

NIH Genomic Data Sharing Institutional Certification for ETCTN trials

About Institutional Certification

- The **Institutional Certification (IC) form** attests that **genomic data** submitted to a NIH-designated data-sharing repository complies with the NIH Genomic Data Sharing Policy, including that it honors the informed consent of the trial participants.
 - The NIH Genomic Data Sharing Policy applies to all NCI-funded research that generates large-scale **genomic** data, as well as smaller-scale genomic studies where NCI chooses to apply the policy (e.g., rare cancers)
 - IC form: <https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form>
 - **One IC form** should be completed **for each ETCTN trial** (i.e., not submitted by every site or LAO participating in the trial, or for every separate publication or analysis)

Signatures on the Institutional Certification (IC) Form for an ETCTN trial

- The following person should ensure the IC form is completed and submitted and sign the IC form as “Investigator”:
 - ETCTN Contact PI (Grant PI) for the Corresponding ETCTN UM1 LAO listed as the lead organization for the clinical trial
- The following person should sign the IC form as the “Institutional Signing Official”:
 - An institutional official with signing authority from the Corresponding ETCTN UM1 LAO for the trial

Completing the Institutional Certification Form for an ETCTN trial

Page One

NOTE: Boxes are used to enter site and study names at the first mention in the IC form. Those names are then used to populate the appropriate fields throughout the form.

Date: Current date

Name of GPA: Grace Mishkin

Select IC: NCI

Name of Institution: *Corresponding ETCTN UM1 LAO institution that led the ETCTN clinical trial*

Original Study Name: *CTEP clinical trial protocol number and a title reflecting the original title*

Project Title for Data to be Submitted: A title briefly describing the data being submitted, for example:

“Correlative studies for Protocol #X, which studied drug X in disease Y”

Collaborating Site Name box: Enter “**See attached list of ETCTN sites**” and click the “Add to list” button.

At the end of the form or as a separate attachment, append a list of names and CTEP IDs of sites that enrolled patients on the original clinical trial.

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Page Two

NOTE: Boxes are used to enter site and study names at the first mention in the IC form. Those names are then used to populate the appropriate fields throughout the form.

The individual-level data are to be made available through: Controlled-access

Is the individual-level, human genomic data to be submitted funded in whole or in part by NIH? Yes

Is the individual-level, human genomic data to be submitted covered by a CoC? Yes

Availability of Genomic Summary Results (GSR): Controlled-access

Explanation: Controlled-access required by NCI DCTD CTEP.

If GSR are designated as sensitive and “controlled access” is checked above, are the GSR covered under (or have been issued) a CoC? Yes

Completing the Institutional Certification Form for an ETCTN trial

Page Three

NOTE: Boxes are used to enter site and study names at the first mention in the IC form. Those names are then used to populate the appropriate fields throughout the form.

Completing the **Data Use Limitations Table** for “Institutional Certification Data Use Limitations (DUL)”:

Collaborating Site Name column (1): Select “See attached list of ETCTN sites” for each “Collaborating Site Name” row. *This value must have been entered in the “Collaborating Site Name” list on page one.*

Data Use Limitation column (2): For ETCTN studies that use the NCI Informed Consent Template, this will generally be “General Research Use.”

Data Use Limitation Modifiers (optional) column (3): For ETCTN studies, select “COL”.

Note: Studies under CTEP IND require a collaborator review process for the CTEP CRADA partner. A letter of collaboration with the Study PI will not be required.

Example of Data Use Limitations Table:

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	Data Use Limitation	Data Use Limitation Modifiers (optional)
<i>Eg: Cold Cohort Study</i>	<i>Health/Medical/Biomedical</i>	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
<i>Eg: Cold Cohort Study</i>	<i>Disease Specific Research [Lung Cancer]</i>	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input checked="" type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
See attached list of ETCTN sites	General Research Use	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input checked="" type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>

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Completing the Institutional Certification Form for an ETCTN trial

Page Four

NOTE: Boxes are used to enter site and study names at the first mention in the IC form. Those names are then used to populate the appropriate fields throughout the form.

Investigator signature: ETCTN Contact PI (Grant PI) for the Corresponding ETCTN UM1 LAO listed as the lead organization for the clinical trial

Investigator must sign before sending to the Institutional Signing Official. The form will lock after the Institutional Signing Official digitally signs and the investigator will not be able to sign at that point.

Institutional Signing Official signature: An institutional official with signing authority from the Corresponding ETCTN UM1 LAO for the trial

Remember: Include a separate attachment with the list of enrolling ETCTN sites.

Submitting the Institutional Certification Form for an ETCTN trial

- Please sign the IC form digitally and submit it in the fillable PDF format so that the GPA can see the full text of the Original Study Name and Project Title.
 - If it is not possible to provide this digital version of the signed IC form, please attach a copy of the unsigned digital form as well as the signed form.
- Include a separate attachment with the list of enrolling ETCTN sites.
- **To begin registering the study in dbGaP, email the Institutional Certification Form and list of enrolling ETCTN sites to the GPA administrator with a request to use them to register a new study in dbGaP:**
 - Grace Mishkin, grace.mishkin@nih.gov



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