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Treatment Use Forms are Available

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The IRB Office is pleased to announce that there is a new application process customized for treatment uses (also referred to as compassionate uses) of drugs and devices available only by special approval from the U.S. Food and Drug Administration (FDA). The following is a summary of the new forms.

Application for Treatment Use of a Drug or Device:

Review by a convened IRB is required to use a Humanitarian Use Device or to administer drugs or devices through an Expanded Access program. This streamlined IRB application form focuses on the physician's planned treatment uses.

Consent Template for a Humanitarian Use Device:

This consent template is available for explaining treatment using a Humanitarian Use Device. The template helps a physician explain the nature of a Humanitarian Use Device and document the risks, benefits, and treatment plan.

Consent Template for Treatment Uses:

This consent template is available for explaining administration, risks, and benefits of a drug or device only available under an Expanded Access program. This template can be used to describe Expanded Access IND programs for single patient INDs, intermediate size patient populations INDs, for large populations under a Treatment IND. Additional customization would be needed for a treatment IDE.

Please examine the new IRB webpage featuring application processes for treatment uses:

<http://www.nationaljewish.org/professionals/research/support/compliance/irb/submissions/initial-submissions/treatment-use/>.

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Emergency Uses

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The Treatment Use webpage also provides the process to follow when a patient is faced with a life-threatening or severely debilitating condition, and a restricted-access drug or device is needed before the IRB can be convened to review the request (<http://www.nationaljewish.org/professionals/research/support/compliance/irb/submissions/initial-submissions/treatment-use/#emergency>).

The webpage outlines the steps for interacting with the IRB Office and the nature of documentation

required. The page also provides links to the FDA website to assist clinicians in finding forms or contact information for processing emergency uses.

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Initial Submission Page Reorganized

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To accommodate the multiple types of research and treatment submissions, the [Initial Submissions page](#) was divided into five distinct application pages:

1. Drugs or Devices Administered for Treatment Use/Compassionate Use or Emergency Use
2. Research on data and/or specimens that does not involve contact with human subjects, such as chart review studies or specimen analyses (non-human subject determinations, exempt review, and expedited review)
3. Research involving contact with human subjects for intervention or collection of health information (expedited or full committee review)
4. Research involving contact with human subjects that typically does not involve

collection of health information, such as online surveys, educational testing, etc. (exempt review)

5. Research at National Jewish Health when another IRB serves as the IRB of record

If unsure which application process to follow, please contact me or the IRB office (303-398-1477) for guidance.

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Update on the HIPAA Omnibus Rule

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Steve Leibold and I have been studying the Omnibus Rule and communicating with COMIRB and other local IRBs to learn how the Rule will be implemented at other facilities.

Most of the changes to the Omnibus Rule will impact protections of health information for clinical care, but there are a few provisions unique to research. Of greatest interest to researchers is the new flexibility to “compound” authorizations, that is, to combine two or more authorizations into a single document.

We will provide updates as the plans are finalized, including posting new templates to the IRB website. Stay tuned!

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Guidance on Waivers of Documentation of Informed Consent

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A Waiver of Documentation of Informed Consent is customarily requested for research where subjects will provide verbal consent but not written consent for some or all of the research. In order to qualify for a Waiver of Documentation of Informed Consent, the IRB requests a detailed justification as to why the waiver is appropriate.

OHRP regulation 45 CFR 46.117(c)(2) and FDA regulation 21 CFR 56.109(c)(1):

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

... That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Sample situation:

A researcher would like to screen prospective subjects by telephone to see if they qualify to participate in a research study. If they appear to qualify based on preliminary screening questions, these individuals will be asked to come to the institution to review the consent form.

The researcher has created a script that will be read to prospective subjects over the phone and the researcher has submitted this script for IRB review. In the script, prospective subjects will be informed about the purpose of the call, the nature of questions that will be asked, the plans to keep their responses confidential, and what will happen to their information if they don't qualify for the study based on telephone screening. Prospective subjects will then be asked to provide verbal consent to initiate the screening questions.

To provide a justification in the Waiver application form...

Do not ... state that this is “just telephone screening” because some screening can involve greater than minimal risk to subjects—especially when asking about sensitive medical history or legal issues.

Try to ... focus on why the screening does not constitute greater than minimal risk. Most researchers focus on the non-sensitive nature of their planned screening questions. Describe the scope of the telephone script and explain that subjects will provide verbal consent.

Example of a detailed justification:

“Based on the nature of the telephone script and screening questionnaire, this screening activity presents no more than minimal risk of harm. The script informs prospective subjects about the types of questions that will be asked and that there are no plans to ask sensitive questions. There are robust confidentiality practices involving limiting access to the information obtained during screening. Prospective subjects will indicate willingness to participate in telephone screening by providing verbal consent. Normally, there is no requirement for written consent for telephone screening outside the research context.”

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