1. **What do both the Institutional Review Board (IRB) review and Data Access review entail?**

IRB review is for research studies to ensure that federal rules and ethical guidelines issued by the Office for Human Research Protections (OHRP) are followed. See <http://www.hhs.gov/ohrp/> for more information about OHRP and Institutional Review Boards. The DPH IRB generally reviews research studies that are conducted by MDPH staff or agents or that are funded by MDPH.

Data Access review (also known as “24A” review, which refers to section 24A of MA General Law c. 111) is for research or studies that typically involve a request for access to confidential MDPH data for purposes of conducting the research or study.(e.g., use of MA Cancer Registry data for a study). The review functions to ensure that federal and state laws regarding the access and use MDPH data are followed, and that all MDPH privacy and security policies are followed. If the project under review involves contact with data subjects, this review also ensures that ethical standards for informed consent and contact procedures are followed.

1. **How long does the review process take?**

New applications take an average of **30-60** days to receive a review decision. Modifications of existing projects take an average of **30-45** days to receive a review decision. However, the timing of the review for a study depends upon a number of factors, including the availability of agenda dates for the appropriate review committee and the schedule of reviewers (See additional factors under #3, below). Applications are assigned to review on a first come, first serve basis, and meeting agendas can fill quickly. Please email dph.irb@state.ma.us to inquire about available review dates. The IRB/Data Access Review Process is as follows:

**Initial Review**

Determine if submission materials are complete and the type of review required

**Assign Reviewers and Schedule Review Date**

**Communicate Review Decision**

(e.g., Approved, Approved with Conditions, Modifications Required)

**Conduct Review**

1. **Besides the volume of applications received, what other factors can slow down the review process?**
* The complexity of the project.
* Whether a linkage to other data sets is anticipated. Multiple linkages require more time.
* Laws or regulations restricting access may require additional legal review.
* Whether there are other data owners besides MDPH. For example, the All Payer Claims Database (APCD) and the Casemix data are managed by the Center for Health Information and Analysis (CHIA). CHIA has a separate review process that is not under the control of MDPH which will add an unknown amount of time to the entire review process.
* Poorly written or incomplete application materials.
1. **What tips are there to make the process go faster?**
* Make sure that the project narrative provides a clear explanation of and rationale for the data elements requested or gathered.
* Clearly explain the project rationale and methods. If your project is complex or involves complex methodology, you will need to be especially thorough in explaining the project.
* Ensure that the details of the project are consistently explained across all application materials.
* If your project involves linking datasets, include a graphic representation of the proposed linkage plan.
* If your project involves contact with participants, make sure that you’ve thought through potential risks to participants. Clearly articulate in your application how you plan to minimize these risks.
* If responding to a previous review, make sure that you understand what is being asked and that your response fully and thoughtfully addresses the concern.
* Use the Application Checklist as a guide to prepare your application. Make sure you have submitted all required Appendices and all supplemental materials (consent form, contact scripts, etc.).
* If your review decision asks that you make modifications to your project or submit additional information, it is important that you respond in a timely manner (within 45 days). This will help the reviewers to quickly review your response and reach a decision. In addition to responding to each question, you should submit revised materials with track changes or highlighted text so reviewers can easily see changes that were made.
1. **Once a project is approved, how long will it take to get the data I’ve requested?**

Allow at least 30 days for MDPH staff to prepare the data files to specification. If the data request is complex and/or involves linking datasets, allow additional time. In all cases, this work is being conducted in the midst of other priorities at MDPH. These priorities can change on short notice, and this may impact the delivery of data files to approved applicants. MDPH staff will make every effort to provide data quickly once approved.

1. **How will I know when my project is undergoing review?**

Some projects are reviewed by the **IRB Committee** and others by the **Oversight Committee**, a working group comprised of IRB co-Chairs and staff.

If you are submitting **a new research study** that involves human subjects contact, and are seeking IRB approval, it must be reviewed by the IRB Committee. The IRB Committee meets on the 3rd Wednesday of each month. All submissions must be received at least three weeks prior to the meeting date to be placed on that month’s agenda. If there is no room on the agenda for the upcoming meeting, it will be placed on the agenda for the next meeting.

See *IRB Committee Meeting Schedule Dates*.

If your project constitutes non-research activities (e.g., program evaluation) and/or does not involve contact with participants, it may qualify for exemption or expedited review from the MDPH IRB or Data Access review only. These reviews are conducted by the **Oversight Committee**, a working group comprised of the IRB co-Chairs and staff. Oversight Committee meets biweekly on Thursdays. All submissions must be received three weeks prior to the meeting date to be placed on the agenda. If there is no room on the agenda for the upcoming meeting, it will be placed on the agenda for the next meeting.

The timeliness of reviews also depends upon the availability of staff with the appropriate expertise. If the availability of these staff is limited due to other Department priorities, reviews may be delayed. However, the Department staff work very hard to ensure a timely review, and if we anticipate significant delays we will inform the applicant of the expected time frame.

1. **I have received approval from my research project from my own institution’s IRB and am seeking access to confidential MDPH data for use in this project. What will the Department be looking for in their review of my application for access to confidential data?**

In addition to obtaining approval from the IRB at the Principal Investigator’s institution, the Principal Investigator must request access to MDPH confidential data for research from  the Commissioner of Public Health in accordance with M.G.L. c. 111, §24A.  In order to obtain this approval, applications need to undergo Data Access review. See the response to Question 1 in this FAQ for additional details regarding Data Access review.