Preventive Oncology International Inc. Study Work-Sheet

Steps to building a possible collaboration begin with:

- 1) Identifying a particular primary cancer site of interest.
- 2) Identify a research question of interest to you.
- 3) Identifying an area of the world where the disease is relatively more common to allow more efficient investigation of the identified research question.
- 4) Identify what type of patient care you could provide along with addressing your research question.
- 5) Go to <u>www.poiinc.org</u> for a more in depth introduction to the P.O.I. concept.

Pre-study

- _____Hypothesis
- _____Research Design
- _____Statistics input/ power calculations
- _____Grant application/Research study agreement
- ____Protocol
- _____Identify possible collaborators and choose one
- _____Informed Consent
- _____IRB (USA and Foreign site) (US submission include recruitment advertising)
- _____Government approvals (i.e. Ministry of Health)
- _____Study specific import permits (equipment/consumables)
- _____Study specific export permits (specimens)
- ____Budget
- ____Collaborators contract
- _____Collaborators contract (if more than one needed)
- _____Develop Study Data Base

<u>Study</u>

Sites

- _____Site visits
- _____Agreements with local officials (political and healthcare)
- _____Transportation (for research staff and participants if needed)
- _____Villages or regions to be served
- _____ Epidemiological data
- _____ Estimates of possible participants meeting study criteria
- _____ Space evaluation

POI Work Sheet for Developing Clinical Trials

| Room | s available |
|-------------------|---|
| | Group Meeting and Informed consent |
| | Questionnaires |
| | Instructional videos (i.e. Self-sampling video) |
| | Self-sampling |
| | Visit 1 Clinic Space |
| | Quality Control |
| | Visit 2 Clinic Space |
| | Laboratory (if needed) |
| | Storage (if needed) |
| Hours | available |
| Will lo | ocal clinic also be going on at the same time |
| Room | size and location |
| Room | assignment |
| Equip | ment available |
| | Lights |
| | Examination tables |
| | Specimen and instrument tables |
| | Specialized exam consumables (i.e. gyn exam and sponges) |
| | Sterilization equipment |
| | Cycle time |
| | Capacity |
| | Two Data Input Computers |
| | Storage (refrigerator, freezer of proper temperature) |
| Housing and a | cost |
| Housing and c | Two Data Input Computers Storage (refrigerator, freezer of proper temperature) cost |

_____Food and cost

Personnel (total required in each category, names, and specific jobs)

- ____PI
- ____Co-PIs
- _____Site coordinator(s)
- ____ Doctors
- _____ Nurses
- _____ Aids
- _____ Drivers
- _____ Technicians
- _____Chief Statistician / Epidemiologist
- _____ Data manager
- _____ Study Monitor
- Interpreters or number of bilingual staff needed

POI Work Sheet for Developing Clinical Trials

Laboratory

- _____Space (appropriate for standard testing)
- _____Space (appropriate for new technology)
- _____Space (storage and other support equipment)
- _____Personnel
- _____ Lab Supervisor
- _____ Technicians
- _____ Cytologist
- _____ Pathologist
- _____ Radiologist

<u>Forms</u>

- ____Protocol
- ____Informed Consent
- ____Enrollment form
- _____Refusal form
- _____Specimen tracking
- _____Shipping forms (if needed)
- ____Data forms
- ____Quality Assurance
- ____Labels
- _____Study forms envelope
- _____Patient ID bracelet

IMPORTANT POINTS TO CONSIDER

- 1. With goal of XXXX patients, I would try to organize a manageable patient flow. That means careful assessment of facilities and personnel to support desired patient flow. If patients have to wait long hours or have unpleasant experiences, they are less likely to return for follow-up.
- 2. For a gynecology screening visit (visit 1) with 2 rooms an efficient system should be able to handle 150 patients/day. However I would plan the first few days at 50 to 75 patients/day to establish our systems.
- 3. You must meet with village leaders, public health officials, local health workers (i.e. clinic nurse) to use their guidance to spread the word about the screening program. You should make them aware the screening program will bring to them for free, the most advance cervical cancer screening available anywhere in the world. We hope to demonstrate ways to make all these systems cheaper and more available for women all around the world.
- 4. We need reliable estimates and a commitment of support for the women of their community to receive cervical cancer screening.
- 5. A schedule needs to be developed, we cannot rely on chance.

- 6. We must know how many women are coming each day. We must find individuals in each village or town who will take responsibility for supporting this project for the women of their community.
- 7. The exact facilities must be identified.
- 8. The exact number of rooms must be identified.
- 9. The exact number of instruments, and supplies needed per clinic session per day must be identified.
- 10. Sterilization equipment must be identified, and it must be clear we will be able to either do a day without sterilizing instruments or we must be able to sterilize as we are working.
- 11. If the decision is made to store specimens in the countryside and move them to a city based laboratory then we need a proper large refrigerator for our specimens of the correct temperature and a plan for specimen transport.
- 12. We need a careful assessment of the exact number of personnel that will be needed, and we need to begin recruiting them for the study. Hopefully most will already be employed by city or local government hospitals or clinics so we have less salary to pay.
- 13. Dates for training should be identified
- 14. Estimate the time needed to do the training based on the protocol,
- 15. I will arrive to do the training. If everyone can be brought together I suspect we can do the training in one full day followed by a nice dinner.
- 16. Management of the specimens, proper labeling is a critical job that must be assigned to reliable individuals who do not lose their concentration. Individuals such as laboratory technicians often do this very well and it adds variety to their involvement in a project. Two or three technicians can share the work. We have also used students or nurses for this part of the project. It all depends on who is available on the team to be assigned to this role.
- 17. Teaching the handling of the biopsy specimens is best done in the clinic not in the lecture room. We will introduce biopsy handling but that is much better taught actively with a patient being biopsied.
- 18. Teaching Materials need to be developed
- 19. Any site visit dates should be scheduled
- 20. Any equipment that is not ours that is to be used by us must be checked out in advance and back-up supplies located and or numbers for emergency repairs identified.
- 21. Make a detailed list of all equipment and supplies and mark the amount and who is responsible.
- 22. A detailed schedule for the screening study should always be established.
- 23. Patient follow-up is EVERYTHING. It starts with proper education of the participants on the importance of follow-up. Patient's who feel well informed and well cared for during their first visit are much more likely to follow instructions and return if indicated. Make sure data forms and Q.A. checks always include having a reliable way to study participants once they leave the clinic.
- 24. Finally, once a team is assembled, the members can often learn 2 or 3 jobs, so that we have an efficient way to give people a rest and to accommodate when someone is ill.