

Exempt Application Mapping Table - Carle Application to UIUC Application

Instructions for using this table:			
1. Use this table to complete a New Study Application in the UIUC IRBOnline system when an application has been submitted to the Carle IRB for an Exempt Determination.			
2. This details how to respond to the UIUC application using the Carle application.			
3. Some of the items above may not be active on your application as they are dependent on prior responses throughout the application. Additionally, some sections/questions may become active based on your responses. When answering questions in the IRBOnline application, ensure all questions have a response and if unclear, answer as it relates to UIUC researchers or locations.			
IRBOnline Question		Carle Application Question or Action Needed	Details
1.1	Title of Study	1. Project Information	Name project "Carle ID# - Project Title" Example: "23CNI13792 - Tumor Exosome Vaccine for the Treatment of Glioblastoma"
1.2	Study Purposes and Objectives	9. Project Summary	Copy and paste full response from 9. Project Summary
1.3	Background and Introduction	8. Categories of Exemption	List the Category number selected and copy and paste any responses from this section
2.1	Research Team Members	Complete	Complete for UIUC Research Team Members ONLY
2.2	Is this a student-led research project?	Answer Yes/No	Is this a student project?
2.3	Does any investigator (any immediate family) have a financial interest or fiduciary relationship with the research sponsor?	Answer Yes/No	Only applies to UIUC research team members
2.4	Does any investigator (any immediate family) have a financial interest or fiduciary relationship that is related to the research?	Answer Yes/No	Only applies to UIUC research team members
2.5	Are two or more members of the same family acting as research team members on this protocol?	Answer Yes/No	Only applies to UIUC research team members
3.1	Is the research funded?	Complete	Complete any additional required questions.

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4.1	Ages of Subjects	Select appropriate check boxes	Ensure response is consistent with Carle Study Protocol document
4.2	Specific Age range of subjects	Complete	Ensure response is consistent with Carle Study Protocol document
4.3	Indicate any vulnerable population groups that will be included	Select appropriate check boxes	Complete any additional required questions.
4.5.1	Total Subjects enrolled by UIUC researchers	Complete	Ensure response is consistent with Carle Study Protocol document. Expected enrollment by UIUC/Carle researchers (number consented, number of patient records, etc)
4.5.2	Total Subjects enrolled by all sites	Complete	Ensure response is consistent with Carle Study Protocol document. Expected enrollment by UIUC/Carle researchers (number consented, number of patient records, etc)
4.6	Participant Inclusion Criteria	10. Research Population	Copy and paste first response box from 10. Research Population (Describe the participants populations that are likely to be involved in the research)
4.7	Participant Exclusion Criteria	Input this response	"N/A - Carle Exempt Determination"
6.1	Non-Experimental and/or Descriptive Research Design	Select appropriate check boxes	Choose the appropriate types of research involved in this project
6.2	Experimental and/or Interventional Research Design	Select appropriate check boxes	Choose the appropriate types of research involved in this project
6.3	This project is Community Based Participatory Research	Answer Yes/No	
6.4	Study includes creating research resources such as repositories, databases, etc.	Answer Yes/No	
6.5	Study will include a research design that is not listed in the previous questions	Answer Yes/No	
6.6	Length of entire study from initiation to closeout	Input this response	"See 6.11 - Carle Exempt Determination"

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6.7	Length of individual subject's participation	Input this response	"See 6.11 - Carle Exempt Determination"
6.8	How will subjects be recruited or identified for inclusion in this study	Select appropriate check boxes	
6.9	Describe the recruitment/participant identification process in detail	10. Research Population	Copy and paste second response box from 10. Research Population (Describe how participants will be recruited)
6.10	How will consent be obtained?	Select appropriate check boxes	Applies to overall study, not just UIUC
6.11	Describe all procedures....	9. Project Summary	Copy and paste full response from 9. Project Summary
6.12	Are all procedures for research purposes only?	Choose One	
6.13	Provide a summary of the statistical methods...	Input this response	"N/A - Carle Exempt Determination"
9.1	Privacy Protections	11. Data Collection & Storage	Select "Other", then copy and paste first response box from 11. Data Collection and Storage (What precautions will be used to protect the privacy interests of participants...)
9.2	Confidentiality Protections	11. Data Collection & Storage	Select "Other", then copy and paste second response box from 11. Data Collection and Storage (Describe how and where data will be kept, and if and when, it will be destroyed).
9.3	Will photos, audio recording, video records, or medical images of subjects be made during the study?	11. Data Collection & Storage	Use Yes/No response and copy and paste third response from box 11. Data Collection and Storage (Will any individually identifiable information be published, or otherwise disseminated.)
9.4	How will study data and documentation be monitored throughout the study	Select appropriate check boxes	All UIUC research requires data monitoring plan
9.5	Who will be the primary monitor of the study data and documentation?	Select appropriate check boxes	

