personal business using personal funds.

- The lowest-cost routing between the city of origin and the destination should always be sought. Selection of other routes must be clearly justified by significant operational advantages, safety concerns, or other valid considerations.
- Trips should be planned and airline tickets booked well in advance to take advantage of lower costs, advance-purchase tickets.
- Airline tickets should be paid directly to the travel agent or airline rather than through travel advances provided to individuals. In the event that a trip involves primarily personal travel, the traveler should purchase the ticket with personal funds and seek reimbursement for the work-related portion. A travel reimbursement may not be issued or used to cover costs that are not work related.
- All individuals travelling on core funds should use the lowest available coach class airfare for travel. Business class may be used for flights, or a series of continuous flights with layovers longer than 14 hours if budgeted and, in the case of project related travel, allowed by the donor. The cost of first class travel may not be charged to INDIACLEN or donor funds. (Note that USAID does not currently allow business class travel under most contracts).

Accommodations

Hotels of moderate price and reasonable comfort should be sought. De luxe or luxury hotels should not be used by travelers on INDIACLEN business except where there are overriding considerations (e.g. moderate accommodations are not available) or when donor regulations allow such costs.

4.14 Institutional Fees

It is INDIACLEN's policy not to provide more than three percent (3%) overhead on grant awards over $25,000. Special circumstances that warrant payment of a higher percentage must be justified in writing.

4.15 Project Audit

As per INDIACLEN's Terms and Conditions, after and/or during each grant award year INDIACLEN may conduct an audit and/or inspection on the project records by an independent public accountant selected by INDIACLEN, USAID, or their representatives. The grantee agrees to provide any additional information, both financial and programmatic, required by INDIACLEN and USAID with respect to questions concerning the audit. The purpose of the audit includes a determination of the propriety and necessity of the Grantee's expenditures in terms of the purposes for which INDIACLEN granted the funds, and to determine the adequacy of the grant's financial management. The audit will also include an inventory of equipment and unused supplies provided to or purchased for the project.

Special purpose audits may take place in addition to any audits carried out by the project and/or its independent public accountants. The audit referred to above differs from a "regular" audit in that it tests that the project has adhered to both financial (the where, who, and what regarding funds) and compliance (INDIACLEN Terms and Conditions and grant document) matters.

The project must take appropriate corrective action within two months after receipt of the audit report in instances of noncompliance with INDIACLEN's Terms and Conditions.

Auditee responsibilities

The auditee shall:

(a) Identify in its accounts, all INDIACLEN awards received and expended and the program under which they were received.
(b) Maintain internal control over INDIACLEN programs that provides reasonable assurance that the auditee is managing awards in compliance with laws, regulations, and the provisions of contracts or grant agreements that could have a material effect on each of its INDIACLEN programs.
(c) Comply with laws, regulations, and the provisions of contracts or grant agreements related to each of its INDIACLEN programs.
(d) Prepare appropriate financial statements, including the schedule of expenditures of INDIACLEN awards.

The auditee shall prepare financial statements that reflect its financial position, results of operations or changes in net assets, and, where appropriate, cash flows for the fiscal year audited. The financial statements shall be for the same organizational unit and fiscal year that is chosen to meet the requirements of this part. However, organization-wide financial statements may also include departments, agencies, and other organizational units that have separate audits and prepare separate financial statements.

Audit findings follow-up

(a) General.

The auditee is responsible for follow-up and corrective action on all audit findings. As part of this responsibility, the auditee shall prepare a summary schedule of prior audit findings. The auditee shall also prepare a corrective action plan for current year audit findings. The summary schedule of prior audit findings and the corrective action plan shall include the reference numbers the auditor assigns to audit findings. Since the summary schedule may include audit findings from multiple years, it shall include the fiscal year in which the finding initially occurred.

(b) Summary schedule of prior audit findings.

The summary schedule of prior audit findings shall report the status of all audit findings included in the prior audit's schedule of findings and questioned costs relative to INDIACLEN awards. The summary schedule shall also include audit findings reported in the prior audit's summary schedule of prior audit findings except audit findings listed as corrected, or no longer valid or not warranting further action.

(1) When audit findings were fully corrected, the summary schedule need only list the audit findings and state that corrective action was taken.
(2) When audit findings were not corrected or were only partially corrected, the summary schedule shall describe the planned corrective action as well as any partial corrective action taken.

