

# Human Research Protections Newsletter

## Investigator IRB records

Remember to retain a copy of the IRB approved version of your protocol, consent document(s) and any instruments for your own records. Should your protocol be selected for a random or directed audit, the research records and procedures will be compared with these documents. Also, electronic copies can easily be revised when a change is submitted for IRB review.

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## Exemption determinations expire after 3 years

Beginning in 2006, IRB exemption determinations were limited to a period of 3 years. This allows for orderly closure of protocols that are usually short-term in nature, and helps to ensure that changes will not be implemented in a project without IRB approval.

The expiration date for your project is listed on the IRB approval letter; the IRB office will also notify the PI via email. Action is required only if the project will continue, and the investigator is responsible for submitting a new protocol to remain in compliance.

**NOTE:** New applications utilizing old versions of the protocol form (prior to 2008) will no longer be accepted for review.

## IRB Approval Stamp

An IRB approval stamp is now available for use on consent documents. CDFS researchers Margaret Fitzgerald and Barbara Chromy have used the stamp to assure prospective participants of study approval. If you would like a stamped copy of your consent document, notify the IRB Office.

## Your Questions:



**Human subjects research is conducted in many diverse disciplines at NDSU**

## Does my project require IRB approval?

This question comes up frequently, and can be confusing because not every survey or interview is applicable to IRB review, and sometimes the involvement of 'human participants' may not be immediately obvious.

Question #1: Will this be a 'research' project (in whole or in part) ? If yes, then:

Question #2: Will NDSU be 'engaged' in the research? If yes, then:

Question #3: Will the research involve 'human subjects/participants'?

If the answer to all three questions is 'yes', prospective NDSU IRB review is required. Visit the website for these definitions; feel free to call the IRB office with any questions regarding your project.

[ndsuh.edu/research/irb/rcatt\\_irb\\_faq](http://ndsuh.edu/research/irb/rcatt_irb_faq)