

**National Heart Lung and Blood Institute  
Office of Biostatistics Research**

**Excerpt of Annual Report 2022**

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The Office of Biostatistics Research (OBR) is the sole biostatistics resource for the National Heart, Lung, and Blood Institute (NHLBI), collaborating with both the intramural and extramural divisions. The members of the Office participate in the planning, design, monitoring and analyses of NHLBI studies, including both clinical and basic biomedical science studies. OBR collaborates with investigators in the Division of Intramural Research (DIR) on their many clinical studies. OBR also works with the NIH project teams to support large extramural research grants from the Division of Cardiovascular Science (DCVS), the Division of Blood Diseases and Resources (DBDR), the Division of Lung Diseases and Sleep Disorders (DLD), and the Center for Translational Research and Implementation Science (CTRIS). The OBR's primary mission is to provide objective, statistically sound, and medically relevant advice and solutions to problems that are presented. When new methodology is needed to answer the questions posed, OBR members are expected to obtain novel solutions.

Here we provide a short overview of the group's major activities in 2022 and the 2022 publications. The activities and publications exemplify the OBR's broad contributions to both biostatistics and to heart, lung, and blood diseases and sleep disorders.

The OBR professional staff conducts research in statistical methodology relevant to clinical research studies including survival analysis, longitudinal data analysis, multiplicity problems, analysis of large data sets, data science, and statistical genetics. The group has broad knowledge of new and efficient study designs for clinical trials, especially monitoring for efficacy and safety while trials are ongoing, midtrial corrections and novel designs, such as platform and multiply randomized trials. OBR members are at the forefront of original statistical methodology research in these and other statistical areas.

The OBR is active and visible both within NHLBI and externally, for example serving on committees for other NIH institutes and professional statistical organizations. Members of the OBR often present invited seminars in biostatistics and statistics departments and organize invited sessions as well as present contributed research at national and international meetings.

In 2022, OBR has predominantly worked remotely. However, the group has held a hybrid weekly meeting to discuss administrative matters as well as for frequent seminars, by both internal and external speakers. Meeting weekly assures that the group maintains its cohesion. The external seminars have been coordinated by Dr. Troendle and are widely attended. This has enabled the group to educate themselves on recent statistical methods and also to share research ideas and projects. OBR hosted one summer student intern in 2022.

### OBR and NHLBI Intramural Projects

The OBR collaborates with the Division of Intramural Research (DIR) on the design and analysis of DIR protocols, and members are named as investigators on the protocols. These protocols provide interesting clinical and statistical challenges. For such a protocol, the DIR investigators first contact the OBR for a consultation. Once an investigator and a biostatistician work together on a project, they often will collaborate on other projects. This leads to stable and productive long-term relationships. The collaborations are broad within DIR and are mentioned by each member of OBR in their one-page summary. The list of publications at the end of this report gives examples of the resulting productivity.

### OBR and NHLBI Extramural Projects

During 2022, the OBR worked on a large number of extramural projects. These included projects sponsored by cooperative agreements and assessing and focusing large grant applications prior to funding.

For many extramural projects, OBR plays an oversight role, attending Data and Safety Monitoring Committee (DSMC) meetings and providing input as requested. For some projects, OBR members work as part of the program office team, collaborating over the course of the project. In such studies, the biostatistician participates in the Steering Committee and sometimes other study committees in addition to the DSMC. For all projects, the OBR statistician provides technical input including decisions on early termination or sample size changes. The OBR statistician plays an important role in meetings with institute leadership when key institute decisions are needed, such as stopping a study for toxicity or futility.

### **2022 PUBLICATIONS:**

- Ahn GS, Hwang K, Kim TM et al. (including **Joo J**). Influence of concurrent and adjuvant temozolomide on health-related quality of life of patients with grade III gliomas: a secondary analysis of a randomized clinical trial (KNOG-1101 Study). *Cancer Res Treat* 54(2):396-405, 2022.
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