



JOHNS HOPKINS

INSTITUTE *for* CLINICAL &
TRANSLATIONAL RESEARCH

ICTR Clinical Research Professionals Lecture Series

Tuesday June 14th 2022

WELCOME



Clinical Research Professionals Lecture Series

- New Lecture Series geared to bring innovative and new topics to Clinical Research Professionals at Johns Hopkins
- <https://ictr.johnshopkins.edu/events/clinical-research-professionals-lecture-series/>
- Topics are based on questions received from Clinical Research Professionals throughout Hopkins
- Welcome topic suggestions: sswords1@jhmi.edu
- Welcome speakers!

Agenda



- No Surprises Act
—Karen Roz & Liza Rodríguez
- New IND/IDE Policy
—Mark Sulkowski
- Questions and Discussion

No Surprises Act and Maryland Outpatient Facility Fee Notice



Karen Roz, MS

Director

Clinical Research Support Services

Liza Rodríguez, MS

Sr. Associate Director

Clinical Research Billing Compliance

No Surprises Act

- Applies to:
 - Emergency services
 - Non-emergency services from out-of-network providers in an on-network facility
 - Services from out-of-network air ambulance service providers
- Bans surprise billing / balance billing
- Facility and providers must provide an easy-to-understand notice explaining who to contact and all applicable protections
- Process to dispute bills

No Surprises Act

- What about self-pay patients?
 - Patient should receive a good faith estimate
 - This can be confusing to research participants



Maryland Outpatient Facility Fee Notice

- Maryland's Facility Right-to-Know Act
 - Effective on July 1st, 2021
- Notice to all outpatient patients- including research participants:
 - Patient has an upcoming visit on a facility outpatient site
 - Patient will receive a facility and a professional fee bill
 - There is financial assistance available if the patient cannot pay
 - The facility fee might change depending on the location


Maryland Outpatient Facility Fee Notice

- The notice is/can be verbal, written and in MyChart
- The facility fee notice (letter) will change slightly, depending if it the scheduled visit is linked to research or not

Language Change in Insurance and Research Participant Financial Responsibility Information

Whenever you receive outpatient care at Johns Hopkins regardless of whether this is for research or clinical care, you will receive a notification from Johns Hopkins prior to your visit that will be an estimate of the total cost of care for that visit. This is required by The Maryland's Facility Right-to-Know Act, better known as the Maryland Outpatient Facility Fee Notice. The cost estimate will cover the cost of all care that will be provided and does not exclude costs that may be covered by the research study. You will not be billed for research activities that are covered as detailed in the Insurance and Research Participant Financial Responsibility Information Sheet that you were provided with when you signed consent for the research study.

The Maryland Outpatient Facility Fee Notice and Research Participant Information



IMPORTANT FINANCIAL INFORMATION

Patient Name: First M Last
Date of Birth: 1/1/2000
Appointment Date: 3/20/2022
Estimate Finalization Date: 2/3/2022
Estimate Reference ID: 1234567
Primary Insurance: Carefirst Bcbi
Secondary Insurance:

Notice of Maryland Estimated Fee Disclosure

****THIS IS NOT A BILL****

We look forward to caring for you at your upcoming visit. Maryland law requires hospitals to send a cost estimate before your scheduled services so that you know what may be billed to your insurance.

Your health and well-being are our priority. If you have any questions or concerns about this letter, please contact Customer Service at (855)662-3017 or email pfscs@jhmi.edu.

- Your appointment with <<provider name/department name>> will take place in a hospital-based outpatient department at the <<hospital location name>>.
- <<Additional information about the appointment, such as the name of the provider, the location of the appointment, and the date and time of the appointment.>>
- <<Additional information about the appointment, such as the name of the provider, the location of the appointment, and the date and time of the appointment.>>

Estimated Cost

Based on appointments like the one you have scheduled, your estimated costs are:

	Estimated Insurance Charges	Estimated Patient Cost
Facility THE JOHNS HOPKINS HOSPITAL		
CPT® 99211: Hospital Facility Fee	\$290.25	
Professional charges for <<provider name>>, MD at Johns Hopkins Internal Medicine		
CPT® 99214: Provider Office Visit Charge	\$172.17	\$10.00
Total	\$462.42	\$10.00

<<Additional information about the estimate, such as the name of the provider, the location of the appointment, and the date and time of the appointment.>>

Charges Related to a Research Study

You are enrolled in a research study and these charges are related to your study. Please refer to the Research Participant Financial Responsibility Information Sheet. This will contain information about costs that will be covered by the study or that may be charged to you or to your insurance. Please contact the research team if you have additional questions.

