

**PRINCIPAL INVESTIGATOR
 APPLICATION FORM**

(Short form for studies of specimens/data/documents)

Form 4.41C (10/17/03)

Send 2 collated sets to IRC	1. This form 2. Your dated <i>curriculum vitae</i> 3. Performance site information	This is an application for an individual person. Study and procedural details should accompany this form.
MAKE A COPY FOR YOUR STUDY BINDER.		

A. THE INVESTIGATOR:

	Principal Investigator	Lead Contact Person
Name (with degrees)		
Mailing address		
City, State, Zip		
Phone		
Fax		
E-mail		
Have you worked with IRC before?	Yes <input type="checkbox"/> - IRCPI Number	

YOUR RESEARCH EXPERIENCE:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you been a Principal Investigator in the last five years?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Has any IRB disapproved, suspended or terminated any of your studies?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Has the FDA ever audited any of your investigations? (Attach the FD 483 or letter, if any.)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Did the FDA - or a study monitor - report any deficiencies? (Please attach explanation)
Explain any yes response	

YOUR POSSIBLE CONFLICT OF INTEREST

<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have any equity or patent position with the sponsor or with a competing company?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you being remunerated for your participation? If yes, in what form? <input type="checkbox"/> Non-Monetary? <input type="checkbox"/> Monetary? <input type="checkbox"/> Salary only
All possible conflicts of interest must be indicated.	

REVIEW PROCESS INFORMATION

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does this study require a Federal Wide Assurance (FWA)? If yes, which federal agency? _____ FWA number
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Process: Full Board Expedited review - Submit the Expedited Review Protocol Form

B. THE STUDY:

Study title	
Version Number /Date	

Within this protocol, what is being done?

Use or collection of Biological specimens	<input type="checkbox"/> from subjects recruited for this donation <input type="checkbox"/> from a repository/bank <input type="checkbox"/> from waste samples
Testing of a diagnostic kit, device, agent	<input type="checkbox"/> from subjects recruited for this donation <input type="checkbox"/> from a repository/bank <input type="checkbox"/> samples sent to a reference lab
Review of private patient/client records	<input type="checkbox"/> from records to which you have direct legal access <input type="checkbox"/> from records for which you need permission to access

Other:

Within this protocol, what will you be responsible for:

acquiring samples,
 banking or transferring samples
 using samples in your research

Yes No Did the acquisition site include any limitations on later distribution?

What will be done with samples when study is done?

Destroyed
 Archived and stored with data in a form that is anonymous or coded
 Given/sold for secondary/tertiary research purposes

D. IRB COVERAGE:

EMPLOYMENT: Where are you employed (50% time or more)?

Yes No Does this employer have an IRB? (If yes, please have that IRB sign the waiver form.)

PERFORMANCE SITE(S): (If there is more than one donor/acquisition site, each must be mentioned.)

Name of facility where the samples are to be collected?	Name of facility of end user?
<input type="checkbox"/> Yes <input type="checkbox"/> No Is there an IRB at this facility? (If yes, please have that IRB sign the waiver form.)	<input type="checkbox"/> Yes <input type="checkbox"/> No Is there an IRB at this facility? (If yes, please have that IRB sign the waiver form.)
It is a <input type="checkbox"/> Hospital <input type="checkbox"/> Reference lab <input type="checkbox"/> Clinic associated with a hospital <input type="checkbox"/> Free-standing clinic	It is a <input type="checkbox"/> Hospital <input type="checkbox"/> Reference lab <input type="checkbox"/> Clinic associated with a hospital <input type="checkbox"/> Free-standing clinic

<input type="checkbox"/> Private practice <input type="checkbox"/> Other	<input type="checkbox"/> Private practice <input type="checkbox"/> Other
<input type="checkbox"/> Yes <input type="checkbox"/> No Are you receiving any identifiable health data? If yes, discuss HIPAA compliance.	<input type="checkbox"/> Yes <input type="checkbox"/> No Are you receiving any identifiable health data? If yes, discuss HIPAA compliance.

