# When to apply for a research ethical approval of research studies

## Guidelines for researchers at Department of Political Science, Aarhus University*

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**Purpose.** The purpose of these guidelines is to help researchers at Department of Political Science, Aarhus University making informed decisions about whether to apply for an ethical approval for a given study/data collection process.[1]

**Background.** The need and demand for ethical approval of research studies has increased significantly in recent years. Furthermore, journal requirements currently in flux, so requirements may change between data collection and manuscript submission. Finally, getting approval post-hoc is very difficult if not impossible. Researchers who are about to collect research data should therefore strongly consider applying for an ethical approval from AU's Research Ethics Committee (or elsewhere; see below). On the other hand, the application process takes time for both the researcher and the committee. Given that time is a limited resource, it is sensible to consider whether to apply or not.

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[1]In line recommendations from AU's Research Ethics Committee, one should distinguish between a study and a research project: A study is an instance of a data collection process (e.g., a field experiment, survey, a panel survey, and a series of interviews), where the collected data may be used in more than one research project (and more than one publication). A project may involve more than one study. It is therefore important that you consider applying every time you about to initiate a new study/data collection process. See also the point on "Research projects/papers with several studies/data collections" below.

**Roadmap and disclaimer.** Three situations are listed below: A) Situations where you should always apply. B) Situations, where you should strongly consider applying. C) Situations where you probably not should apply. Afterwards a few cross-cutting issues are discussed as well as the (lack of) connection between GDPR compliance and ethical approval.

Note that requirements and norms are changing rapidly currently and vary across fields. These guidelines may therefore be misleading. It is advisable to consult colleagues in your field, the target journal(s), and, in the case of data collection outside Denmark, local experts. You should also note that formal ethical review and approval does not take away the researcher's responsibility to make situated ethical judgments throughout the project.

**A) Situations where you should always apply.** Obtaining an ethical approval is sometimes required by law, in which case application of course is mandatory. For instance, you must apply if your study involves health related experiments involving medical treatment of human subjects (including deceased, fetuses etc.), medical equipment or pharmaceutical products in Denmark from the regional research ethics committee (See [1] for more info). You should also always apply if it is required by the founder of your project (e.g., EU's framework programs) or collaborators (institutions, public or private).

**B) Situations, where you should strongly consider applying.** An increasing number of journals require that research that involves human subjects (i.e. living individuals) is ethically approved (see e.g., requirement in the *American Journal of Political Science* [2]). The definition of "research that involves human subjects" is not entirely consistent, but it likely involves surveys (regardless of mode of collection), interviews and experiments in the field and in the lab. A broad definition would encompass any research that make study subjects do something they would not otherwise have done in that instance (e.g., answer a question in a survey or in an interview) or exposing study subjects to information and stimuli (e.g., in a field experiment), they would not otherwise have been exposed to in that instance. This definition can potentially also include collecting data about other units than individuals (e.g., organizations, countries, etc.) where individuals are the informants (e.g., experts etc.), but this would be less clear cut. Finally, it should be noted that collection of identifiable private information through the internet or public registries can be considered to be subjected to ethical review requirements from journals etc. despite lack of contact between researcher and subject because the object

may suffer harm from the existence of your database.

If you are in doubt, you can also think about whether the participants are particularly vulnerable, busy etc., if the stimuli are atypical or involves deception, or if participating in itself puts the participants at risk. In such cases there are very good reasons to apply, and you should definitely apply if you yourself find the study ethically problematic. But note the asymmetry here; a study with direct interaction with resourceful, non-busy participant with a trivial, typical stimuli does not make the study exempt from ethical review if a ethical review is required for publishing etc.

**C) Situations where you probably not should apply.** Studies based on data collection that does not involve interaction with human subjects will probably not be met with a requirement for an ethical approval. This would probably apply to data about other subjects than individuals or data based on existing registries (but note the remark about collection of identifiable private information through the internet or public registries above or through experts etc.)

**Cross-cutting issues**

*Studies with data collection in a country outside Denmark.* An approval from the AU review board should suffice in most cases but be aware of *legal* requirement for local ethical approval or very different (higher) standards regarding research ethics in specific countries.

*Studies with similar data collections in more than one country.* In principle, only one approval is required as long as the approval engages with the entire data collection.

*Studies with participating researchers from more than one institution, but with data collection in one of the participating countries only.* Here the assumption would be that an ethical approval from one institution is enough. Note, however, that some institutions positively require approval from the local ethical review board, in which case that requirement of course should be met.

*Studies with participating researchers from more than one institution, and with data collection more than one of the participating countries.* Again, an ethical approval from one institution should be enough if it concerns the entire data collection—and again, some institutions positively require approval from the local ethical review board.

*Research projects/papers with several studies/data collections.* As discussed in footnote 1, there

should be an approval of each study requiring approval. However, panel surveys or other studies that engage with the same subjects several times or employ the same instruments to different subjects across time can be considered as one study (as long as the entire data collection is subjected to review).

**Ethical approval vs. GDPR compliance.** GDPR compliance and ethical approval are independent of each other and concern two different things (protection of data about individuals and protection of participants from harm). This means that an ethical approval does not imply that the data collection and storage is GDPR compliant, and GDPR compliance does not imply that a study is ethically sound. Similarly, collecting data that are not subjected to GDPR compliance (i.e., data that cannot be attributed to a person, because of e.g., anonymization) does not necessarily imply that an ethical approval is unnecessary. Likewise, one cannot reject the need for ethical approval by referring to that the data is collected for "scientific research purposes" (i.e., "forskningshjemlen"). In fact, there instances where the use of "forskningshjemlen" would be problematic from an ethical perspective as "forskningshjemlen" does not imply informed consent. Also note that if your study requires informed consent for ethical reasons (many studies do), this is not the same as consent in a GDPR sense. An ethically sound informed consent form should provide information about the study, so that the potential participant can make an informed decision about participation. The form should be written in language targeted to the potential group of participants and not in the legal lingo typically defining GDPR forms.

All that said, when submitting an application for ethical approval to AU's committee you will be asked if your study comply with GDPR regulations and to provide a case number from the registration in AU's record of studies processing personal data ("Fortegnelsen") if registration is relevant.

**References**

[1] AU's page for Ethical approval of research projects

[2] p. 4 in AJPS' Editorial Report, March, 2022