(3) When corrective action taken is significantly different from corrective action previously reported in a corrective action plan or in an INDIACLEN management decision, the summary schedule shall provide an explanation.

(4) When the auditee believes the audit findings are no longer valid or do not warrant further action, the reasons for this position shall be described in the summary schedule. A valid reason for considering an audit finding as not warranting further action is that all of the following have occurred:

(i) Two years have passed since the audit report in which the finding occurred was submitted to INDIACLEN;

(ii) INDIACLEN is not currently following up with the auditee on the audit finding; and

(iii) A management decision was not issued.

(c) Corrective action plan

At the completion of the audit, the auditee shall prepare a corrective action plan to address each audit finding included in the current year auditor's reports. The corrective action plan shall provide the name(s) of the contact person(s) responsible for corrective action, the corrective action planned, and the anticipated completion date. If the auditee does not agree with the audit findings or believes corrective action is not required then the corrective action plan shall include an explanation and specific reasons.

4.16 Final Reporting and Close-out Procedures

At the end of the project, the grantee must submit a final accounting and project report within 60 days from the close of the project-funding period. If the project has outstanding obligations to pay which include purchases which the project has incurred, documentation must be provided in writing and dated prior to the project termination date, listing as an obligation the good or service to be acquired. Late submission of Progress and/or Financial Reports will affect prompt disbursement of the balance of funds to your project.

Along with these final reports, enclose a copy of any journal article(s) or monograph(s) generated by using these grant funds. Accordingly, INDIACLEN, Inc. and USAID should be acknowledged as a co-funder and co-contributor to the project endeavor in all publications (ie. monographs or journal articles), manuscripts or presentations.

Title to all equipment purchased during the project resides with INDIACLEN. In addition to the final financial report, you must submit to INDIACLEN within (60) days of the project termination date a list of all equipment valued at over $250 with a letter in which you request to continue using the items listed to further carry out project activities.

IV. MINIMUM CONTROL STANDARDS TO MEET

Accountants define internal accounting control as the plan of organization procedures, processes, and records designed to safeguard assets and the reliability of financial records. Absolute internal control does not exist, and INDIACLEN knows that projects both at primary or secondary locations may not possess adequate staff to assign responsibility and totally segregate the steps in processing transactions.

Nevertheless, you should make every effort to apportion duties in such a manner that no one individual, including the project director or senior grantee personnel, controls all aspects of a transaction.

Whether your organization uses its existing accounting system, or combination of accounting and reporting requirements of INDIACLEN's Terms and Conditions, the following control objectives and procedures will generally satisfy those requirements:

5.1 General records keeping and control objectives

a) Financial records must clearly indicate the source of funds received (e.g. INDIACLEN-furnished, Program Income, Interest) and the allocated use of the funds.
b) Support all transactions (both receipts and expenditures) by original documents, to include invoices, payment receipts, bank receipts, or bank statements. Organize and store these documents safely and have them readily available.
c) Document in writing all responsibilities and functions of personnel (accountants or others) involved in the accounting system of the project as well as all changes to these duties. Separate responsibilities so that the same staff person cannot request, approve and make payments. The achievement of this objective, however, depends on the number of staff and of the arrangement of the project itself. Make every reasonable effort to involve at least two persons in each transaction.
d) Stamp or mark invoices and vouchers supporting the use of funds "Paid" with the date of payment and check or voucher number.
e) Use pre-printed, sequentially numbered receipts and payment vouchers; if not readily available, number documents manually. Account for all numbers, whether pre-printed or manually assigned.
f) Complete monthly bank reconciliations for project expenses and income on a timely basis. If possible, let a knowledgeable person who does not have access to cash, authority to sign checks, or responsibility to record cash transactions prepare, or at least review, these documents.
g) Allow a review of the financial records by the project director or other senior staff person different from the person who maintains the accounts.
h) Maintain a stock (issues) register for all expendable supplies and commodities. The register should indicate receipts, issuances, and the balance for each item controlled.
i) Pay salaries by check. If you must disburse payroll in cash, observe the following points :
   (1) Do not allow the individual who calculates and prepares the payroll to distribute the cash.
   (2) Obtain signed receipts.
   (3) Adequately safeguard unclaimed wages.
j) When paying salary and benefits by check, do not allow the individual who prepares or signs the checks to distribute the payroll.
k) Maintain time and attendance records (sign-in register) for all project staff.
l) All procurement must comply with the stipulations specified in the INDIACLEN grant Terms and Conditions and with any restrictions therein.
m) Keep all accounting and financial records for a minimum of three years after the end of the project.

