

- Prosthetics
- Gynecological services
- Others, specify.....
- Organ transplantation, specify.....

9. IONIZING RADIATION USE (X-rays, radioisotopes, etc):
 None Medically indicated only

10. INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

None

IND

DRA No.:.....
 Name:.....
 Sponsor:.....
 Holder:.....

IDE

DRA No.:.....
 Name:.....
 Sponsor:.....
 Holder:.....

11. PROCEDURE USE: Invasive Non-invasive

12. MULTI-SITE COLLABORATION: YES, number of sites... NO

13. FINANCIAL DISCLOSURE: YES NO, why
 not.....

14. PARTICIPATING INVESTIGATORS:

Name/ Institution	License No.	Title and Role	Telephone / Fax No.
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

15. Has the principal investigator ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority?

No Yes, explain.....

16. Does the PI, the study colleagues or their families have any financial relationship with the sponsor other than payment for the conduct of the study?

No Yes, describe the relationship.....

17. For this study, how many of the following will the PI supervise?

Sub-investigators..... Study sites.....

18. How many (in total) of the following does the PI currently supervise?

Open studies..... Location..... Sub-investigators..... Study staff.....

19. Type of facility at the research site:

- Medical office
- University
- Other, specify
- Health facility (specify)
- Community

20. Clinical Monitor Name, if applicable:.....

Tel.....E-mail:.....

21. For genetic study, indicate whether it involves any form of gene transfer.

- No
- Yes, the study has been reviewed by
- NA
- None
- Bio-safety
- Recombinant DNA
- Advisory boards

22. How long will the research data be stored by the PI?years after closing the study.

23. Is there a request for informed consent waiver ?

- No
- Yes

If No, does the informed consent include following information

- a. Informed consent information sheet
- b. Informed consent form
 - i. Literate person
 - ii. Illeterate person for witness
 - iii. Ascent form for children if applicable
- c. Translation of informed consent sheet and form to National Language

24. What precautions will be used to maintain the confidentiality of identifiable health information?

- Records will be kept in a secured location and only accessible to personnel involved in the study.
- Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Before accessing to any study-related information, personnel have to sign statements agreeing to protect the security and confidentiality of identifiable health information.
- Whenever feasible, identifiers will be removed from study-related information.
- Other, specify.....

25. What kind of means will be used to recruit subjects for the study?

- Personal contact
- Referrals
- from database other than the PI's list
- Advertising (All recruitment materials must be approved by REBH before use.)

Other, specify.....

26. TYPE OF REVIEW:	
<input type="checkbox"/> Initial Review <input type="checkbox"/> Resubmission Review <input type="checkbox"/> Amendment Review <input type="checkbox"/> Expedited Review	<input type="checkbox"/> Emergency Review <input type="checkbox"/> Continuing Review <input type="checkbox"/> Report Review <input type="checkbox"/> Protocol Termination
27. Has the research study been disapproved or terminated by any other Research Board? <input type="checkbox"/> No <input type="checkbox"/> Yes, explain.....	
SIGNATURES: _____ Date: Principal Investigator _____ Date:..... Protocol Chairperson (if applicable) COMPLETION: _____ Date:..... Member-Secretary, REBH	
APPLICATION NUMBER : <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	