<<Additional information about the research study, such as the name of the study, the location of the study, and the date and time of the study.>>

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Important Information about Your Estimate

Whenever you receive outpatient care at Johns Hopkins regardless of whether this is for research or clinical care, you will receive a notification from Johns Hopkins prior to your visit that will be an estimate of the total cost of care for that visit. This is required by The Maryland's Facility Right-to-Know Act, better known as the Maryland Outpatient Facility Fee Notice. The cost estimate will cover the cost of all care that will be provided and does not exclude costs what may be covered by the research study. You will not be billed for research activities that are covered as detailed in the Insurance and Research Participant Financial Responsibility Information Sheet that you were provided with when you signed consent for the research study.

You can call 844-986-1584 for information about estimates or visit the *Billing and Insurance* webpage at https://www.hopkinsmedicine.org/patient_care/patients-visitors/billing-insurance/ for details about insurance, estimates and more. *Should you have additional questions, please contact the research team.*



The Maryland Outpatient Facility Fee Notice and Research Information for Research Staff

The Maryland's Facility Right-to-Know Act, better known as the [Maryland Outpatient Facility Fee Notice](#), became effective on July 1st 2021 and it requires Johns Hopkins Medical Institutions located in Maryland to provide a written notice with an estimate of outpatient hospital fees (thereafter "facility fee") for a scheduled service or procedure at the location selected.

Below you will find a few frequently asked questions about the process used by Johns Hopkins Medical Institutions (JHM) to comply with the required notice that will help you address inquiries from your research participants:

What is different for the research participant when scheduling an outpatient hospital-based appointment?

Research participants will be provided information, orally or through MyChart, at the time an appointment is scheduled. This includes statements about the location (i.e. that an outpatient hospital setting was selected), that the research participant will receive a facility and a professional fee bill, that there is financial assistance available if the research participant cannot pay, and that the facility fee might change if the service or procedure is performed in a location where facility fees may not be charged. Additionally, the research participant will receive a written notice in MyChart or by regular mail with an estimate of the charges. The estimate is based on typical or average facility fees for the same or similar appointments.

Is the facility fee notice a bill?

No. It is an estimate of hospital charges based on the services/procedures scheduled and the Maryland outpatient hospital-based facility selected.

Does the research participant have to make a payment based on the notice before the scheduled appointment?

The notice letter is an estimate and not a bill.

Will research participants receive these notices for standard of care and research services or procedures?

Research participant might receive letters related to the standard of care portion of the clinical trial that will be billed and processed as before. Note that costs specifically related to research may be included on the estimate and will not be billed to the research participant. These charges are reviewed and routed to the study prior to the issuance of a bill. If the study pays for all costs related to research, you can advise the research participant to ignore the letter for scheduled visits linked exclusively to the clinical trial.

Why is the facility fee being sent to the research participant instead of the participant's insurance being billed?

The letter is automatically generated by the Epic system based on the information available at the time the appointment was scheduled. If there is no insurance attached to the appointment or if the research participant was scheduled as self-pay, the full amount of the expected hospital charges will appear in the notice. The research participant will be able to update their insurance when they arrive and register for their scheduled appointment.

What can I do to help research participants understand the actual likely cost of their participation on the study?

- Review the *Financial Responsibility Information Sheet* at the time of the informed consent and any time that research participants have questions about research-related charges. This form outlines the services and procedures that will be covered by the study.
- Provide "The Maryland Outpatient Facility Fee Notice and Research Participant Information FAQs" document to the research participants.
- Please note that the outpatient facility notice letter directs questions to the research staff and advises points the research participant to use the *Financial Responsibility Information Sheet*.

What should I do if a research participant on my study has questions I cannot answer?

The research participant should call the cost estimates assistance line at 844-986-1584 for more information.

New Epic Research Icon!