5.2 Control of Cash

As cash represents the project asset most easily lost, abused or misappropriated, you should accord special attention to the management of project money. Maintain the following controls to ensure the adequate safeguarding of project cash:

(a) Whenever feasible, make payments by check. When not possible, you may pay small project expenses out of a petty cash imprest fund. If necessity requires larger purchases or payments paid in cash rather than by check, the project may relegate a specific short-term imprest fund to a responsible staff person. This individual must then make the payment (generally in no more than two working days), submit receipts for review, and return remaining cash for redeposit.
(b) The project may make small purchases from a petty cash imprest account. Management should set the upper limit amount for such transactions according to the usual and customary practice of similar organizations.
(c) Hold all cash receipts, including project-generated income, outside the bank for the shortest time practical. When possible, make deposits daily; otherwise, as often as local conditions permit.
(d) When using cash advances to carry out project activities and if staffing permits, the person who functions as the cashier should not have record keeping or accounting responsibilities other than recording and tracking advances.
(e) Maintain all INDIACLEN project funds in separate interest-bearing accounts, held in the name of the project and institution.

5.3 Control of Expenses

(a) The project director and/or designate should approve all payments made with project funds. Before signing checks or making cash payments, the project director should review all supporting documentation and approve the disbursement prior to the project making payment. Obtain signed receipts from the payee for all payments.
(b) Separate the duties of payment approval and delivery acknowledgement.
(c) Clearly define the authority for approving purchases of goods and services. Establish procedures to ensure securing proper approval prior to ordering goods and services, and that all procurement follows the project budget and the Terms and Conditions of the grant.
(d) A person not involved in the preparation or approval of payroll should distribute salary checks.

5.4 Control of Budgets

Record all payments in a timely manner in a ledger to allow comparison of budget to actual spending, and prior to requesting payment approval and disbursement consult the budget status. Except for salaries and training, you have the ability to modify your budget up to 10% within budget categories.

Regular analysis of actual spending patterns versus budgeted amounts will alert project management to possible areas for tightened controls, reduction of waste, and will bring to light any need for a request for a total budget amount revision.

V. RECOMMENDED PROJECT ACCOUNTING RECORDS AND PROCEDURES

This section presents the minimum accounting and record-keeping requirements for your INDIACLEN funded project. At its base, the system used should ensure that project accounting records provide an accurate, complete history of the project resources. As with any accounting cycle, four steps accomplish these objectives:

(1) Documentation (includes receipts, vouchers, canceled checks, invoices, and deposit slips).
(2) Recording (includes recording the figures from the documents in special journals and ledgers).
(3) Classification (includes grouping the recorded transactions and comparison with the budgeted amounts for each category of receipts of expenditures).
(4) Summary and preparation of financial reports.

The following sub-sections on accounting procedures follow the above outline, and also present examples of recording certain common transactions. Again, your project's records might not exactly match those illustrated here; however, as long as your procedures and records satisfy the minimum requirements as explained, feel free to continue using your own methods.

6.1 Documentation

Support all transactions with valid documentation, including:

- vendor receipts
- signed statements of receipt by individuals not in a position to issue their own receipts
- bank deposit ticket
- appropriate vouchers and other internally-generated forms.

In order to account for transactions properly documented by the above, we recommend using the following forms:

(a) Checking and Petty Cash Payment Vouchers (see Annexure I)
(b) Checking and Petty Cash Receipt Vouchers (see Annexure II)
(c) Check and Petty Cash Request Form
(d) Advance forms
(e) Time and attendance records
(f) Pay slips
(g) Supplies voucher
(h) Per diem calculation form
(i) Certification of unavailability of US flag air carriers for international travel.

In addition to attaching proper documentation, the responsible project authority must approve every transaction. A project manager, director, or other senior staff member who holds no check signing or other accounting capacity should serve as the individual who gives authorization.

