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| Aurora IRB  **Representation for Reviews Preparatory to Research** | | |  |
|  | | | *For IRB Office Use Only* |
| **\*\*\* Use This Form to use protected health information (PHI) for Preparatory to Research purposes (see** [**Aurora System Policy *Use and/or disclosure of PHI for research***](https://iconnect.aurora.org/DotNetNuke/LinkClick.aspx?fileticket=q04bTo2MDJU%3d&tabid=3378)**).**  **Under this representation, PHI may be disclosed to a non-Aurora** [**Workforce Member**](https://iconnect.aurora.org/DotNetNuke/LinkClick.aspx?fileticket=q04bTo2MDJU%3d&tabid=3378) **as long as the PHI does NOT LEAVE AURORA. If PHI will be removed from Aurora, you must submit a Waiver or Alteration of Authorization request (Form 502.3). If PHI is DISCLOSED to a non-Aurora Workforce Member, *an accounting of disclosure must be made per* Aurora System Policy *Use and/or disclosure of PHI for research.* \*\*\*** | | | | |
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| **SECTION I Requestor Information** | | | | |
| Requestor: | | | E-Mail Address: | |
| Contact Person: | | | Contact Person’s E-Mail Address: | |
| **SECTION II Information Being Used** | | | | |
| 1. Title or brief description of the Preparatory to Research activity: | | | | |
| 1. Provide the purpose for the use/disclosure of PHI: | | prepare protocol/grant | | determine if enough potential subjects |
| develop a research hypothesis. | | Screening/determining eligibility/recruitment of potential research subjects (includes creating a list of potential subjects and contacting patients to determine interest in participation) - can only be done once IRB approval of the study has been secured |
| 1. Who will use the PHI for the Preparatory to Research activity? List the titles of the individuals: | | | | |
| 1. List the HIPAA identifiers and patient information/data elements that will be used.   *Check here if you have attached a separate document that lists the identifiers and patient information/data elements.* | | | | |
| 1. What is the maximum number of patient records to be used?  less than 50  50 or greater (Provide estimate): | | | | |
| 1. Explain why the PHI listed above is the minimum necessary need for the preparatory to research activity? | | | | |
| 1. Under a Preparatory to Research Representation, PHI may only be disclosed to a non-Aurora Workforce Member while he/she is on site at Aurora. 2. Are you a non-Aurora Workforce Member or will the PHI be disclosed to a non-Aurora Workforce Member?  NO  YES*. If “Yes,” this disclosure must be accounted for per* ***Aurora System Policy Use and/or disclosure of PHI for research***. Provide the name(s) / address(es) of the person(s) **OR** the department/team of people and the address to whom PHI will be disclosed.  *Check here if you have attached a separate document.* 3. Provide the name of the sponsor for the project, if applicable. 4. Why is this disclosure necessary? 5. What PHI and related information will be disclosed? 6. What criteria will be used to select records for this disclosure (e.g., patients between the ages of 40-65 with a history of breast cancer that were treated at X location over the past 10 years)? 7. Provide the planned date of disclosure or if more than one disclosure to the same entity is planned, provide the timeframe (start and end date, the frequency, periodicity, or number of disclosures made during the timeframe) of the disclosure(s) *NOTE: If PHI must be removed from Aurora facilities, you must submit a Waiver/Alteration of Authorization Request (Form 502.3) rather than file a Representation.* | | | | |
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| **Preparatory To Research Representation**  *By signing this form, you are representing and agreeing to the following:*  ***–****The use or disclosure is requested solely to review PHI as necessary to conduct Preparatory to Research purpose noted above.*  ***–****The PHI for which use or disclosure is requested is the minimum necessary for the preparatory to research purpose noted above.;*  ***–****No PHI will be removed from Aurora in the course of the review. If I am an Aurora Workforce Member, I am allowed to view PHI via Aurora standard remote access processes, but if I do so, I agree that I will not print, download, copy, save or retain the PHI including any temporary files stored on a device. If I am not an Aurora Workforce Member, I will only access PHI while physically on site at an Aurora facility.*  ***–****I will account for any disclosure of PHI to a non-Aurora Workforce Member while that member is on site at Aurora.*  ***–****If my responses to any of the above questions change, I will modify and resubmit this form prior to continuing with the Preparatory to Research activity.* | | | | |

Signature of Requestor Print name Date

**NOTE: *The Aurora RSPP office requires the signature of the requestor. The request will not be returned to the requestor until the Aurora RSPP office has received his/her signature on this document.***

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| ***IRB Use Only*** The Aurora IRB has determined that the Preparatory to Research activities described above meet the criteria set forth at 45 CFR 164.512(i)(1)(ii).         Aurora IRB Chair or designee Date |