- Epic August 4th upgrade (vMay2022)



The screenshot displays the Epic patient chart for a patient named Tstrsh, Jhmworkerone. The interface includes a sidebar on the left with various tabs like 'Lab Flowsheet', 'In process', and 'Final result'. The main content area shows patient demographics, including name, gender, age, date of birth, MRN, and code. It also displays 'POLST: Missing', 'Patient Reminders: None', and a search bar. A red arrow points to the 'Research Participant' button, which is highlighted in yellow. Below this, there is a section for 'Allergies: Not on File' and 'Preferred Lab: None'. The bottom section shows 'LAST 3YR' with 'Ped Infect' and 'No results'. The 'PROBLEM LIST (0)' is also visible. On the right side, there is a table with columns for 'g Provider', 'Lab', 'Encounter Type', 'Research', and 'Result Link'. A red box highlights the 'Research' column, which contains the new Research icon (a hexagon with a circle inside) for two rows of data.

g Provider	Lab	Encounter Type	Research	Result Link
arie Clark...	JOHNS HOPKINS ...	Appointment		
arie Clark...	JOHNS HOPKINS ...	Appointment		

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Johns Hopkins University

IND-IDE Policy, Effective June 1, 2022



Mark Sulkowski, MD

Senior Associate Dean for Clinical Trials
and Capital Research

JHU Policy for investigator- sponsored IND/IDE

Background

- Faculty who serve as IND/IDE holders commit to additional regulatory responsibilities [e.g. safety reporting to the FDA]
- JHU is ultimately responsible
- Until recently, no institutional policies outlining who may serve in the role of IND/IDE sponsor nor any institutional checks
- New COI policy imposes restrictions on faculty's ability to serve in this role but there are no early system checks for conflicts
- Starting in 2019, peer comparison was initiated – most peers offer some centralized IND/IDE registration, qualification, and support

JHU Investigator-held IND/IDEs

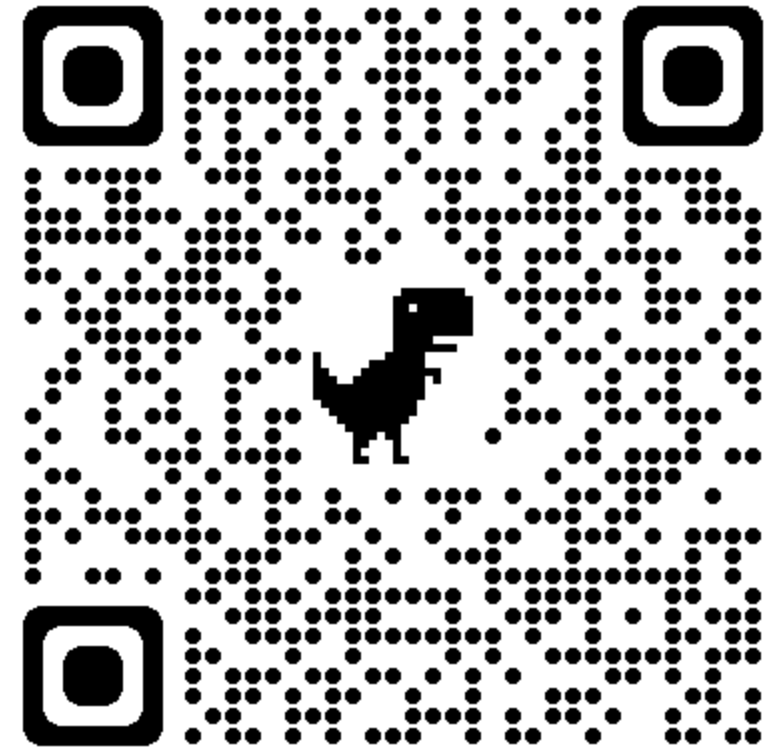
- JHU SOM IRB: investigator-held “full” IND/IDEs (2021)
 - 251 protocols with investigator-held INDs:
 - Expanded access/compassionate use – 19 [Not included in the JHU policy]
 - 232 protocols under 165 INDs held by 95 JHU investigators
 - 20 protocols with investigator-held IDEs:
 - Expanded access/compassionate use – 3 [Not included in the JHU policy]
 - 17 protocols under 17 IDEs held by 15 JHU investigators
- Largest # of protocols associated with investigator-held INDs/IDEs are in SKCCC (~36%) and Radiology (~26%)
- Minimal IND/IDEs held outside SOM

Insufficient IND/IDE support structure: Creates inefficiency and non-compliance risk

- Robust infrastructure needed to adhere to the FDA requirements
- Inefficiency due to limited guidance/directions for investigators
- Learning of requirements/restrictions at the time of IRB/COI review is “too late”
- Anticipate a significant increase in IDEs to implement Machine Learning/AI algorithms and INDs for first-in-human trials.
- Investigators encounter barriers when trying to develop Hopkins-generated IP
 - Central process with the potential to improve throughput