The basis for recording all transactions rests primarily in the voucher. A voucher presents the authorization for a transaction to occur. The project should vest

authority in a responsible project officer(s) (project director, project manager, board member, or other senior official), and only this individual(s), approve(s) disbursements by check or cash.

In general, establish a series of vouchers for each fund, i.e. each checking and petty cash account. Give each voucher a sequential number from the beginning of the year to allow ready reference and to serve as a control over the number of vouchers used to date. This number serves also as a reference in the journals and ledgers to locate a transaction and its original documentation.

Attach each supporting document to its numbered authorization voucher. File all supporting documents with their vouchers according to month and in proper voucher numerical sequence.

6.2 Checking and Petty Cash Payment Vouchers

Utilize payment vouchers for transactions by check and petty cash to control the issuance of cash and checks, aid in categorizing expenses, and ensure that the proper authority gives approval for the expenditure. This form will assist in a "paper trail" : a way to follow cash flows back to the beginning of a transaction which can serve to locate any errors.

The formats include space to mark relevant information such as the date of the operation, an explanation for the disbursement, the amount, and the budget line item to note under which category the expenditure falls. Also, number each voucher sequentially; you could prefix checking account vouchers with a "B" for Bank account (or other letter as appropriate) and petty cash vouchers "PC" in order to distinguish between the two sources when posting. The amount of the total payment should match the figure shown on the supporting document, although you may distribute individual portions to various budget line items as necessary. Finally, the person preparing the form should sign it, and before writing the check or distributing cash, an authorized person should also sign for approval.

After having paid an invoice, stamp it "PAID". By canceling in this way the project will know they paid the bill and will not risk making duplicate payments for the same charge.

VI. REVISION OF GRANT AWARD BUDGET

The approved grant award budget is the financial statement – authorization of the recipient's program as approved during the award process.

The recipient is required to report deviations from budget and program plans, and request prior approvals from INDIACLEN for any of the following:

- To change the scope or the objectives of the project and/or revise the funding allocated among project objectives.
- To change a key person where specified in the award, or allow a 25% reduction in time devoted to the project.
- Additional funding is needed.

- The inclusion of costs that require prior approval in accordance with the applicable set of Cost Principles.
- The transfer of funds allotted for training allowances (direct payment to trainees) to other categories of expense.
- The recipient intends to contract or sub-award any of the work under this award, and such contracts or sub-awards were not included in the approved award budget.

If specified, the recipient may be further restricted from transferring funds among cost categories. Such a restriction would require the recipient to get the prior approval of INDIACLEN before making budget shifts, when the recipient expects to exceed 10% of a specific budget category in the approved budget. INDIACLEN is under no obligation to reimburse the recipient for costs incurred in excess of the total amount obligated under the award.

VII. TERMINATION AND SUSPENSION

INDIACLEN may terminate this award at any time, in whole or in part, upon written notice to the recipient, whenever it is determined that the recipient has materially failed to comply with the terms and conditions of the award.

This award may be terminated at any time, in whole or in part, by INDIACLEN with the consent of the recipient. Both parties shall agree upon termination conditions, including the effective date and, in the case of partial terminations, the portion of the award to be terminated. The agreement to terminate shall be set forth in a letter from INDIACLEN to the recipient.

This award may be terminated at any time in whole or in part by the recipient upon sending written notification to the INDIACLEN with the following information; the reasons for the termination, the effective date, and, in the case of a partial termination, the portion to be terminated.

8.1 Termination and Suspension Procedures.

Upon receipt of and in accordance with a termination notice as specified above, the recipient shall take immediate action to minimize all expenditures and obligations financed by this award and shall cancel such unliquidated obligations whenever possible. Except as provided below, the recipient shall not incur costs after the effective date of termination.

The recipient shall within 30 calendar days after the effective date of such termination repay to INDIACLEN all unexpended funds, which are not otherwise obligated by a legally binding transaction applicable to this award. Should the funds paid by INDIACLEN to the recipient prior to the effective date of the termination of this award be insufficient to cover the recipient's approved obligations in the legally binding transaction, the recipient may submit to INDIACLEN within 90 calendar days after the effective date of such termination a written claim covering such obligations. The INDIACLEN shall determine the amount(s) to be paid by to the recipient under such claim in accordance with the applicable Cost Principles.

Non-liability

INDIACLEN does not assume liability for any third party claims for damages arising out of this award.