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IRB Update

APRIL 2014

THIS ISSUE

National Jewish Health Advanced Diagnostic Laboratories

Interim Executive Director – Max Salfinger, MD
Medical Director – Ron Harbeck, PhD
Director of Operations – Sara Dirscherl, PhD

OVERVIEW

Who we are and what we do:

National Jewish Health Advanced Diagnostic Laboratories has been in existence for a considerable length of time, having developed with the intent to support clinical programs at National Jewish Health. Over the years, Advanced Diagnostic Laboratories has been expanding its offering in immunology, including complement; microbiology; mycobacteriology; pharmacokinetics; and molecular genetics; in addition to the traditionally recognized diagnostic core services in clinical chemistry and hematology. A pre-analytical team manages and distributes samples for testing, a phlebotomy team coordinates the sample draws, and a customer service team provides support for both our internal and external clients. In addition to supporting our physicians at NJH, Advanced Diagnostic Laboratories is well-known nationally and internationally for its scientific expertise and serves as a reference laboratory for a number of facilities.

Advanced Diagnostics Laboratories also provides clinical trial services and has a variety of biotechnology and pharmaceutical clients. The laboratories' expertise spans the breadth of assay development and validation, assistance with study design, data analysis, report generation and quality assurance for all phases of clinical trials.

Advanced Diagnostics Laboratories is ISO15189, College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) certified and holds certification/permit in a number of states, including California, Florida, Maryland, and New York.

Laboratory Locations:

B'nai B'rith – basement:
Microbiology and Core laboratories; Director - Ronald J. Harbeck, PhD;
Immunology and Beryllium laboratories; Director - Vijaya Knight, MD, PhD

CONTACT US

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Neustadt:
Molecular Diagnostic laboratory; Interim Director – Sara Dirscherl, PhD
Complement laboratory; Director – Patsy Giclas, PhD, Asst. Director – Ashley Frazer-Abel, PhD

Goodman:
Mycobacteriology and Pharmacokinetics; Director - Max Salfinger, MD

WORKING WITH ADVANCED DIAGNOSTIC LABORATORIES

Advanced Diagnostics Laboratories support not only diagnostic testing at NJH but multiple other activities.

Co-development efforts with Advanced Diagnostics Laboratories

Advanced Diagnostics Laboratories has been involved in co-development of diagnostic tests with NJH researchers, as well as diagnostic companies and other industry partners. Co-development efforts within NJH often take place through grant-funded studies and collaborative research. Examples include a patented, flow cytometry-based test for chronic urticaria and the recently developed nickel lymphocyte proliferation test for implant failure. Laboratory directors are involved in these efforts from co-writing grants, developing experimental or study design, execution of the study plan to development of a validated test. The project management team assists with evaluation of the (a) feasibility (b) operational resources and (c) financial cost of co-development projects. For more information contact Michael Pace at pacem@njhealth.org.

Routine testing for grant- or industry-funded studies at NJH

Advanced Diagnostics Laboratories support routine laboratory analyses for clinical trials and work collaboratively with the Clinical Research Unit (CRU) at NJH. The laboratories' searchable test menu can be accessed via njlabs.org. Pricing varies for tests intended for grant-funded or industry-sponsored studies and can be discussed with Advanced Diagnostics Laboratories project managers. In addition, the Advanced Diagnostics Laboratories pre-analytical team can assist principal investigators with developing processes for special specimen handling and can act as honest brokers for specimens requiring de-identification. For pricing for grant- or industry-funded studies, please contact Michael Pace at pacem@njhealth.org.

Good Laboratory Practice (GLP) studies

The Advanced Diagnostics Laboratories complement laboratory is unique in its involvement in clinical and preclinical trials requiring compliance with GLP regulations. The complement laboratory has participated in hundreds of preclinical and clinical trials, working in compliance with the FDA GLP and Good Clinical Practice (GCP) regulations as well as European Organization for Economic Co-operation and Development (OECD) regulations. The complement laboratory is well-recognized for its expertise in the analysis of unwanted pro-inflammatory and anaphylactoid responses, many of which may be potential unwanted effects of oligonucleotide and protein-based therapeutics. For more information on requirements for GLP regulated studies, please contact Dr. Ashley Frazer-Abel at frazer-abela@njhealth.org.

Research and Development projects

Advanced Diagnostics Laboratories work collaboratively with NJH researchers and clinical staff to generate preliminary data for grant applications or ongoing funded studies and for specialized analysis of clinical samples under Institutional Review Board (IRB) approved protocols. These projects may have the potential to (a) lead to new diagnostic test development (b) generate intellectual property or (c) provide data for grant applications or publications. Advanced Diagnostics Laboratories works closely with the Technology Transfer Office and the IRB and has participated in grants and publications with several of the NJH faculty.

For more information on research collaborations with Advanced Diagnostics Laboratories, contact:
Michael Pace
pacem@njhealth.org
303-270-2578

Reminder: Consent form templates were revised in November, 2013

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs

To include the latest provisions from the HIPAA Omnibus Rule, the IRB Office revised the consent form templates in November, 2013 to include more information about subjects' rights under the Omnibus Rule.

Please download the latest versions of the consent form templates from the IRB website: http://www.nationaljewish.org/professionals/research/support/compliance/irb/submissions/informed-consent.

Please note: If you reuse an existing template or modify an existing consent form, your document will not contain all required elements.

Problems with double-sided submissions

Wendy Charles

The IRB office asks for researchers' cooperation in making photocopies that will be usable to IRB staff.

What does the IRB need and why?

For every submission, the IRB office needs the following:

Original signature: The IRB needs an original of each submitted document. Most importantly, **the IRB needs an original signature from the Principal Investigator** to confirm that he or she is personally involved with each submission and that he/she verifies the accuracy of the submission. [NOTE: There are limited circumstances there a co-investigator can sign a submission on behalf of a Principal Investigator.]

Photocopy: The IRB office needs at least one complete, collated photocopy of each submission. Each copied document (within the submission) must be discrete so that the office can stamp each individual document to indicate IRB approval or acknowledgement.

Why are there problems with some double-sided copies?

Rather than making photocopies of each individual document, several researchers have been placing an entire stack of documents in the photocopier at once, creating a situation where the first page of one document is photocopied to the back side of the previous document. The IRB office is then unable to process or stamp these documents.

The IRB office requests the following:

1) The original, signed submission be submitted single-sided.
2) The photocopy be provided as either:
    a. single-sided
    b. double-sided where each document in the submission is photocopied individually

Unusable photocopies submitted to the IRB office will be returned to the researchers.

Research Managers Meeting – April 4, 2014. New location: M115

Wendy Charles

In the April Research Managers Meeting, I will present information on the shift to Risk-Based Monitoring. As a group, we will discuss what to ask for in the budget to account for risk-based monitoring, the need for internal quality checks, and how to limit a sponsor's access to medical records.

The next Research Manager's Meeting will be held:

Friday, April 4, 2014, 2014
M115
Noon – 1pm

I've been compiling an email distribution list of research managers and team leads. Please send an email to charlesw@njhealth.org if you would like to receive future Research Manager meeting notices.