Review Preparatory to Research (RPR) Form

If an investigator wishes to review protected health information (PHI) to determine the feasibility of a research project, he/she may do so by notifying the IRB of a planned ?Review Preparatory to Research? (45 CFR 164.512(i)(1)(ii)). By this notification the investigator declares that he/she will use the PHI solely as needed to prepare a research protocol or for similar purposes preparatory to research, that the PHI will not be reused or re-disclosed for another purpose or leave the investigator?s institution (covered entity), and that the PHI is necessary in order to develop the protocol.

Note that a Review Preparatory to Research may be used by an investigator, prior to IRB approval, in order to review the PHI of potential research subjects; however, the investigator may not contact potential subjects to ask for their participation in the research without first obtaining IRB approval of the research. Likewise, the investigator may wish to record PHI or other identifiable private information obtained from a Review Preparatory to Research; however, the investigator may not do so without first obtaining IRB approval of the research and either consent of the research subject or IRB-approved waiver of consent, as described at: http://privacyruleandresearch.nih.gov/

When notifying the IRB of plans for a review preparatory to research, complete this interactive RPR form. After you complete and submit the RPR form, shortly afterward you will receive an email containing your RPR Number.

<table>
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<th>Principal Investigator</th>
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<td>Name *</td>
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<td>Degree *</td>
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<td>- Select -</td>
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<tr>
<td>DUHS Faculty/Senior Staff? *</td>
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<td>- Select -</td>
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<tr>
<td>Duke Unique ID Number *</td>
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<tr>
<td>Email *</td>
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<tr>
<td>If within Duke, please provide Department/Division</td>
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If outside of Duke, please provide location

Faculty Sponsor (if applicable)
Name
Email

Submitter (if not the principal investigator)
Name
Duke Unique ID Number
Email

Protocol Information
Does this refer to an existing IRB protocol? *
? Yes
? No
If yes, what is the IRB Number?
If yes, what is the Protocol Title?
Is the review of PHI for the purpose of developing a new research protocol? *
? Yes
? No
If yes, please state the working title
Is the review of PHI for the purpose of ascertaining or recruiting subjects for a study? *
? Yes
? No

Protected Health Information PHI to be Reviewed
Please describe the specific PHI that will be reviewed to prepare a research protocol and/or to ascertain and/or recruit subjects *

**Principal Investigator’s Affirmation * **

? The PHI is necessary for the purposes of this activity.

? The PHI will be used solely for this activity.

? The PHI will not leave DUHS.

? The PHI will not be written down or recorded prior to the subject signing a research consent form.

? I will not use the information accessed through this RPR procedure for any other purpose, including for presentation or publication.