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| **Study Stage:**  Start-up, Conduct |

**Purpose:** The Participant Identification Code Key template will link the assigned study identification (ID) number to the actual patient identity. This templatecan be used to link enrolled participant identity or protected health information to their research data.

**Useful to:** Principal Investigators, Study Coordinators, and other research study team members. This template is useful for Investigator-initiated studies and Industry-sponsored studies.

**Instructions:**

* The study team should follow all IRB eResearch approved confidentiality procedures.
* Add study participant name and unique identifying information to create the link.
* Additional unique personal identifiers, such as Medical Record Numbers (MRNs) may be included to minimize participant misidentification. If participants have more than one ID number to be linked together (for instance, a screen number), you can add columns.

Pages may be added to the template as needed.

**Best Practice Recommendations:**

* The following template is recommended for study teams that need to have a link between participant study specific ID numbers, the participant’s identity, and additional identifiers such as Medical Record Number (MRN).
* When using this template or your customized version of this template, make sure that all identifiers used in this template are approved by the IRB. Similarly, make sure to follow the secure data storage practices that were approved by the IRB. This key should be kept separate from the informed consent documents and other research data.
* If a Sponsor provides a Participant Identification Code Key, study teams may use it. Note that study teams should review the keys provided by the Sponsor for accuracy and appropriateness to the specific study. If a Sponsor does not provide a Participant Identification Code Key for a specific study, use this template and customize it based on your study specific requirements.

**Template History:**

**Last Updated: 6/07/2022**

**Reference(s):** ICH GCP section 8.3.21

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

“**Enrolled” definition for human subjects studies in eResearch**
[enrollmentdefinition\_additionalhelp.pdf (umich.edu)](https://research-compliance.umich.edu/sites/default/files/resource-download/enrollmentdefinition_additionalhelp.pdf)

**Version:** 2.3

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| **Study name:**  | **IRB HUM #:** |
| **Principal Investigator:**  |  |

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| **Study Identification Number** | **Participant Name** | **Additional Personal identifiers applicable to your study (add separate columns as needed)** |
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