

In This Issue

- NIH Guidance: GWAS

Quick Links

[University Hospitals
Center For Clinical Research
Office of Research
Compliance
UHCMC IRB
UHCMC Grants and
Contracts
William T Dahms Clinical
Research Unit
Clinical Trial Listing](#)



Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Education Updates!

[Click Here](#)

Contact Us

Office of Research Compliance
Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576

E-mail us!

NIH Guidance on Genome-Wide Association Studies

Genome-Wide Association Studies (GWAS) are any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. Recent technologies and computational methodologies have allowed for the comprehensive analysis of any part of the 10 million variable genetic points across the human genome—an incomparable tool for evaluating diseases associated with common afflictions such as diabetes and heart disease.

The primary motivation of a PI to be involved in a GWAS is the ability to build a large genetic database. Any qualified researcher will have the ability to access a GWAS for the purpose of comparison across a much larger population of information. This effectively allows for unprecedented research analysis and greater scientific discovery.

The National Institutes of Health (NIH) has developed a position and directives regarding GWAS in order to successfully utilize data and advance Human Subjects Research. The elements of successful GWAS include three main components: data management, scientific publication and intellectual property.

Data Management

- ✓ **PI** removes HIPAA identifiers and retains data keycode.
- ✓ **IRB** reviews and approves the submission plans.
- ✓ **Local institution** approves submission of data to GWAS data repository and certifies that applicable laws and regulations have been observed.

Scientific Publication

- ✓ Contributing PI retains exclusive right to any publication for twelve months after a GWAS is made available for analysis.

Intellectual Property

- ✓ Consensus is that GWAS data should be for the purpose of scientific discovery and should not be used competitively.
- ✓ Users acknowledge NIH position: data is available to all investigators and claims must not be premature.
- ✓ NIH “Best Practices for Licensing with Genomic Invention” provides guidance.

In the future, the UHCMC IRB will require information in a research plan/protocol regarding an investigator’s intent to submit data for the purposes of GWAS.

The complete GWAS guidance, data submission and usage facts and NIH contact information can be found at <http://grants.nih.gov/grants/gwas/>. Also, attached to this edition of Collaboration Corner is an NIH GWAS Policy Overview brochure; other helpful links are provided. For information regarding specific practices at UHCMC, contact the IRB administrative office in the Center for Clinical Research and Technology: 844-1529.