JOHNS HOPKINS
SCHOOL of MEDICINE

COURSE TITLE
Working as a Genetic Assistant

PRE- AND CO-REQUISITES
None

COURSE DESCRIPTION
This course applies the concepts from Fundamentals of Clinical Genomics to the duties of the genetic assistant. The course material walks the learner through a typical patient case, starting with the patient visit, then transitioning to pre-test coordination, sample submission, laboratory processes and regulations, and post-test follow-up. Practical exercises will expose learners to the world of genetic laboratories, test coordination, and patient interactions.

COURSE OBJECTIVES
By the end of this course, you should be able to:

1. Explain the function and role of Genetic Assistants in various healthcare settings
2. Apply the concepts of basic clinical genomics to perform tasks such as creating basic pedigrees, assisting healthcare providers with test coordination and sample submission, and filling out and compiling paperwork for genetic testing
3. Explain how to solve problems related to genetic testing samples
4. Explain genetic test results and follow-up testing recommendations to other healthcare providers

REQUIRED READINGS AND OTHER COURSE MATERIALS
All required reading and other materials are included in the online course site.

ASSESSMENT SUMMARY
The following activities will be assessed in this course.

All assessments will be graded as Pass/ Fail, with a passing score being equal to or greater than 80%.

At the end of the course, all assessments will be averaged and you will need to have an average of 80% or greater in order to receive a passing grade for the course.

Assessment	Points Possible
Quizzes (6)	100 (each)
Discussions (3)	100 (each)
Pedigrees	100
Choosing a Lab	100
Send-out Paperwork	100

LATE ASSESSMENT POLICY

All assignments must be turned in by the specified due date and time. Once the due date and time have passed, 5% of the total points of the assignment will be deducted per day (per 24 hour period).

Please contact the course instructor prior to the due-date to request an extension on an assignment due to any extenuating circumstances. Your instructor will then work with you to determine a modified assignment due date.

Any assignment submitted later than 7 days past the assigned or modified assignment will receive a grade of Fail.

Any assignments with modified due dates cannot be submitted any later than 7 days after the end of the course.

COURSE GRADING

The course will be graded on a Pass/Fail scale with a passing grade being equal to or greater than 80%. In order to receive a passing grade for the course, it is essential that you submit work for each of the 10 modules throughout the entire duration of the course. Any incomplete weeks, where work is not submitted, will result in an automatic failure for the course.

At the end of the course, all assessments will be averaged and you will need to have an average of 80% or greater in order to receive a passing grade for the course.

CERTIFICATE OF COMPLETION & LETTERS OF RECOMMENDATION

A certificate or completion can be achieved for the program by completing ***both*** the *Fundamentals of Clinical Genomics* and *Working as a Genetic Assistant* courses with a passing grade.

The courses do not have to be taken in the same semester, and you will receive the certificate of completion after successful completion of the second course. If you are in need of a letter of completion after completion of the first course you take, please contact JHOnline@jhmi.edu.

Please also note that we are unfortunately not able to write/ provide letters of

recommendation.

COURSE REQUIREMENTS AND ASSESSMENTS

RESOURCES

Most modules will include presentations and required resources, including readings and handouts. It is recommended that you listen to the presentations and read/review the resources, as this will best facilitate your successful completion of course assessments.

DISCUSSION POSTS

You are required to contribute to discussion board topics as posted.

You should post a thoughtful and complete response and reply to at least two classmates' posts by the due date to receive full credit.

Suggested length is one to two paragraphs. High quality posts will contribute substantive content, illustrate a strong understanding of course material, reflect professionalism, and be free of grammatical errors. Please cite sources using APA guidelines and include links as appropriate. Guidelines for this style can be found at: APA Style Guidelines

QUIZZES

Regular quizzes will test your understanding of course content. Quizzes can be attempted three times each and you are encouraged to consult course materials as needed to complete each quiz.

These quizzes are not timed tests, but please understand that if you walk away from your quiz while taking it, depending on your computer and the length of time, you may be automatically logged out of Blackboard and may lose your quiz responses.

WRITTEN ASSIGNMENTS

Written assignments should be composed in complete sentences and include proper grammar, spelling, and punctuation. Files can be submitted in .docx, .pdf, and .png or .jpg formats.

All work submitted should include references for any resources consulted. Please cite work in formats consistent with the American Psychological Association (APA) Style. Guidelines for this style can be found at: APA Style Guidelines

LIVE Q & A SESSIONS (OPTIONAL)

Throughout the semester, there will be three live (synchronous) optional Q & A sessions with the course instructors for this course and the *Working as a Genetic Assistant* course. The instructors will be available to answer questions about the course and subjects related to the course material.

