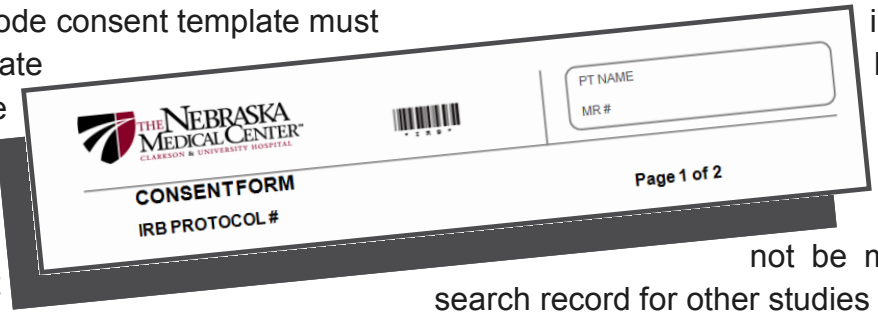
IRB FREQUENTLY ASKED QUESTIONS

WHEN DO I USE THE CONSENT TEMPLATE WITH THE NEBRASKA MEDICAL CENTER IRB BARCODE AT THE TOP OF IT AND WHERE DO I GET IT?

When a copy of the consent form is to be placed in the subject's medical records (per The Nebraska Medical Center Medical Records Policy #MS22), then the barcode consent template must be used. This template can be found on the UNMC IRB website (www.unmc.edu/irb) under Forms – Examples -Hospital Consent Letterhead.



Consent/addendum forms for genetic research will not be placed in the subject's medical record when the IRB has concerns over: 1) third party accessibility and subject confidentiality, 2) the subject's health insurance status or employability may be jeopardized, and 3) the subject's medical safety will not be compromised by excluding the consent form from the medical record (e.g., biochemical/molecular studies which have predictive implications; family history studies).

The IRB reserves the right to require that consent forms not be maintained in the research record for other studies where breach of confidentiality constitutes a risk.

It is the responsibility of the person completing the submission to put their consent form on the correct letterhead. Study consent forms that do not go to Medical Records need to be submitted on Department letterhead to maintain the integrity and professionalism of the Institution.

WHEN DOES THE IRB CONSIDER A SUBJECT "ENROLLED" IN THE STUDY?

A subject is considered enrolled in the study if they have signed the consent form. Be careful not to confuse "randomized" with "enrolled". Even if the subject is never randomized, is a screen failure or never participates in any research interventions or study procedures, they are still considered enrolled and count toward the accrual number approved by the IRB.

WHAT IS THE DIFFERENCE BETWEEN PROSPECTIVE & RETROSPECTIVE WHEN FILLING OUT A MEDICAL RECORDS OR HUMAN BIOLOGICAL MATERIALS APPLICATION?

Prospective records or specimens are those that do not exist at the time that the IRB Application is signed, whereas retrospective do exist at the time that the IRB Application was signed. A study can classify as either prospective, retrospective or both.

ARE FULL BOARD CONTINUING REVIEWS REVIEWED AT EACH MEETING?

Adult Full Board Continuing Reviews are only reviewed at the second meeting of each month. Because the PedsIRB meets only once per month, those Continuing Reviews are reviewed at each meeting. Please keep the following in mind with consideration to your Continuing Review submission to ensure that the study does not go into Approval Expired status: 1) dates of the meeting, 2)the date of expiration of the study and 3) possibility that the Board may request modifications or clarifications .

HOW CAN I GET A SUBMISSION TO THE UNMC IRB IF I AM AT UNO OR CHMC?

You can address and label your submission in an envelope or box with "UNMC 7830 via courier".

WHY DO THE 30 COPIES OF MY FULL BOARD SUBMISSION NEED TO BE DOUBLE-SIDED AND STAPLED WITH A SINGLE STAPLE?

The IRB will accept up to 15 new or previously tabled submissions for each meeting. Each of those submissions comes with 30 copies, one for each Board Member. Having those copies double-sided significantly reduces the size of the packet that each member receives to review. Keep in mind that IRB members travel either across campus or from other institutions to attend the meeting and must carry these packets with them. One single staple in that packet makes it easy for the IRB staff and Board Members to differentiate the studies during the check-in and IRB review process. If you do not have access to a stapler that is large enough to accommodate the size of the packet, feel free to come to the IRB Office on the 3rd floor of the ARS (Academic and Research Services) Building during regular business hours to utilize ours. Please follow the specific submission instructions at the back of the application, as studies that are submitted incorrectly will be returned without regard to deadlines.

IS IT RESEARCH OR A QUALITY IMPROVEMENT ASSESSMENT?

Research is defined at 45 CFR 46.102(d) as, *"any **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** knowledge."*

Quality improvement projects are not considered research if all of the following criteria are met:

A) The primary intent of the project is to:
   1) Improve the quality of patient care or efficiency of a healthcare operation, or
   2) Improve the quality or efficiency of a non-health care operation
B) The project design uses established quality improvement methods.
C) The project does not impose any increased physical or psychological risk or burden on patients or other participants.

Publishing or presenting the results of a quality improvement project does not necessarily mean the activity is research. Descriptions of non-research activities (e.g., an account of the quality improvement project) are often an expected outcome of the project. On the other hand, re-analysis of the data derived from the quality improvement project in order to prove or disprove a hypothesis is research. Depending on whether or not subject identifiers are maintained, it may qualify as exempt research.

If you have questions whether your activity qualifies as research, please contact Gail Kotulak @ (402) 559-6540 or Sue Logsdon @ (402) 559-3779.

IRB Frequently Asked Questions
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Once your study has been assigned an IRB#, please put the full IRB# (# # # - # # - X X) on any documents sent to the IRB office.

Please email questions to be addressed in future issues of "IRB Frequently Asked Questions" to Jenny Kucera (jikucera@unmc.edu)

STATUS:

☐ New Submission
☐ Revised protocol, IRB #_____;

The only time that a submission should be checked as "New Submission" in Section I of the IRB Application is before it has an IRB#. Once the IRB# has been assigned, the IRB Application should always be checked as "Revised Application" with the assigned IRB# documented.