

Department of Radiation Oncology

Monthly Research Update: August 2023

Clarifying NIH Data Sharing Requirements

AUGUST AT A GLANCE TOTALS

Clinical trials	
Total enrolled	31
GCC, other	8
NRG, NCI, co-ops	1
PCG Registry	22
Grants and contracts	
New awards	0
Submitted	1
Articles published	5

As noted in the January issue of the *Monthly Research Update*, all applicants for National Institutes of Health (NIH) funding are now required to comply with a [Data Management and Sharing Policy](#) (DMS policy). Any applicant planning to generate scientific data and accompanying metadata must prepare a DMS plan that describes how these data will be managed and shared. To clarify the requirements, NIH has published a [list of activity codes](#) subject to the DMS policy.

Many applicants have been confused about differences between the DMS plan and the more familiar Resource Sharing plan, which are separate attachments to grant submissions. NIH issued a [statement](#) clarifying these differences. These are only 2 of multiple NIH sharing policies introduced in the last decade, and applicants are encouraged to consult additional information at [Which Policies Apply to My Research?](#) Perhaps most useful is the post on [Writing a DMS Plan](#), including not only detailed information on requirements and applicable policies but complete sample plans for various types of basic, translational, and clinical research.

More on NIH sharing policies can be found on the [NIH scientific data sharing site](#). [Additional information and FAQs](#) have been posted. Compliance with this policy requires a detailed and specific plan that is likely to add time and effort in the funding application process, as well as tasks that must be completed throughout the proposed funding period and included in any associated timelines and personnel planning.

Information for this monthly update should be provided no later than the second Wednesday of each month to Miek Segers at msegers@som.umaryland.edu. The update will be published on the second Friday of each month.

Have questions about identifying a funding source? Finding research partners across the UMB/UM campuses or at another university? Defining future research strategies? Or organizing your thoughts on (virtual) paper? Contact Nancy Knight, PhD, Director of Academic and Professional Development for the department, at nknight@umm.edu

Clinical Trial Enrollment

- 22 patients at MPTC on the **PCG Registry**
- 2 patients at MPTC on the **Deep Thermal Therapy HUD**
- 1 patient at MPTC on the **Pediatric Proton Registry**
- 1 patient at MPTC and 1 patient at BWMC on **NRG GU009**: Parallel phase III randomized trials for high-risk prostate cancer evaluating de-intensification for lower genomic risk and intensification of concurrent therapy for higher genomic risk with radiation.
- 1 patient at MPTC on **GCC21136**: Phase 2 randomized total eradication of metastatic lesions following definitive radiation to the prostate in de novo oligometastatic prostate cancer (TERPS) trial.
- 1 patient at UMMC on **GCC1944**: A randomized phase III trial of two standard dose fractionation regimens for adjuvant vaginal brachytherapy in early-stage endometrial cancer.
- 1 patient at MPTC on **GCC 15100**: Pragmatic phase III randomized trial of proton vs. photon therapy for patients with non-metastatic breast cancer: A Radiotherapy Comparative Effectiveness (Radcomp) Consortium trial.
- 1 patient at MPTC on **GCC19140**: Pilot study of laser interstitial thermal therapy followed by hypofractionated radiation therapy for recurrent high-grade gliomas.

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Grants and Contracts

Submitted

- **Arezoo Modiri, PhD, PI/PD**, to the Department of Defense. HT9425-23-PRCRP-PWSA (Peer Reviewed Cancer Research Program Patient Well-Being and Survivorship Award) for “Improving well-being of lymphoma survivors through outcome-risk-focused treatment planning” (\$1,434,674).

Articles Published

Entered into PubMed August 10–September 8. Titles link to PubMed abstracts, with full-text links.

1. **Bazyar S**, Sutura P, Deek MP, Marshall CH, **Tran PT**. Cell-free DNA sequencing sheds additional insights on BRCA-altered metastatic castration-resistant prostate cancer. *EBioMedicine*. 2023 Aug 9;95:104756. Online ahead of print.
2. **Poirier Y**, DeWerd LA, Trompier F, Santos MD, Sheng K, Kunugi K, Satyamitra MM, DiCarlo AL, Winters TA. Minimum reporting standards should be expected for preclinical radiobiology irradiators and dosimetry in the published literature. *Radiat Res*. 2023 Aug 8. Online ahead of print.
3. *Simone CB, Serebrenik AA, Gore EM, Mohindra P, Brown SL, Wang D, Chetty IJ, Vujaskovic Z, Menon S, Thompson J, Fine G, Kaytor MD, Movsas B. Multicenter phase 1b/2a clinical trial of radioprotectant BIO 300 Oral suspension for patients with non-small cell lung cancer receiving concurrent chemoradiotherapy. *Int J Radiat Oncol Biol Phys*. 2023 Aug 29:S0360-3016(23)07845-8. Online ahead of print.
4. Taylor SI, **Cherng HR**, Shahidzadeh Yazdi Z, Montasser ME, Whitlatch HB, Mitchell BD, Shuldiner AR, Streeten EA, Beitelshees AL. Pharmacogenetics of sodium-glucose co-transporter-2 inhibitors: Validation of a sex-agnostic pharmacodynamic biomarker. *Diabetes Obes Metab*. 2023 Aug 22. Online ahead of print.
5. Tchelebi LT, Winter KA, Abrams RA, Safran HP, **Regine WF**, McNulty S, Wu A, Du KL, Seaward SA, Bian SX, Aljumaily R, Shivnani A, Moore TD, Crocenzi TS, DiPetrillo TA, Kuykendal AR, Crane CH, Goodman KA. Analysis of radiation therapy quality assurance in NRG Oncology RTOG 0848. *Int J Radiat Oncol Biol Phys*. 2023 Aug 18:S0360-3016(23)07781-7. Online ahead of print.

*Represents research performed in our department.

Important Dates for Upcoming Funding Submissions

Below is an updated calendar with firm due dates for upcoming major NIH deadlines (individual RFA/PA dates may differ). Contact the Department Office of Research Administration (DORA) (msegers@som.umaryland.edu) ASAP if you plan to submit any funding proposal, regardless of funder. Failure to meet these deadlines may result in delaying your submission until the next cycle (if available).

NIH deadline	DORA budget, prelim materials	Dean/SOM prelim materials	FINAL Dean/SOM/SPA
R01	10/05/23	09/22/23	09/26/23
R21	10/16/23	10/03/23	10/05/23
R01 Resub	11/05/23	10/24/23	10/26/23
R21 Resub	11/16/23	11/03/23	11/07/23

NIH: A Cautionary Note on the Use of AI

An NIH blog on June 23 clarified the policy that using artificial intelligence (AI) in its peer-review process constitutes an actionable breach of confidentiality. NIH explained that its scientific peer reviewers are prohibited from using natural language processors, large language models, or other generative AI technologies for analyzing and formulating peer-review critiques for grant applications and R&D contract proposals. All such proposals are considered confidential, and use of AI platforms would breach that confidentiality, which could lead to “terminating a peer reviewer’s service, referring them for government-wide suspension or debarment, as well as possibly pursuing criminal or civil actions.” NIH staff also cautioned that use of AI in writing/preparing a funding application is done at the PI’s “own risk.” Use of AI tools may introduce concerns related to [research misconduct](#), such as [plagiarized text](#) from someone else’s work or [fabricated citations](#). If these are identified in a grant submission, NIH will take appropriate actions to address the noncompliance.