

IRBs must review studies at regular intervals to determine if - in light of any changes in the study or the world around it - it remains approvable. This is also a good time to review your files to make sure all your documentation is in order.

A. IDENTIFICATION of STUDY AND PEOPLE

DATES

IRC Approval Number	IRB Expiration Date	Date - Last Possible Submission
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THE STUDY

Study Title
Protocol date/version
Sponsor or Agency
Activity <input type="checkbox"/> acquisition , <input type="checkbox"/> repository , <input type="checkbox"/> research use

CONTACT

Investigator

Place for invoice to be sent

Name		
Title		
Phone		
Fax		
e-mail		

EDUCATION All investigators must now demonstrate basic research education. Describe any relevant training taken in the past two years. Attach website or course work completion documentation.

Date/Name of course (evaluation if possible)	Date on site	Name and location of the subject	Code of Ethics of your professional organization
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Principal Investigator			
Any other			

* The Belmont Report is available at www.irb-irc.com. It should be read periodically.

CONFLICTS OF INTEREST Describe amounts and changes

Sponsor or competitor stock Bonuses

Future interests, gifts, other

Principal investigator			
Coordinator/staff			

B. STUDY ACTIVITY - UPDATES AND INFORMATION

Continuing review is intended to assess whether anything has happened that would alter the original decision to approve. The major change in this area might be a change of source material, consent at acquisition, or measures to assure protection of privacy.

Describe any changes made in this protocol after the last complete review. Include IRC approval number for the change if approval was sought & granted. (e.g. include all expedited reviews).

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Describe any changes requested at this time. (HIPAA changes must be included.)

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Source/Acquisition SITES List all sites from which you received biological specimens

Contact info?	Site 1	Site 2
Name		
Address		
Phone		
Fax		
What kind and number of specimens?		

Research Use SITES List all sites where the specimen was used in research

Contact info?	Site 1	Site 2
Name		
Address		
Phone		
Fax		
What kind and number of specimens?		
A few words on the study goals		

C. CONSENT AND PRIVACY EVALUATION

CONSENT EVALUATION Summarize here or attach information

What information is available about the consent of the donor?
Do you have a (sample) copy of the consent document?

EXTERNAL EVENTS Summarize here or attach information

Any changes in this field that impact your work?	<input type="checkbox"/> None or N/A or
Any social, legal, economic or other change that would alter donor perception (if they knew)?	<input type="checkbox"/> None or N/A or

RISK AND DISCOMFORT EVALUATION Summarize here or attach information. A frequency table can be very useful.

Has it been necessary to break any code to return any information to a donor?	<input type="checkbox"/> No or N/A or
Have any results had an impact on the group the donor represents?	<input type="checkbox"/> None or N/A or

BENEFIT EVALUATION Summarize here or attach information

What benefit has come from your work?	<input type="checkbox"/> None or N/A or
Has any publication resulted? If yes, attach it.	<input type="checkbox"/> No or N/A or

REVIEW EVALUATION Summarize here or attach information

Has this study been submitted to any other IRB? Is there something we can learn from that review?	<input type="checkbox"/> No or N/A or
Please use one or two adjectives to describe your views of IRC and of the IRB. (Add an evaluation if you wish.)	

SIGNATURES

- Everything on this is true. It is also complete.
- If you can attach an electronic signature, we will accept it. If not, we will accept the form electronically but a signed copy must be sent.

Person who prepared the response

Investigator: Person responsible for it.

Signature		
Printed name		
Date		