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**Supplement Form J**

**Research That Includes Storing Data/Specimens for Future Use**

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| --- | --- |
| **PI Name:**  | **Date:** Click here to enter a date. |
| Protocol Title:  | WMed IRB #:  |

This form is intended to supplement the information provided on the Initial Submission Form. This applies when specimens or data will be retained after the completion of the study proposed in this application for possible future research studies (i.e., secondary uses).

***Note:*** *Future use of stored data for research will require a separate application to the IRB unless the data are completely de-identified. Future use of stored specimens for research will require a separate application to the IRB if the research is FDA-regulated (e.g., use of the specimens to evaluate the safety or effectiveness of a diagnostic device), if the research involves the use of Newborn Blood Spots, or if the specimens are labeled with or associated with identifiable information.*

1. **Describe what data and/or specimens from this research will be stored for future research use:**

1. **Do the consent and authorization (when applicable) for this research disclose the plan to store data and/or specimens for future use?**

[ ]  NA

[ ]  Yes. Is the proposed storage/future use presented as an opt-in?

[ ]  Yes [ ]  No, explain why?

[ ]  No. Explain why:

1. **Will the stored data and/or specimens include direct identifiers?**

[ ]  Yes, explain:

[ ]  No

1. **Will the stored data and/or specimens include** [**Protected Health Information**](https://privacyruleandresearch.nih.gov/pr_07.asp) **(PHI) or** [**Personally Identifiable Information**](http://www.gsa.gov/portal/content/104256) **(PII)?**

[ ]  Yes. Describe what PHI or PII will be included and explain why it is necessary:

[ ]  No

1. **Will the stored data and/or specimens be labeled with a code?**

[ ]  Yes

[ ]  No

**If yes:**

* 1. Is the code derived from PHI or PII (e.g., includes initials or part of a SSN)?

[ ]  Yes, explain:

[ ]  No

* 1. Will a linking key be maintained that could be used for re-identification in the future?

[ ]  Yes. How will the linking key be secured and who will have access?

[ ]  No

1. **Will the stored data and/or specimens include sufficient information that alone, or combined with other sources, investigators could readily ascertain the identity of subjects?**

[ ]  Yes, explain:

[ ]  No

1. **Where will the data and/or specimens be maintained?** (If the data and/or specimens are being added to an existing research repository, list the name of the repository, IRB of record for the repository, IRB reference number, and summarize or attach the repository’s policies for storage, security, and distribution of data and/or specimens. The remaining questions on this form can be skipped.)

1. **How will the data and/or specimens be secured?**

1. **Who (individuals or categories of individuals) will have access to the data and/or specimens?**

1. **Who may use the data and/or specimens for future research? Check all that apply:**

[ ]  **Principal Investigator**

[ ]  **Sub-investigators**

[ ]  **Students**

[ ]  **Other researchers at WMed**

[ ]  **Researchers at other institutions**

[ ]  **Potential future uses are unknown at this time**

[ ]  **Other, explain:**