Johns Hopkins University IND/IDE Policy

- Approved January 2022: [Investigator-held INDs/IDEs](#)
- Effective June 1, 2022
 - Investigators seeking to file a [new IND/IDE on/after this date](#) must comply with the policy
 - Not single patient/compassionate use requests*
 - All JHU investigators- not just JHM
 - Office of Clinical Trials is responsible for operationalizing this policy



Core Components: Faculty Qualifications

- Full-time member of JHU faculty and be a JHHS credentialed, U.S. licensed medical provider (physician or dentist), unless the exception set forth in section II.B for certain Ph.D. faculty applies.
 - Designated medical monitor in these circumstances
- Knowledge of FDA IND/IDE regulations and Good Clinical Practice (GCP)
 - Must at a minimum complete GCP training
- Demonstrate the availability of adequate resources to meet the obligations of a Sponsor-Investigator inclusive of:
 - Research staff experienced with FDA regulated research
 - Adequate time and resources

Core Components: Faculty Qualifications

- No outstanding, unresolved compliance concerns
- No individual Financial Conflict of Interest (FCOI) with respect to either the funder of the study, or the drug, biologic, or device under investigation, and not directly report to someone who has such an FCOI.
 - Exceptions considered for minimal risk research
- Additional restrictions may be imposed where there are institutional conflicts of interest

