Guidelines for research use of Epic reporting tools

This document outlines the guidelines for research use of in-scope tools, specifically within the context of Epic and Epic data.

Tools in scope include:

SlicerDicer, Reporting Workbench, Analytics Catalog, Business Objects (BOBJ), Radar or Epic Dashboards and Metrics

Out of Scope tools include:

Cognos, Polaris, Tableau, Office 365 tools (e.g., Excel), statistical tools (e.g., R, SPSS, etc.), other third-party tools

Database access (for example, Clarity and Caboodle)

Target Groups:

Multi-Use – Users that access Epic for multiple purposes (e.g., clinicians that also participate in research)

Research Only – Research personnel specified as such in Epic (e.g., research coordinators)

# Compliance Requirements

Please see [Checklist for working with human research data](https://ohsuitg.sharepoint.com/sites/CT.Research-Data2/SitePages/Policies-and-Regulations.aspx#checklist-for-working-with-human-research-data)

### When using any tools in which Protected Health Information (PHI) will be viewed, Institutional Review Board (IRB) approval is necessary. Please note that low cohort numbers (11 or fewer) can also be considered identifiable information. Therefore, IRB approval is required when viewing low cohort numbers, regardless of whether any of the HIPAA identifiers are accessed.

* Note that some tools (e.g., SlicerDicer, BOBJ) do not place limits on cohort numbers. Therefore, it is the investigator’s responsibility to ensure that the appropriate IRB approval is obtained prior to accessing low cohort counts.
* The threshold of 11 or fewer has been adopted by other tools (e.g., Cosmos) and was selected to match CMS’s recommendation on the [Limited Data Set Data Use Agreement form (section 8a)](https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms-r-0235l.pdf) to not show cell counts lower than 11.

Viewing/Using de-identified, aggregate cohort data (for cohorts with total counts greater than 11), does not qualify as human subjects research, and would not require IRB approval. This means that no [HIPAA (Health Insurance Portability and Accountability) identifiers](https://o2.ohsu.edu/information-technology-group/hipaa-and-research) can be included. If an investigator has any questions regarding whether their research qualifies as human subjects research, it is recommended they contact the IRB or submit a [Request for Determination](http://ohsu.ellucid.com/documents/view/7703/?security=aedbd2f8241ba3a19414fd43d96d750c306acc6a).

* Federal Regulation: 45 CFR 46.102 (e)(1)(ii) “Basic HHS Policy for Protection of Human Research Subjects – Definitions for the purposes of this policy - Human subject means a living individual about whom an investigator (whether professional or student) conducting research: - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” - [HHSPolicy\_45\_CFR\_46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102)

# Access and Workflows

General access is currently no different for these reporting tools for research than access for clinical purposes. Some tools require training before access can be granted (See Training and Support section, below).

Currently, SlicerDicer is the only tool that has a research-specific workflow, and only for Research Only users. When a Research Only user attempts to access line level detail (specifically through SlicerDicer), they will receive a prompt asking if the data are research-related, and then an additional prompt for an IRB number. This is not the case for a Multi-Use user.

# Monitoring/Auditing

### All Epic use

The Information Privacy and Security Offices run a program called Protenus (this replaced HIPAA scout on 6/1/21). The program uses AI technology to monitor the workflows of users. Any outliers in a user’s workflow will be flagged (e.g., a physician who has never accessed a trauma patient’s chart before accesses the chart of a trauma patient). The user’s supervisor will be contacted to ensure there was a work reason for access. If so, the flag will be marked unsubstantiated. If access is deemed not work-related, a fact-finding meeting is scheduled to find out more about why the information was accessed, and to ensure the user understands the reasons behind the inquiry. This would involve the implicated user, the supervisor, Privacy and HR. Lastly, a recommendation letter would be issued, and potentially sanctions placed upon the user.

* If users accidentally access material in EPIC, they can write to [OIPS@ohsu.edu](mailto:OIPS@ohsu.edu).
* If users access MCMC Epic content, the MCMC privacy office will be notified

### Research use

There is currently no regular additional monitoring or auditing done for research use of Epic reporting tools at this time, but this may be implemented in the future. Ad hoc audit reports can and may be run for SlicerDicer and Reporting Workbench sessions.

# Training and Support

There is annual HIPAA training as part of the required Integrity Booster training for all users.

Basic service level support and training will be provided by ITG (requests via the service desk - <https://service.ohsu.edu/servicedesk/customer/portals>).

* Specific research compliance language has been added to the training material for EPIC tools.

All report building will be self-service for these tools for research purposes. No service is available to build reports using these tools for researchers (note however that services are available to generate EPIC data reports outside of these tools – <https://ohsuitg.sharepoint.com/sites/CT.Research-Data2/SitePages/Epic-Data.aspx#data-extracts>). No requests for changes to templates, additions to models or universes, new metrics, etc. will be addressed for research purposes.

Help guides and training material can be found on these sites:

* ITG Bridge site: <https://bridge.ohsu.edu/community/bioc/SitePages/Explore.aspx>
* Research Data website: <https://ohsuitg.sharepoint.com/sites/CT.Research-Data2/SitePages/Epic-Data.aspx>

### SlicerDicer, Reporting Workbench, Analytics Catalog

* The Research Data Concierge can walk through typical use of the tools and can help troubleshoot, but cannot build reports for research teams.

### BOBJ, Radar or Epic Web Executive Dashboards and Metrics

* No additional support for use of these tools will be provided.