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Quick Tips for Exempt Submissions

In general, research may qualify for an exemption when the research poses no greater than minimal risk to participants and all of the research procedures fit within one or more federally defined exemption categories: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html. Like other types of human subjects research, exempt submissions must be submitted to the Human Research Protections Office/Institutional Review Board (HRP/IRB) for review and must receive a final determination letter before research activities are initiated. Questions related to exemption determinations not covered in this document may be directed to HRPP@drexel.edu.

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Q.1. What documents, forms, applications, or materials need to be included in an exempt submission?

A.1 Make sure you include all study measures, questionnaires, interview questions, recruitment materials, and any other participant-facing documents in your submission. If it's being used with subjects, the IRB needs to review it. Be sure to review the **How to Submit** instructions under the Researcher tab on the HRP website to make sure your submission is complete before you send it to the IRB for review: Researchers | Office of Research & Innovation | Drexel University

Note that all exempt submissions must include an **HRP-504 Protocol** attached to the electronic application in COEUS.

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Q.2 What are the most common errors related to submitting an exempt study, and how can I avoid making these mistakes?

A.2 Here is a summary, organized by topic, of some of the most common problems that occur during the exempt submission and review process:

Timelines

One of the most common errors is a misconception about the meaning of the terms "exempt" and "expedited" as used in relation to IRB reviews. These terms do not refer to the *speed of the review* but instead indicate *different types* of IRB review. Investigators often do not give themselves enough time to complete the entire review process as they believe that an exempt or expedited review will, by definition, be completed quickly.

Depending on a number of factors including current volume of submissions, it may take more than a week before an IRB staff member can begin their review of your study, and most projects do not obtain a final determination letter without at least some minor revisions required. Drexel, like most research compliance programs, utilizes a first-in/first-out methodology to try and promote equity and fairness across submissions. Requests that staff prioritize a project, which would negatively impact their colleagues who have submitted previously, are typically only permitted in extenuating circumstances.

Generally, you should give yourself between 1-2 months between the submission in COEUS being received at the HRP/IRB and receiving your exemption determination allowing you to move forward with the project.

Project Completeness

Double-check to make sure that each relevant section of the protocol form and electronic application has been completed and all directions within the forms have been followed.

Initial submissions are screened by the HRP/IRB Office for certain required attachments and you will be notified if the submission fails screening, but as noted above, if the submission passes screening it may be more than a week before an IRB Analyst is able to begin their review of your project, and missing information could delay your review and final determination.

Submitting the Application in the Electronic System

Often individuals engaged in the submission process may forget to hit the final submit button so that their submission actually enters the routing in the COEUS system or those in the routing process may forget to sign off on the submission, causing the study to be stuck in in that routing process without ever appearing in the HRP/IRB Office's intake queue.

When submitting your study, be sure to follow all submission directions found in the IRB's How to Guides. A link to these guides can be found on the HRP website under the Researcher Tab: Researchers | Office of Research & Innovation | Drexel University

Q.3 Who should be listed as study personnel on an exempt application?

A.3 Be sure to add all of the study personnel who will be engaged in human subjects research activities to the submission. If you're a student researcher, remember to list your faculty advisor/mentor as the Principal Investigator on the COEUS Application and review the submission with them before routing it to the HRP/IRB. Remember that all personnel need to have completed the required CITI ethics training (Researchers | Office of Research & Innovation | Drexel University) prior to submission.

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Q.4 What are the consent form/information sheet requirements for exempt submissions?

A.4 The process of providing potential participants with study information *and* the opportunity to ask questions about this information is fundamental to human subjects research. A robust and informed consent process allows potential participants to ultimately determine if they want to participate in a research study.

For your consent form/information sheet to most effectively meet the Drexel IRB's standards for exempt research, please adequately describe the participant enrollment process in your HRP-504 Protocol and use the **HRP-506 Information Sheet for Exempt Research** template found under the Tools & Templates section on the IRB website: Researchers | Office of Research & Innovation | Drexel University.

