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Contact Us

Human Research Protections Office

Blount Hall, Room 408
1534 White Ave.
Knoxville, TN 37996-1529
865-974-7697
utkirb@utk.edu
irb.utk.edu

Office Hours
M-F: 8 a.m. – 5 p.m.

COVID-19 and Human Subjects Research

For the latest information about COVID-19 and its impact on human subjects research at UT, please see our guidance on the Office of Research & Engagement's [COVID-19 Responsible Conduct of Research](#) webpage.

Publicly-Available Information and IRB Review

It can be challenging to distinguish between information (records, data, etc.) that is publicly available and information that is not.

Publicly available information is:

- published or broadcast for public consumption;
- accessible to anyone in the general public, without the need for special permissions or privileges;
- sometimes available to the public by subscription or purchase;
- could be seen or heard by any casual observer;
- made available at a meeting that is open to the public; or
- obtained by visiting any place or attending any event that is open to the public.

Publicly available information is not:

- associated with restrictions on its access, storage, use, or subject to the researchers or investigator entering into an agreement with the data owner/provider.
- limited to specific groups, like researchers, physicians, professionals, etc.; or
- limited to individuals with certain qualifications.

The best example of information that is truly publicly available is **open data**. Open data, such as Data.gov and Census.gov, is information that can be freely used, reused and redistributed by anyone - subject only, at most, to the requirement to attribute and share.

Oftentimes data repositories provide both publicly-available data and restricted data. This often leads to confusion about what information requires review. An examples of such a provider is the Inter-university Consortium for Political and Social Research ([ICPSR](#)).

Data Sets Requiring Review

A data set requires IRB review if one or more of the following apply:

- Data provider/owner **requires** the data recipient/user to enter into an agreement (i.e., data use agreement) or the data set has associated restrictions on its access, storage or use);
- Data set will be **merged with any other non-public data sets** in such a way that individuals might be identified;
- The researcher will **submit identifiable, or potentially** identifiable, information to a public data set; or
- Data are from the NIH [dbGaP](#) or GWAS (Genome Wide Association Studies) data repositories.

If uncertain whether a data set requires review, please contact our office (865-974-7697 or utkirb@utk.edu).

Data Use Agreements

A Data Use Agreement (DUA) is a written contract used to govern the transfer and use of data between a data user and a data provider. The DUA describes the provisions associated with the transfer and use of those data. These provisions address important issues such as storage requirements for the data, limitations on use of the data, publication, and any related privacy rights that are associated with those data.

UT researchers cannot sign DUAs on behalf of the University. The agreement needs to be set up as a contract between institutions and signed by an Authorized Official who is capable of binding the University to the terms of the agreement. Agreements related to research are reviewed by the [Office of Sponsored Programs](#) before they can be signed.

Investigator Responsibilities

If a DUA is associated with a study being submitted for IRB review, it must be submitted with the IRB application. It is the researcher's responsibility to understand and strictly follow the terms of the DUA.

Tips for Studies Using Data Sets

If your research involves obtaining and using existing data sets from a data provider and requires IRB review, or if you are unsure IRB review is required, submit an IRB application and follow the tips below.

- Identify the data source.
- Provide a list, or an attachment, of all the variables to be obtained.
- Describe how those data will be obtained or received (researcher has direct access but will record information onto a data sheet, data will be downloaded from data provider, etc.)
- Describe how those data will be stored, who will have access, and what will happen with those data once the research is completed.
- Submit a copy of any application the researcher is submitting to the data provider.
- Submit a copy of any agreement the required by the data provider, such as a data use agreement.
- Submit a copy of any data security plans associated with the data set.

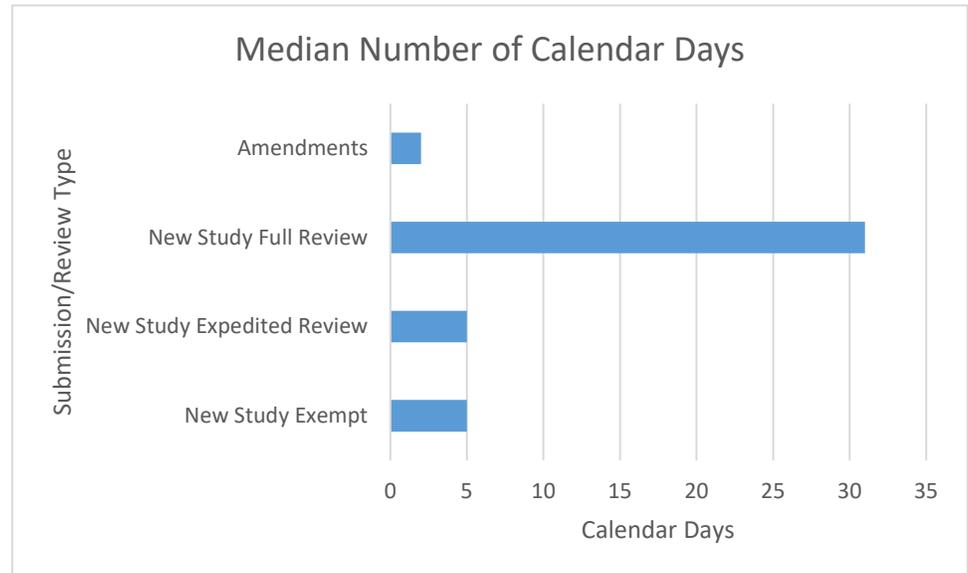
- The IRB application must reflect the requirements in any agreements or data security plans.