Additional information about the sessions, including dates, times, and web conference access information can be located in the **Web Conference – Q & A** area on the left

menu of the online classroom.

COMMUNICATION POLICY

You may communicate with the instructor by email. The instructor will respond within 48 hours.

Assessment feedback will be provided within one week of each assessment due date.

E-CULTURE POLICY

All official communication, notices, and announcements will be distributed through e-mail (to the account you registered for the course with) via Canvas. You are accountable for checking your e-mail account regularly and for all course communication sent to it.

Students are responsible for reading "*Netiquette*" which is located under **Course Information** area on the Canvas site. Netiquette provides simple guidelines for civil on-line discourse & behavior, that participants are to follow and expect of one another.

ACADEMIC ETHICS POLICY

In this course, a fundamental principle is the emphasis on individual learning and achievement. Sharing work, in part or in whole, is not acceptable under any circumstances. However, we encourage active engagement with your peers, such as asking questions and studying together, to enhance your understanding of the material. Nevertheless, assignments are expected to be completed independently, and all work submitted must be your own. Any violations of this policy, including unauthorized collaboration, may result in penalties ranging from the loss of credit for submitted assignments to the extreme measure of removal from the Genetic Assistant Training Program. It is crucial that all students adhere to these guidelines to ensure the integrity and fairness of the learning experience.

This course places a strong emphasis on integrity and honesty, requiring learners to uphold these principles at all times when carrying out assignments, taking course examinations, fulfilling their patient obligations, and interacting with others. Both learners and instructors share the responsibility to report any instances of dishonesty within the course. In our commitment to maintaining an environment of complete trustworthiness, any act of dishonesty not only undermines a learner's suitability but is also regarded as unprofessional behavior. To reinforce these core values, the honor code underscores the significance of ethics in their development as scientists. The honor code delineates the School of Medicine's expectations for learners' conduct and necessitates each learner's formal declaration of personal honor. The code, as follows, articulates our shared commitment:

"As a learner at the Johns Hopkins University School of Medicine, I pledge to be honest in:

- Course work, including examinations and all assignments;
- The reporting and presentation of research data, with proper attribution and

citation; and
- Professional interactions with all members of the scientific community."

It is essential for all learners to fully embrace and adhere to these standards to ensure the highest level of integrity.

DISABILITY STATEMENT

Johns Hopkins University adheres to the policies of the Americans with Disabilities Act to ensure that students, employees and visitors with disabilities have equal access to university programs, facilities, technology and websites. Blackboard Learn's course management system complies with the WCAG and Section 508 guidelines for accessible websites. The full disclosure statement from Blackboard may be found on Blackboard's Accessibility webpage.

For complete information on Johns Hopkins University's Disability Services, please visit the Office of Institutional Equity's website.

Blackboard has security and privacy policies that allow users to control who sees their information and files. Please refer to the information on their Privacy Center website and Blackboard Cookie Statement web page.

COURSE SCHEDULE

Presentations and Learning Resources and Assessments will be explained in detail within each learning module under **Learning Modules** area in Blackboard.

At the start of the semester, the first two learning modules (Modules 1 & 2) will be open for your review. Then, beginning with Module 3, each learning module will open on the Sunday night (by 5 p.m. ET) prior to the module start date.

Unless otherwise noted, **all assessments are due at 11:59 p.m. ET on the date noted**.

Permission for late submission of assignments must be requested from instructor before the due date under special circumstances.

Module	Topic(s)	Presentation & Required Learning Resources	Assessments
Module 1: Role of the Genetic Assistant and Medical Terminology	• Role of the Genetic Assistant (GA) • GA job duties • Differences between Genetic Assistant, Genetic Counselor, and Office Assistant • Medical terminology	**Presentations** Module 1 Presentations **Learning Resources** Pirzadeh-Miller, S., Robinson, L. S., Read, P., & Ross, T. S. (2017). Genetic counseling assistants: An integral piece of the evolving genetic counseling service delivery model. *Journal of Genetic Counseling*, *26*(4), 716-727. Cohen, S. A., & Tucker, M. E. (2018). Movement of genetic counselors from clinical to non-clinical positions: Identifying driving forces. *Journal of Genetic Counseling*, *27*(4), 792-799. Heart Anatomy (PDF) Eye Anatomy (PDF)	**Discussion** **Initial Post** **Response Posts** **Quiz** **Course Introduction Survey**

