IRB Wise Exempt Submission Example and Guidance

This presentation includes an example of a new Exempt study submission in IRB Wise and also includes guidance for each section in IRB Wise. The screen shots are of an example and the responses are not to be taken as the correct response. Each study is different, and therefore each response and each section will need to be filled out to tailor to your study. Please contact the Office of Research Integrity Assurance if you have any questions.
To submit a new protocol, please click “Submit New Protocol” (circled in red) in the Tasks dropdown menu on the top right of your alerts screen.
Section I. General Information

This is the first section of IRB Wise. In this section, you are asked for a title, brief description, your department, and a list of all of the research personnel.
When adding study personnel, please click on the Add/Modify Certified Personnel link (circled above).
Section I. General Information – Add/Modify Personnel Window

In this pop-up window, you are asked to list all of the research personnel who will be involved in the research. Please type the name in the first text box and select the correct individual. Please be sure to also select a role for each individual. Please note that only faculty can be listed as PI and Co-PI. Additionally, we manually check for CITI once we receive your submission. Therefore, do not worry if you have completed the training and “No Certifications” is listed next to your name. We will check on our end once we receive your submission.
Section I. General Information – Exempt Study Window

Only studies that meet the specific criteria can be reviewed under Exempt Review. Please see our website for more information. If your study does meet the criteria, then please complete this section (circled above) and skip the rest of the submission unless instructed otherwise.
Section I. General Information – Exempt Study Window

After clicking "Answer Exempt Review Determination Questions," this pop-up window will appear. Please be sure to review the information in the green box and the instructions listed above question A prior to completing this section. If your study does fall under one of the federally defined exempt categories, then please answer complete this section.
Section I. General Information – Exempt Study Window

F. Is the research a taste and food quality evaluation and/or a consumer acceptance study? Specifically: (i) wholesome foods without additives are consumed or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- N/A
- No
- Yes

G. Please select all of the procedures that you will use to collect data:
- Audio recording/video recordings/photographs
- Behavioral intervention/interactive tasks
- Bio-specimen collection
- Blood draws
- Focus group
- Interview
- Other, please attach a description with the other study documents
- Passive observation
- Research on educational practices
- Sensor recordings (EMG, EKG, MRI, pedometer, etc.)
- Survey, educational test, psychological tests

H. Will vulnerable populations be included in the study?
- No
- Yes, please describe in the box below

I. Describe how you intend to use the data/information collected in this study.

J. What are the provisions (physical/technical safeguards) to protect the privacy of subjects and to maintain confidentiality of data? If using PHI please attach approval from GT IRB.

This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section.
Section I. General Information – Exempt Study Window

K. Will identifiers (e.g., name, address, audio, video, birth date, IP address, etc.) be associated with the data at any point?*

- No
- Yes, please describe in the box below

CT ID, audio, and video will be collected during the study.

L. Describe the extent to which identifiable private information will be coded or linked.*

All of the data will be coded by random alphanumeric code. This code will be associated with each individual in a master key file, which will be encrypted and only accessed by the study team. This file will only be stored on the PI's encrypted computer.

M. What is the potential risk of harm to a subject should the data/information be re-identified, lost, stolen, compromised or used in way that was not described in the research study?*

The data being collected is innocuous and if the data were to be re-identified, lost, stolen, or compromised, there would be little to no risk to the individual.

N. Will the data/information be shared or transferred to a third party (outside the approved study team) or otherwise disclosed or released? If sharing data containing PHI/PII outside of the study team please upload the Data Use Agreement (DUA).*

- No
- Yes, please describe in the box below

File Uploaded:

O. What is the likely retention period or life of the data/information?*

- 0-05 years
- 06-10 years
- 11 + years

This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section.
Section I. General Information – Exempt Study Window

This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section. Once finished completing this section, please follow the instructions in question R and click "Save and Continue with Application."
If your study is supported by research funding: Section II. The Protocol: Research Design and Methodology

This is a screen shot of the last two questions in Section II (the rest of section II can be skipped). If your Exempt study is supported by research funding, then you will need to select the type of funding and then click on the link (blue text) in question N to fill out the information regarding the funding.
Section II. The Protocol: Research Design and Methodology – Funding Window

This is the pop-up window after clicking “Add/Modify Funding.” In this window, please either type the PI name or grant title in the first text box and select the correct funding. If the funding is internal, then please complete the text boxes at the bottom of the page.
If you are obtaining an identifiable data set or identifiable human specimen for your research, you will need to answer question E of this section. In question E, you will be asked multiple questions including to fully describe where the data or specimen are being stored, how they will be maintained, and who will have access to them. The rest of this section can be skipped.
Section IV – Studies Involving Department of Defense, Radiation, or Nanotechnology

After completing Sections I, II, and III, you will need to complete Section IV. This is a required section. Please fully answer each question. If your study does involve the Department of Defense, including any of the military branches, then additional requirements may be needed. Please see our Policies and Procedures for more information.
Section V – Key Words that Describe this Protocol

In this section, please select all of the key words that relate to your study. If the key words do not appear on the predetermined list, then please type the key words in the text box underneath the list of key words.
Section VI – Attach Documents

In this section, please click the “upload documents” link and upload all relevant documents to your study. This includes protocol documents, funding documents, recruitment, surveys, interview questions, pictures and descriptions of an experimental apparatus, device brochures, etc.

Templates for certain required documents can be found on our website: https://oria.gatech.edu/irb/submitting-protocol/forms
Submitting the Study for IRB Review

When you are ready to submit your study, please click the “Save and Continue Application” button. If you want to finish your submission at a later date, then please click “Save and Finish Later.”
After clicking “Save and Continue Application,” you will be brought back to your full submission to review. At the bottom of this submission is an additional section that asks if you or any study team members have a financial conflict of interest. If you are unsure about this, please either contact the Office of Research Integrity of Assurance or the Conflict of Interest Management Office. When finished, please click “Save and Continue” at the bottom of the screen.
Submitting the Study for IRB Review

After clicking “Save and Continue,” you will be brought to this screen. You will first need to endorse the protocol at the top of the page. After doing so, please select who the study will be sent to for review at the bottom of the page. Please read the instructions next to each selection, for that there are specific rules on who can submit.
Congratulations! You have officially submitted your Exempt application to the IRB.

Please contact the Office of Research Integrity Assurance if you have any questions regarding the submission process.

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