Addressing these issues will help avoid delays in review.

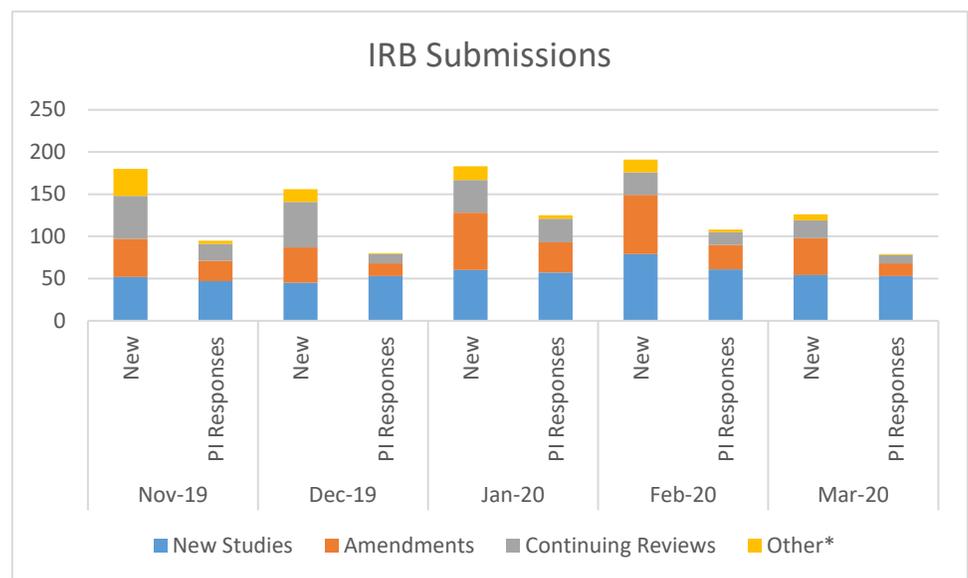
Performance Metrics

Review Turnaround Times in Calendar Days

1st Quarter 2020 (January - March)



IRB Submissions



* Other submissions include unanticipated problem reports, study closure requests and miscellaneous submissions.

Announcements

New Recruitment Guidance Available

Also, please see our newly posted [Guidance for Investigators on Recruitment Materials](#).

Updated iMedRIS Guidance

Updated [iMedRIS Guides](#) have been posted on our website. These step-by-step guides will walk you through logging into iMedRIS for the first time, submitting a new study, routing and signoff, responding to requested changes, and submitting amendments. These guidance documents are posted on our website's iMedRIS page.

IRB 101 Workshop - Registration Required

The IRB 101 Workshop scheduled for **Tuesday, May 5**, from 1:00 to 3:00 pm will take place on Zoom. Please register at tiny.utk.edu/irb101 ahead of time. Dr. Gilrane will then send you the Zoom link and the workshop materials.

Suggestions

Please contact us with any suggestions you have for future issues such as topics of interest or questions you would like answered. Submit your questions to utkirb@utk.edu and use **HRPP Newsletter** in the subject line.

Contact Us

General Questions (submission procedures, application and materials development, iMedRIS, etc.) contact us at 865-974-7697 or utkirb@utk.edu.

Submissions that are currently in review, contact your unit's [liaison](#).

Reportable New Information (unanticipated problems, adverse events, complaints, concerns about participant welfare or safety, etc.), contact Colleen Gilrane (865-974-7697 irbchair@utk.edu) or Kristine Hershberger (865-974-7687 kh@utk.edu).

Reliance Agreements/Single IRB and Other Collaborative Research, contact Kristine Hershberger (865-974-7687 kh@utk.edu).

Education and Training, contact Colleen Gilrane (irbchair@utk.edu).

ClinicalTrials.gov, contact Kristine Hershberger (865-974-7687 kh@utk.edu).

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Phone: 865-974-7697
Fax: 865-974-7400
Email: utkirb@utk.edu
Website: <https://irb.utk.edu/>