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9.6	How often is study data and documentation monitoring planned?	Complete	
9.7	Is there a safety monitoring plan for this study?	Answer Yes/No	Safety Monitoring plan only applies for Greater than Minimal risk research
10.1	Describe the reasonable foreseeable risks or discomforts to the subjects	Input this response	"N/A - Carle Exempt Determination"
10.2	Describe the potential direct benefits to subjects.	Input this response	"N/A - Carle Exempt Determination"
10.3	Describe the potential benefits to society	Input this response	"N/A - Carle Exempt Determination"
10.4	Using lay language, please describe the significance of the research and what you hope to show with the results of the project.	Input this response	"N/A - Carle Exempt Determination"
10.5	Are there any costs to the subjects from participating in the research?	Answer Yes/No	
10.6	Is there any compensation to subjects (including monetary or class credit)?	Answer Yes/No	Complete any additional required questions.
12.1	State and justify the qualifications of the study staff	Complete	Complete for UIUC Research Team Members ONLY
12.2	Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their researcher-related duties and functions.	Input this response	"N/A - Carle Exempt Determination"
12.3	Describe the facilities where the research activities will be performed.....	Complete	Describe locations UIUC research team will be conducting research activities. For campus locations, specific details are required.
12.4	Describe the medical or psychological resources available at this site....	Input this response	N/A

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13.1	Does this study involve any of the following:	Complete	Complete this section and any additional questions required. Utilize section 7. Exempt Confirmation from the Carle application.
13.1	Note: Collecting, analyzing, or banking human cells, tissue, fluid, DNA or other human biological samples	Answer Yes/No	Answer "Yes", ONLY if biological materials will be collected, analyzed, or stored on UIUC campus or at university facilities
13.1	Note: Exposure to radioisotopes or ionizing radiation	Answer Yes/No	Answer "Yes", ONLY if radiation exposure is occurring on UIUC campus or at university facilities
22.1	(HIPAA Section) What UIUC department is conducting the research	Complete	
22.2	Is that department part of the covered entity	Answer Yes/No	Use the link provided to confirm response
22.3	Where will the data be stored?	Complete	If all PHI stays within Carle systems, input the following, "All PHI remains in Carle electronic systems, no data will be shared with UIUC systems." If Carle will be exporting data to UIUC and UIUC researchers will be storing in UIUC systems, complete this response as appropriate.
22.4	Select the method(s) of authorization that will be used	Select appropriate check boxes	Complete any additional required questions.
22.5	Select the method of de-identification	Complete	
22.6.1	This declaration applies to the following part(s) of this study"	Select appropriate check boxes	"All of the information used or disclosed in this study" is most likely the appropriate response
22.8.1	Purpose of the Waiver Request	Input this response	"Carle Waiver of Authorization Request form Attached"
22.8.2	Type of Request	Complete	"Waiver of Authorization..." is most likely the appropriate response
22.8.3	List of identifying information you plan to collect or keep a link to...	Input this response	"Carle Waiver of Authorization Request form Attached"

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22.8.4 Explain why the PHI to be used or disclosed in the minimum necessary to accomplish the research objectives	Input this response	"Carle Waiver of Authorization Request form Attached"
22.8.5 Explain why the research could not be practicably conducted without the waiver of authorization...	Input this response	"Carle Waiver of Authorization Request form Attached"
22.8.6 Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the PHI will be stored and who will have access	Input this response	"Carle Waiver of Authorization Request form Attached"
22.8.7 The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research....	Input this response	"Carle Waiver of Authorization Request form Attached"
22.8.8 Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity....	Input this response	"Carle Waiver of Authorization Request form Attached"
22.9.1 This assurance applies to the following part(s) of this study	Select appropriate check boxes	"All of the information used or disclosed in this study" is most likely the appropriate response
22.10 Will PHI (identifiable or de-identified) be disclosed outside the Covered Entity	Answer Yes/No	This applies to if UIUC researchers will be sharing PHI with someone outside of UIUC NOT including sharing with Carle.
23.1 Consent Documents	Do not attach any documents	Consent documents are generally approved by Carle, do not attach anything to this section unless the Carle IRB <i>specifically</i> asks you to obtain UIUC approval and for UIUC IRB to stamp the consent.

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23.2	Recruitment Materials	Possibly attach documents	Attach only recruitment materials that are specific to UIUC, for example, flyers posted on UIUC campus, emails sent to UIUC faculty/staff/students including Eweek or other departmental advertising
23.3	Surveys, Questionnaires	Attach Documents	Attach draft or final version of surveys, questionnaires, scripts
23.4	Grant Application	Possibly attach documents	Attach grant applications if grant is managed via SPA
23.5	Investigator's Brochure, Package Insert	Possibly attach documents	Unlikely any documents meet this requirement for Exempt research
23.6	Literature Review/Cited References	Do not attach any documents	Exempt research reviewed by Carle does not require additional documents attached here.
23.7	Other Documents	Attach Documents	In this section include: Consent Documents submitted to Carle, Carle Exempt Initial Review Application including Waiver of HIPAA Authorization Form if applicable, Carle Study Protocol document, Carle IRB Approval/Determination letter if available.