

**Form HS-9 Decision Tree<sup>1</sup>**

Review of medical records only?<sup>2</sup>      No      →      Submit Form HS-1 &  
HS-1(a) HIPAA application

↓ Yes

Intent to use medical record review      Yes      →      Submit Form HS-1 &  
to identify & contact patients      HS-1(a) HIPAA application  
for future research?

↓ No

Submit Form HS-9 to the IRB.

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Is it possible to obtain informed      Yes      →      Submit an informed consent  
consent from the patient-subjects?      form with the Form HS-9  
to the IRB

↓ No

Use the HS-9 to request a waiver of  
informed consent & waiver of  
HIPAA Authorization.

↓ Yes

Submit the HS-9 application to the IRB.

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<sup>1</sup> Submission of the HS-9 replaces both the HS-1 and HS-1(a) HIPAA sub-application.

<sup>2</sup> The Form HS-9 applies to medical record review only. If the research includes any other interaction or intervention with subjects, please use the Form HS-1 and HS-1(a).