E. STUDY SUBJECTS AND PROCEDURES

<p>SUBJECTS:</p> <p>_____ Total number of subjects/donors to be involved in this study?</p> <p>_____ How many samples/records are to be collected?</p>	<p>RECRUITMENT: Where will you find subjects and/or specimens or records?</p> <input type="checkbox"/> your own client base or data base to which you have both legal and ethical access <input type="checkbox"/> employees <input type="checkbox"/> advertising <input type="checkbox"/> samples previously gathered for a different primary purpose <input type="checkbox"/> a repository or bank that will obtain samples or data <input type="checkbox"/> other
<p>COMPETENCY AND CAPACITY:</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Will all subjects be legally competent? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Will all subjects be mentally capable? If no to either, please explain,	<p>REPORTING OF RESULTS (POTENTIAL BENEFIT OR RISK)</p> <input type="checkbox"/> Yes <input type="checkbox"/> No Will any reports or results be returned to the subject? <input type="checkbox"/> Yes <input type="checkbox"/> No Will any reports or results be returned to the referring physician or facility? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, will the information be labeled as experimental?

CONSENT PROCESS: Please give some idea about the consent process leading to signing of the consent form.

If consent was gained elsewhere, document what you know about that consent. <input type="checkbox"/> We have a copy of the approved consent form. (attached) <input type="checkbox"/> We have no idea but ... <input type="checkbox"/> we have a copy of the approval from the local IRB (attached) or <input type="checkbox"/> we have assurance from our source that consent was appropriate (attached).	If you are responsible for gaining consent: PROCESS <input type="checkbox"/> Yes <input type="checkbox"/> No Is there to be any consent discussion? If yes, who will request subject consent? If no, explain the reason DOCUMENTATION OF CONSENT <input type="checkbox"/> Yes <input type="checkbox"/> No Are you asking for a waiver from getting documenting consent (An explanation of how the waiver requirements have been met is attached.) If consent is documented, where is the form to be stored?
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F. MONEY:

<p>SUBJECT PAYMENT:</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Are subjects/donors being paid for participation?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Is there a chance donors could share in the profit from product development?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Are subjects being reimbursed for expenses?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No Are samples being re-sold or transferred out?</p>	<p>SUBJECT CHARGES:</p> <p>Will subjects (or their third party payor) pay for any part of participation?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No Laboratory tests</p> <p>\$ _____ Estimate of total amount subject might be asked to pay</p> <p>\$ _____ Estimate of total amount insurer might be asked to pay</p>
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G. SUBJECTS AND COMMUNITY:

The IRB is charged with considering "community values", but the members may not know your area of the country or of the place where samples are collected. This section should help acquaint us with your community (e.g., the community involved in the work described in your application).

Are there any "community values" or "local issues" that the IRB should consider?

<input type="checkbox"/> Yes <input type="checkbox"/> No	legal issues or state law?
<input type="checkbox"/> Yes <input type="checkbox"/> No	value judgments about the condition or procedure being studied?
<input type="checkbox"/> Yes <input type="checkbox"/> No	disagreements with local hospitals or care-providers?
<input type="checkbox"/> Yes <input type="checkbox"/> No	privacy?

Discuss any other community possible concerns:

H. CERTIFICATION AND ASSURANCES: Biological Specimens, data, or documents

As a Principal Investigator, I recognize I am responsible for the conduct of this study, including the conduct of my sub-investigators and staff. I certify that:

- ✓ The information in this document is correct and is complete.
- ✓ I will follow the protocol, the pertinent regulations and any additional requirements of the IRB.
- ✓ I will notify the IRB of
 - ✓ any deviations from protocol taken to protect the subjects from harm.
 - ✓ every serious or unusual or unanticipated adverse event.
 - ✓ the result of any FDA clinical investigator audit, *and*
- ✓ I or my designee will obtain informed consent from each subject on the approved consent form, allowing each person adequate time before the study to consider the question.
- ✓ I give permission for IRC or its agents to check the information in this form and accompanying information.
- ✓ I will protect the rights and welfare of each subject to the best of my ability.

INVESTIGATOR SIGNATURE: _____

DATE: _____