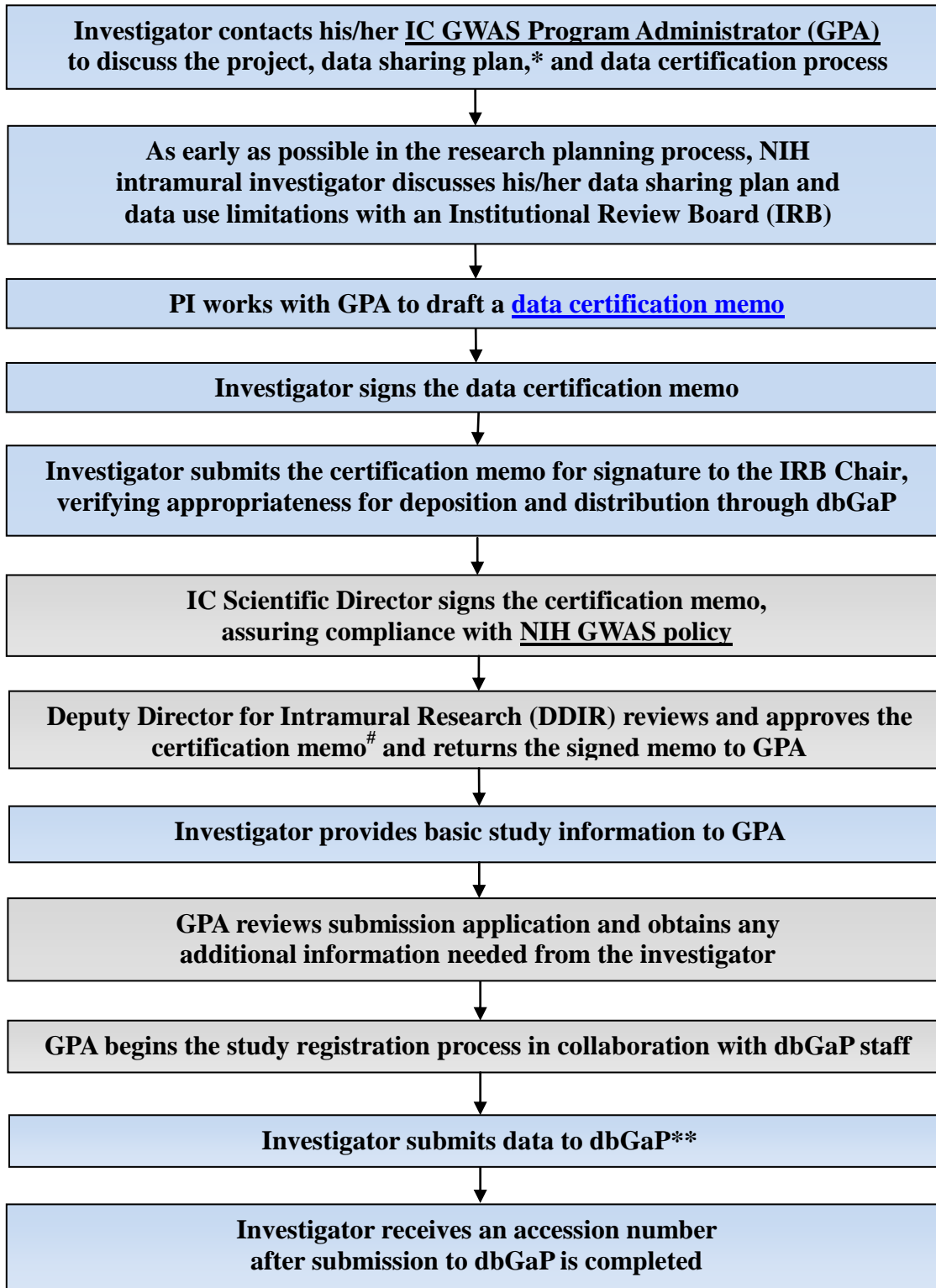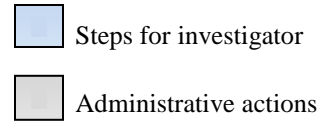# Model Process for NIH Intramural Investigators to Register and Submit Genomic Studies to dbGaP

Color Code

Steps for investigator

Administrative actions

Investigator contacts his/her IC GWAS Program Administrator (GPA) to discuss the project, data sharing plan,* and data certification process

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As early as possible in the research planning process, NIH intramural investigator discusses his/her data sharing plan and data use limitations with an Institutional Review Board (IRB)

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PI works with GPA to draft a **data certification memo**

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Investigator signs the data certification memo

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Investigator submits the certification memo for signature to the IRB Chair, verifying appropriateness for deposition and distribution through dbGaP

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IC Scientific Director signs the certification memo, assuring compliance with NIH GWAS policy

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Deputy Director for Intramural Research (DDIR) reviews and approves the certification memo# and returns the signed memo to GPA

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Investigator provides basic study information to GPA

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GPA reviews submission application and obtains any additional information needed from the investigator

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GPA begins the study registration process in collaboration with dbGaP staff

↓

Investigator submits data to dbGaP**

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Investigator receives an accession number after submission to dbGaP is completed

* In limited cases, following consultation with the GPA, an exception to deposit data in dbGaP may be granted by the DDIR. In these cases, investigators will still follow the process outlined above. Reasons for the exception will be made publicly available.

In cases were an exception to deposit data in dbGaP is sought, the NIH ICD (or delegate) reviews and approves the application for an exception.

** In lieu of data submission when an exception is granted, investigators are expected to provide an acceptable alternative data sharing plan.

Last revised by NIH: November 19, 2012