For each submission, be sure to download all IRB forms and templates directly from the Drexel HRP/IRB website. This guarantees you are using the most updated versions.

Important information to provide subjects during the consent process
Name and contact details for investigators
Name of the study sponsor (if applicable)
Contact details for the HRP/IRB
A statement that the activities involve research
A description of the purpose of the research
A description of the research procedures, including study activities and duration
A description of any compensation or incentive
A statement that participation is voluntary
A statement that declining or withdrawing will not affect your relationship with Drexel
A description of the risks and benefits
A description of confidentiality, including a statement that confidentiality cannot be guaranteed
If there is deception, a statement that subjects will be unaware or misled regarding the nature of the research (if applicable)

Q.5 When developing recruitment materials for my project, what are Drexel's guidelines?

A.5 Make sure you include all proposed recruitment materials, and that the recruitment materials conform to Drexel's standards. Are you emailing potential participants? Include an email script. Are you advertising on social media? Include the advertisement.

Often studies get sent back because the researchers will only include one form of recruitment material when there are multiple recruitment methods that will be employed in the study, so be sure to include all materials you plan to use to advertise your research. The HRP/IRB applies the following considerations to advertisements:

Important considerations for recruitment materials
Name(s) and contact details for investigators are included.
The location where research activities involving subjects will take place is included (if applicable).
A statement that the activities involve research is included.
A description of the research purpose is provided.

Exclamation points and catchy words like “free” or “exciting” are not used to induce potential participants.
Compensation is not emphasized (e.g., through use of bold type, larger font, exclamation points, or inclusion in subject lines or tag lines).
Key eligibility criteria are provided (if applicable).

Q.6 What is the difference between the terms anonymous, coded, de-identified, and confidential?

A.6 Make sure you understand the difference between the terms “anonymous”, “coded”, “de-identified” and “confidential” as these terms are used in relation to research data and the HRP/IRB. Misuse of these terms is a common mistake in submissions.

Anonymous means that there is no way that anyone, including the researchers, can connect information collected in the study back to the participants. True anonymity is rare given scientific advancements and current technology as even a few data points may be enough to identify individuals when used in combination with or compared to other information (https://aboutmyinfo.org/identity/about).
Coded means that direct identifiers (such as names) have been replaced with a code such as a study ID number or pseudonym.
De-identified means that the data does not include any direct or indirect identifiers or codes linking the data to an individual subject’s identity.

Confidential means that the researchers may collect potentially identifiable information from the participants, but they will not share that information with anyone.
Ideally, you should simply explain whether you are collecting identifying information (such as “data is de-identified, no identifying information will be collected” or “identifying information will be collected, including email addresses and IP addresses”) and avoid using the term “anonymous” in participant-facing materials all together. You should also avoid any promises or guarantees of confidentiality, and instead describe the steps that will be taken to protect confidentiality.

Q.7 Once I receive feedback from Drexel HRP/IRB, how do I respond?

A.7 Please know that receiving feedback and obtaining clarification, additional information, or changes is very common, and generally can be resolved by following all directions in the feedback you receive. In your response, don’t forget to include both clean and tracked versions of any documents that you may need to revise to address the reviewer's comments. As an investigator you know your research better than anyone, so please ensure that this translation of knowledge is evident in the protocol, supporting documents, and responses as this will help the Drexel HRP/IRB facilitate moving your project forward in the most effective manner.

Q.8 There is a category for exempt research utilizing surveys and interviews, and also an expedited category for research utilizing surveys and interviews of participants. What is the difference and why would one survey/interview project be exempt while another is not?

A.8 *Whether a project meets the criteria for an exemption as opposed to requiring IRB approval and continuing oversight will depend on a number of factors. The identifiability and the sensitivity of the data are considered. Information collected from participants that could negatively impact them should the data be compromised*

(employability, reputation, etc) are strongly considered as this increases the risk to participants. Research involving surveys and interviews with children does not qualify for an exemption. Research involving prisoners as participants may also not qualify for an exemption.