



## User's Guide: IRB Issues

There is a common misconception that IRB (institutional review board) review is not needed for studies using secondary data. This is incorrect. In many cases, IRBs will exempt a study from full review if the data does not contain any personal health information such as names, social security numbers, dates of birth, or other such identifiers. However, typically the investigator is required to formally seek an exemption from their IRB, rather than just assuming the research is exempt without ever asking.

Also note that many databases comprise a “limited data set”, whereby they lack identifiers such as names and social security numbers but contain other forms of personal health information such as dates (for example, the dates of visits to a doctor’s office, dates of laboratory tests, dates of death, etc.). In this situation, many IRBs require an expedited application, which entails a higher level of detail and scrutiny than an application for exempt status.