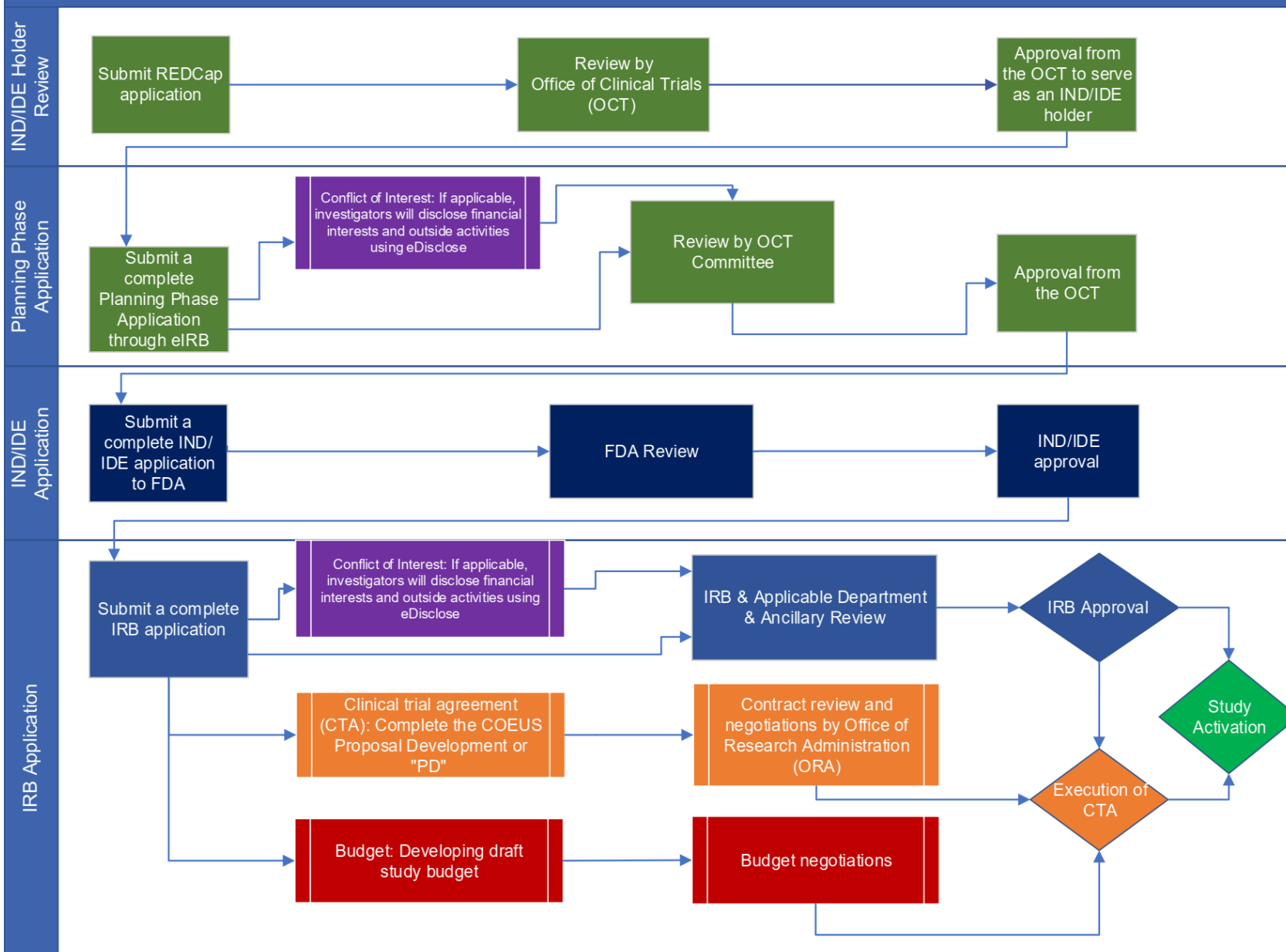
Core Components: Key Requirements

- Creates a mandatory registration process prior to filing new INDs/IDEs
- Correspondence to the FDA is copied to the OCT
- Investigational drugs managed by IDS or an alternative approved process
- Investigational device storage approval
- Additional requirements for the manufacture of drugs or devices, where applicable

Core Components: Multi-site studies conducted under a JHU investigator-held IND/IDE

- Plan for monitoring all sites where the research will be conducted
- Monitoring carried out by an appropriately qualified CRO or monitoring program pre-approved by the OCT
- Reports from the monitoring copied to the OCT
- Outline a plan detailing which IRB will serve as the IRB of record

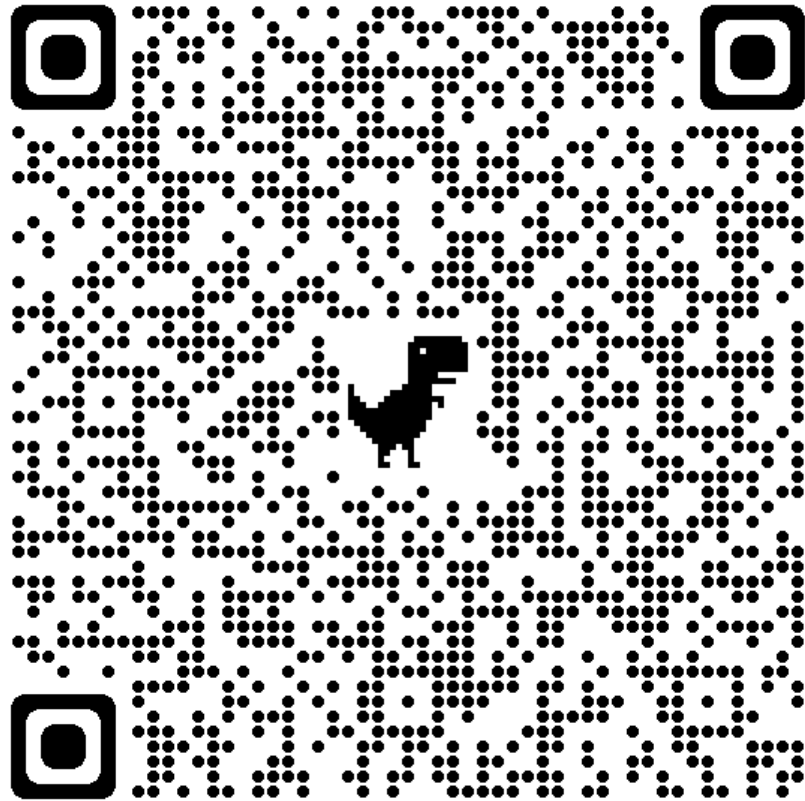
Investigator-held INDs/IDEs Review Procedures



Core Components: Procedural Requirements

- Registration requires a letter of support from the Chair/Director of the Department/Institute to which the proposed sponsor-investigator reports
- OCT will issue a Notice of IND/IDE Suitability if the individual is approved to serve as sponsor-investigator
 - Faculty experts may be consulted if needed
- If there are concerns the faculty member and Department/Division Chair/Director will be notified and given an opportunity to address the concerns
- IRB needs documentation of this notice before approval

Investigational New Drug/Investigational Device Exemption Regulatory Program Website



IND_IDEprogram@jh.edu

Questions?



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