2022 version: FY22-Q3



**EPIC Research**

**UMMS U EPIC RESEARCH TRAINING FOR RESEARCH COORDINATORS**

Training guide link to UMMS Research Website

 <https://intra.umms.org/-/media/intranets/umms/office/departments/research/2021-updates/research-coordinator-and-research-specialist-workflow-guide12021.pdf?upd=20210209185137>

UMMS U Epic Research Access course is strongly recommended for all research staff involved in subject interaction.

<https://www.umms.org/hr-connections/employee-information>

Below guide can assist with acquiring UMMS Remote Access for UMMS website and UMMS U.

 Quick Start Guide link

<http://intra.umms.org/umms/departments/ist/large-projects/dual-factor-remote-access>

**RESEARCH STAFF EPIC PORTAL ACCESS REQUEST**

**Link:** <http://intra.umms.org/umms/departments/ist/request-application-access>

**Research Manager or Administrator**: Use Cherwell portal to request access for research staff. The request will then be reviewed and approved by Joanne Marshall.

There are set research roles for research staff:

Research View only - data capturing, not requiring documentation in the medical record

Research specialist / Research coordinator - for coordinators involving both inpatient and outpatient research that require documentation of research encounters, notes and possibly research specific orders in EPIC

Research Nurse- UMMS Nurse Access provided

REMINDER: Select- **EPIC RESEARCH** (drop down) used for all research staff requests.

**(DO NOT USE- Epic Portfolio)**

<http://intra.umms.org/umms/departments/ist/request-application-access>  Instructions and portal link)

[https://istportal.umms.org](https://istportal.umms.org/)  (Internal link to UMMS Portal)

<https://cher-prd-web.umms.umm.edu/CherwellPortal/ITOOTBAccessRequest> (Offsite link to UMMS Portal)

**MyPortfolio for research recruitment**

Recruiting patients through MYPortfolio is possible, the forms to request and tip sheet showing the process are attached.

<http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/my-portfolio-submission-template-final.docx?la=en&hash=61E142E9EEC0C6AC1E6D641D27C60BAC9F71D7D6>

**Research Monitor Access to Epic**

Monitors can directly sign in to Cherwell portalto complete access request through PortfolioMD. . The attached tip sheet can be provided to the study monitor for completion.

**COORDINATORS-** Please provide the monitor with the following information:

**EPIC RSH record for the protocol (HP-000xxxxx); Site location address; Principal Investigators Name and contact information; Coordinator name and contact information; Site phone number and fax**

A report can be run by the coordinator from Epic Research (RSH) Record used to associate the subjects. (Reporting Tip Sheet attached) Coordinators provide the report to the monitor to see research subjects associated to the to that RSH/research record



**UMMS Research**

**Affiliate Research**

Please remember that PI’s must submit an investigator packet to their site-specific Scientific/Research Review Committee for approval prior to study initiation.

<http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/2021-updates/umms-research-investigator-packet-2021.docx?la=en&hash=DC4C4D0E0CBB308A4D78087B1771DA540CF8F8FD>

**External IRB**

UMMS has created a single FWA (#) for the entire system this facilitated the ability to have master agreements with external an IRB. University of Maryland Medical System (UMMS) has secured master Institutional Authorization Agreements (IAA) between several external Institutional Review Boards (IRB) covering all Hospitals under UMMS. These external IRBs include WIRB, Advarra-CIRBI, UMB IRB, NCI-CIRB and UMD-College Park. UMMS is now a relying institution with SMART IRB.

**Requirement for an IAA**

An External IRB other than those listed above will require a separate IAA to be completed. Please contact Joanne Marshall (joanne.marshall@umm.edu) to provide the UMMS IAA document.

<http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/2021-updates/10581umms-iaatemplate-edit-gourdine-2719.docx?la=en&hash=9F87EBD38868B6F7E4B0B6EBF2A471D3D101946D>

**UMMS Research Website**

**Quick start Guide to Remote Access for UMMS**

[**http://intra.umms.org/umms/departments/research**](http://intra.umms.org/umms/departments/research)



**Research Revenue Integrity**

**Coverage Analysis Review**

All human subject research studies regardless of funding source must be routed for coverage analysis review.

University of Maryland, Baltimore: Complete an application to Center for Clinical Trials and Corporate Contracts (CCT) via UMBiz portal.

UMMS Affiliates: Complete an Investigator Packet and submit to: umms.research@umm.edu

**Cost Estimates for Grant Proposals**

Federally-funded clinical trial budgets should be based upon coverage/cost analysis during the proposal development process (pre-award). Instructions for submission are located above in the Coverage Analysis Review section.

<http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/02132019-updates/ummc-research-billing-compliance_16july2018.pptx?la=en&hash=E535C17C97BFC725E8DC3402A595CEE8341D0912>



**COVID-19**

**New COVID -19 UMMS Visit Policy for Research Monitors and Vendors** <http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/2021-updates/ummc-covid-monitors.docx?la=en&hash=5898CCADF9A4F3E08C7DC1A0EC223DDC37797FAC>

**COVID-19: UM Medical Center (UMMC) local visit requirements for Research Monitors:**

1. Research monitors that require entrance into the University of Maryland Medical Center must be escorted by a research team member.
2. The Research Monitor must be screened at the front screening desk to have the questions answered per the UMMS policy.

**New UMMS Risk Statement for research subjects**

Please see attached UMMS risk statement for research subjects that are being seen at UMMS affiliates. This must be signed prior to a subject participating in any research protocol.

Of note: There is a separate UMB/UMMC risk statement distributed by HRPO that is to be used for research protocols being conducted in the medical center location.

[**http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/2021-updates/11117covid19-risk-statement-for-human-research-participants\_15oct20\_revised.docx?la=en&hash=E94E2A88321C0BFD12E48A2A5C2774B8F1E65550**](http://cms.redesign.umms.org/intra/-/media/intranets/umms/office/departments/research/2021-updates/11117covid19-risk-statement-for-human-research-participants_15oct20_revised.docx?la=en&hash=E94E2A88321C0BFD12E48A2A5C2774B8F1E65550)



**Contacts**

**UMMC Office of Research Operations**

Joanne Marshall, BSN MS CHRC | Office Research Operations| UMMS Human Protections Administrator | University of Maryland Medical Center, Clinical Practice and Professional Development

joanne.marshall@umm.edu | Office 410-328-2874

**UMMS Research Revenue Integrity** umms.research@umm.edu

Megan Irwin, MBA| Senior Manager, Research Revenue Integrity| University of Maryland Medical System Mirwin@umm.edu | Office 443-462-3327

Katrina Schrader, MA, CCRP, CHRC| Senior Clinical Trial Analyst| University of Maryland Medical System KSchrader@umm.edu

Tiana Jones, MS, CHRC| Clinical Trial Analyst| University of Maryland Medical System tiana.jones@umm.edu

Luigi DiRende| Clinical Trial Analyst| University of Maryland Medical System Luigi.Dirende@umm.edu