# Patient Drug Interactions Handout and Wallet Card

A Patient Drug Interactions Handout and Wallet Card must be provided as a protocol appendix for a trial of a non-marketed agent that has potential drug interactions.

* For studies under CTEP IND, the Handout and Wallet Card will be authored by CTEP PMB.
* For studies not under CTEP IND, the lead protocol organization is responsible for authoring the Handout and Wallet Card.
* Additional patient-specific fields in the Handout and Wallet Card are to be filled out by the site with the appropriate information for each patient.

Please note the drug interactions handout and wallet card require IRB approval before distribution to patients.

**Instructions to authors:** Fill out the appropriate information as instructed by the template. Use or delete sections below as appropriate. **Only edit the fillable text fields – do not alter any text outside of the fillable fields. The bracketed instruction text will disappear once you begin typing.**

**Template: Patient Drug Interactions Handout and a Patient Drug Interactions Wallet Card**

* + 1. To be given at the time of enrollment and when updated.
    2. A protocol that has more than one non-marketed investigational agent with PK interactions will have a drug interactions handout and drug interactions wallet card for each agent.
    3. Assign a letter or a Roman numeral to the Appendix.
    4. A convenient wallet-sized information card for the patient to cut out and retain at all times.
    5. **Suggested texts to complete the templates are on the next page.**
    6. **Use the fillable template and enter information in the fillable fields**.

## Template: Patient Drug Interactions Handout and Wallet Card

**APPENDIX      : PATIENT DRUG Interactions handout and wallet card**

**Information for Patients, Their Caregivers and Non-Study Healthcare Team on Possible Interactions with Other Drugs and Herbal Supplements**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient Name:** |  | **Diagnosis:** |  | **Trial #:** |  |
| **Study Doctor:** |  | **Study Doctor Phone #:** |  | **Study Drug(s):** |  |

Please show this paper to all your healthcare providers (doctors, physician assistants, nurse practitioners, pharmacists), and tell them you are taking part in a clinical trial sponsored by the National Cancer Institute.

**These are the things that your healthcare providers need to know:**

*[Insert study drug]* interacts with [certain specific enzyme(s) in your liver or other tissueslike the gut],[certain transport proteins that help move drugs in and out of cell]*,* [the heart’s electrical activity (QTc prolongation)]*.*

|  |  |
| --- | --- |
|  | **Explanation** |
| CYP isoenzymes | The enzyme(s) in question is/are *[enter name of CYP isoenzyme(s)]*. [Insert brief, easy explanation of the nature of the interaction, i.e., for substrates: “[insert study drug name] is broken down by this enzyme and may be affected by other drugs that inhibit or induce this enzyme.”] |
| Protein transporters | The protein(s) in question is/are *[enter name of transporter(s)]*. [Insert brief, easy explanation of the nature of the interaction, i.e., for substrates: “[insert study drug name] is moved in and out of cells/organs by this transport protein.”] |
| Heart’s electrical activities | The heart’s electrical activity may be affected by [Insert study drug]*.* The study doctor may be concerned about QTc prolongation and any other medicine that is associated with greater risk for having QTc prolongation. |

**These are the things that you need to know:**

The study drug [Insert study drug],may interact with other drugs which can cause side effects. For this reason, it is very important to tell your doctors about all your medicines, including: (a) medicines you are taking before this clinical trial, (b) medicines you start or stop taking during this study, (c) medicines you buy without a prescription (over-the-counter remedy), (d) herbals or supplements (*e*.*g*. St. John’s Wort). It is helpful to bring your medication bottles or an updated medication list with you.

Before you enroll onto the clinical trial, your study doctor will work with your regular health care providers to review any medicines and herbal supplements that are considered *[“strong inducers/inhibitors or substrates] of [name(s) of CYP isoenzyme(s)], [transport protein(s), or any medicine associated with greater risk for having QTc prolongation.”]*

* Please be very careful! Over-the-counter drugs (including herbal supplements) may contain ingredients that could interact with your study drug. Speak to your doctors or pharmacist to determine if there could be any side effects.

* + [Add other specific medications here, if necessary. Examples include acid suppressing drugs, NSAIDS, St. John’s Wort.]
* Make sure your doctor knows to avoid certain prescription medications.

* + [Add other specific medications here, if necessary. Examples include acid suppressing drugs, anticoagulants, NSAIDS.]
* Your regular health care provider should check a frequently updated medical reference or call your study doctor before prescribing any new medicine or discontinuing any medicine.

Version *mmm/yyyy*

## Template: Patient Drug Interaction Wallet Card

****

|  |  |  |  |
| --- | --- | --- | --- |
| NCI logo |  |  |  |
| **EMERGENCY INFORMATION** |  | **dRUG INTERACTIONS** | |
| **Show this card to all of your healthcare providers. Keep it with you in case you go to the emergency room.** | Tell your doctors **before** you **start** or **stop** any medicines.  **Check with your doctor or pharmacist if you need to use an over-the-counter medicine or herbal supplement!** | **Carry this card with you at all times**  [insert study drug]interacts with [a specific enzyme in your liver or other tissues like the gut, transport proteins that help move drugs in and out of cells, the heart’s electrical activity,] and must be used very carefully with other medicines. | |
| **Patient Name:** | **Use caution and avoid the following drugs if possible:**  [List specific medications here. Examples: OTC drugs, herbal supplements, vitamins, acid suppressing drugs, anticoagulants, NSAIDs, digoxin.] | Your healthcare providers should be aware of any medicines that are [strong inducers/inhibitors/substrates of [insert CYP isoenzymes], interact with [insert transport proteins], or affect your heart’s electrical activity]. | |
| **Diagnosis:** |
| **Study Doctor:** |
| **Study Doctor Phone #:** |
| **NCI Trial #:** | **Before prescribing new medicines**, your health care provider should check a **frequently-updated medical reference** for a **list of drugs to avoid** or contact your study doctor. | |
| **Study Drug(S):** |
|  | Versionmmm/yyyy |
| **For more information:** 1-800-4-CANCER | **For more information:** 1-800-4-CANCER | **For more information:** 1-800-4-CANCER | **For more information:** 1-800-4-CANCER |
| cancer.gov | clinicaltrials.gov | cancer.gov | clinicaltrials.gov | cancer.gov | clinicaltrials.gov | cancer.gov | clinicaltrials.gov |

|  |  |  |  |
| --- | --- | --- | --- |
| *Fold at dotted lines*: |  |  |  |