The UW dbGaP Certification Process

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The recent implementation of the NIH GWAS requirement for IRB certification of data submitted to the NIH GWAS Data Repository, database of Genotypes and Phenotypes (dbGaP), prompted individual IRBs to interpret and operationalize the requirements into a sustainable practice. With the creation of policy, guidance, and standardized internal processes, the University of Washington Human Subjects Division (UW HSD) has established a consistent and reliable method for their IRBs to certify submission of data to the dbGaP while providing the UW research community, HSD staff, and IRB members with the necessary information to understand both the federal requirements and the UW IRB process in certifying such submissions.

Development of Forms/Process

1 What is required of the IRBs to certify data for dbGaP submission?

The primary documents used in the development of our certification process were the "National Institutes of Health (NIH) Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) policy", and "NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)". While neither document defines a process by which to certify dbGaP data, the "Points to Consider" document (or, the latter document) clearly delineates NIH policy as well as "specific points to consider for institutions and IRBs in their review and certification of an investigator's plans for submission of data to the GWAS data repository, including the adequacy of consent forms for data submission."

2 Are there any additional institutional or state regulations that we need to consider?

Unlike the federal definition that a human subject involves only living individuals, Washington State requires that authorization be obtained for data not originally consented to be released for research. This includes data from a medical record or residual specimens (RCW 70.02). We also sought clarification on a previous institutional interpretation pertaining to this RCW that further defined an individual's DNA as potentially identifiable. Watch out…the local regulations proved to be more difficult to incorporate into the dbGaP certification process.

3 The certification process is not an IRB "action" but a "determination." Is there an existing internal review process that we can utilize?

Initially, we found that dbGaP certification requests were submitted as modifications to existing approved studies. As time passed, initial submissions began to include dbGaP certification requests. These types of requests were relatively straightforward to approve and process, as they accompanied an IRB action and subsequent IRB study number. What proved to be more of a challenge was how to provide a dbGaP certification for a research activity that did not meet the federal definition for "research with human subjects" yet would be posting data from this activity to dbGaP.

4 Who will certify the submissions?

We receive requests for dbGaP certification for studies reviewed by the convened IRB as well as for studies that are reviewed via expedited review. We also receive requests on forms that allow for determinations (e.g., not human subjects and exempt). The UW has embraced the flexibility found in the federal regulations and has a subset of staff that primarily reviews studies involving 'minimal risk' – known as the Minimal Risk team – as well as research activities in which exempt and "not human subjects" determinations are made. The Minimal Risk team is comprised of staff who are also IRB members and who therefore have authority to approve research activities on behalf of the IRB for which they serve. Given this arrangement, dbGaP certification requests that accompany studies reviewed by the convened IRB are routed to their respective IRB. Additionally, those dbGaP certifications that accompany 'minimal risk' studies or those in which determinations are made are routed to the appropriate Minimal Risk team member. The dbGaP certifications reviewed by the Minimal Risk team is reported to the convened IRB at the next available IRB meeting, in accordance with federally mandated reporting of an expedited action.

5 What forms/documents do we need?

For the UW research community, we created a *Policy and Guidance Document* that outlines UW principles for submission of data to the dbGaP, provides an overview of internal processes, and outlines the materials that need to be submitted to the IRB. The *dbGaP Supplemental Form* was created to assist researchers in providing the IRB with the necessary information for dbGaP certification. This form queries researchers about the source, type of data (i.e., retrospective, prospective, or both), populations to be included (i.e., adults, children, or vulnerable populations), the investigator's de-identification plan, and a checklist for text that should be included in the informed consent document. The creation of standardized consent form text has been especially helpful in creating consistent language in consent forms that collect data for submission to dbGaP.

For the UW HSD staff and IRB members, we created an *Internal Guidance Document* that provides staff and members with an overview of processes for dbGaP submission requests including: triage, submission preparation, IRB review and verification, file and database documentation, correspondence to the investigator, and the preparation of the dbGaP certification letter.

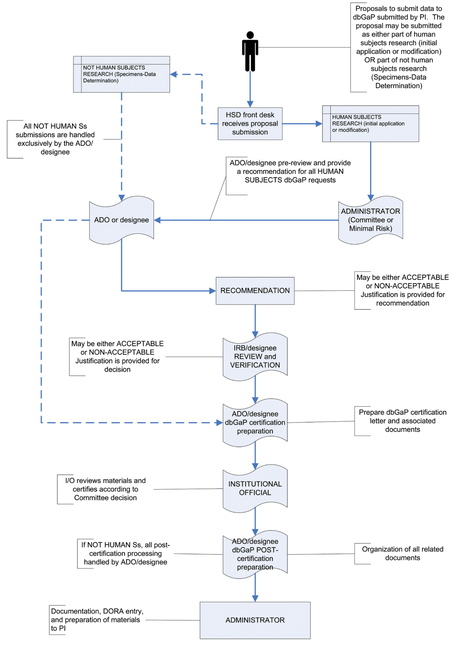
To assist in determining the presence or absence of NIH required elements of consent for submission to the dbGaP, the *dbGaP Certification Checklist* was created. During IRB review, any discrepancies, information that precludes submission or omission of information is indicated on the checklist. We have also created a *dbGaP Submission Flowchart* to provide an overview of the dbGaP certification process within the HSD and act as a quick reference for UW IRBs and HSD staff.

6 How do we "get the word out" about the UW dbGaP certification process?

How do you successfully implement a dbGaP certification process when no one is really sure what dbGaP is, that it involves the submission of data that do not meet the federal regulatory definition of a human subject, and does not involve an IRB "action"? Very carefully!

For the research community, we held several 'brown bags', sent out campus-wide announcements, prominently displayed our dbGaP certification process on our website, and had a dedicated point-person for all dbGaP certification questions.

For IRB members, we held 'brown bag' sessions, and provided education at each IRB meeting for several weeks to account for variable member attendance. To date, a dedicated staff member attends every IRB meeting in which a dbGaP certification is presented for review, in order to assist the IRB with any questions and provide additional information as necessary.

For staff, we chose a limited number of individuals who would be responsible for the oversight of dbGaP certification. These individuals are considered our dbGaP experts and triage any questions that the rest of staff may have. By limiting the number of dbGaP experts, we were able to provide in-depth training to a limited number of people. To the rest of our staff, we provided a limited overview. This proved to be a huge saving in time and resources.

How it works