Module	Topic(s)	Presentation & Required Learning Resources	Assessments
		Brain and Nervous System Anatomy (PDF)	
Module 2: Working in Medical Genetics	• Professional behavior in healthcare settings • HIPAA • Record releases • Consent for genetic testing	**Presentations** Module 2 Presentations **Learning Resources** McGuire, A. L., & Beskow, L. M. (2010). Informed consent in genomics and genetic research. *Annual Review of Genomics and Human Genetics*, *11*, 361-381.	**Discussion** **Initial Post** **Response Posts** **Quiz**
Module 3: Pedigrees	• Symbols • Electronic tools • Inheritance patterns • Testing strategies	**Presentations** Module 3 Presentations **Learning Resources** Bennett, R. L., French, K. S., Resta, R. G., & Doyle, D. L. (2008). Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. *Journal of Genetic Counseling*, *17*(5), 424-433.	**Pedigrees**
Module 4: Insurance & Billing	• ICD and CPT codes • Insurance and billing terminology • Insurance types • Billing scenarios • Letters of Medical Necessity (LMNs)	**Presentations** Module 4 Presentations **Learning Resources** Phillips K. A., Deverka P. A., Hooker G. W., & Douglas M. P. (2018).Genetic test availability and spending: Where are we now? Where are we going? *Health Affairs*, *37*(5), 710-716.	**Quiz**
Module 5: Laboratory	• Pre-analytical (Or Examination)	**Presentations** Module 5 Presentations	**Discussion** **Initial Post**

Module	Topic(s)	Presentation & Required Learning Resources	Assessments
Regulations	○ Sample Check-In ○ Identifiers ○ Extraction/ Quantification • Analytical (Or Examination) ○ LIMS Systems ○ Sample Tracking ○ Variant Interpretation • Post-Analytical (or Examination) ○ Reporting of Results ○ Communication	**Learning Resources** Centers for Medicare and Medicaid Services (CMS). (2018, October). *MLN fact sheet: CLIA program and Medicare laboratory services*. Baltimore, MD: Author. New York State Department of Health. (2019, January). *Clinical laboratory evaluation program: A guide to program requirements and services*. Albany, NY: Author. Occupational Safety and Health Administration (OSHA). (2018). *All about OSHA*. Washington, DC: Author.	**Response Posts**
Module 6: Choosing an Assay & a Lab	• Test strategies • Considerations ○ Total cost and TAT ○ Sensitivity & specificity • Billing options	**Presentations** Module 6 Presentations **Learning Resources** Concert Genetics Genetic Testing Registry	**Choosing a Lab**
Module 7: Sample Submission	• Specimen types & collection • Dangerous goods • Sample submission considerations • Test requisition forms	**Presentations** Module 7 Presentations **Learning Resources** The Joint Commission National Patient Safety Goals (PDF)	**Send-out Paperwork**

Module	Topic(s)	Presentation & Required Learning Resources	Assessments
	(TRFs) & other supporting documents • Laboratory online portals		

Module 8: Lab QA/QC and Lab Flow	• Quality Management Systems
	  ○ QA Activities
	  ○ QC Activities
	• Quality Metrics
	• Organization Structure of a Lab
	• Institutional Trainings (what to expect)
		Presentations
		Module 8 Presentations
		
		Learning Resources
		Clinical Laboratory Standards Institute (CLSI). (2018). *CLSI: Global laboratory standards for a healthier world* [Video]. Wayne, PA: Author.
		
		International Organization for Standardization (ISO). (2010). *What ISO standards do for you* [Video]. Geneva, Switzerland: Author.
			Quiz

Module 9: Variant Interpretation	• Result classifications • ACMG/CAP guidelines • Online databases • VUS resolution	**Presentations** Module 9 Presentations **Learning Resources** Richards, S., Aziz, N., Bele, S., Bick, S., das, S., Gastier-Foster, J., . . . ACMG Laboratory Quality Assurance Committee. (2015). Standards and guidelines for the interpretation of sequence variants: A joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. *Genetics in Medicine*, *17*(5), 405-424.	**Quiz**
Module 10: Results	• Result communication	**Presentations** Module 10 Presentations	**Quiz**

Module	Topic(s)	Presentation & Required Learning Resources	Assessments
	○ Clinic and laboratory perspectives • Follow-up testing • Referrals to other specialties	**Learning Resources** Biesecker, L. G., Nussbaum, R. L., & Rehm, H. L. (2018). Distinguishing variant pathogenicity from genetic diagnosis: How to know whether a variant causes a condition. *JAMA*, *320*(18), 1929-1930.	