## Transitioning to ClinCard: Frequently Asked Questions (FAQs)

### What is ClinCard?
ClinCard is a debit card and software tracking system for the provision of research subject payments for participation in a clinical research study.

### What studies must transition to ClinCard?
All **ACTIVE** studies that provide remuneration (payments) to subjects for which enrollment or follow-up visits will continue past **12/31/18**, must transition to ClinCard.

### Changes to Informed Consent Forms and Consent Processes

**If the consent form names cash or gift cards as the payment method,** you will need to:

- Revise the consent form to include Children’s National required ClinCard language (as included in the current CNMC informed consent template available at [www.IRBear.org](http://www.IRBear.org)).
- Submit the revised consent form as part of an amendment to the IRB describing the use of ClinCard instead of other payment mechanisms. In the amendment, also describe plans for providing current subjects with the ClinCard information sheet and Terms of Agreement.
- Once the amendment is approved by the IRB, use the revised consent form when enrolling new patients.
- Inform current subjects about CNMC’s transition to ClinCard and provide them with the ClinCard information sheet and Terms of Agreement documents either during their next scheduled visit or by mail. Current subjects should also be asked to sign a document stating that the use of ClinCard has been explained to them and they have received the information sheet and Terms of Agreement. These materials are available at [www.IRBear.org](http://www.IRBear.org).

**If the consent form language is more general,** *i.e., it does not name the mechanism of study incentives,* such as, “You will receive $50 at Visits 4 and 5,” you will not need to revise your consent form or reconsent your subjects. All enrolled subjects should be provided with the ClinCard information sheet and ClinCard Terms of Agreement documents either during their next scheduled visit or by mail. These materials are available at [www.IRBear.org](http://www.IRBear.org).

### Studies with a one-time payment only

Gift cards may be used to provide remuneration for studies offering a one-time payment of $25 or less to subjects.
### Studies with a waiver of documentation of informed consent

Gift cards may be used to provide remuneration for studies for which the IRB has granted a waiver of documentation of informed consent per 45 CFR 46.117(c) or 21 CFR 50.109(c). The waiver criteria include a requirement that there is no record linking the identity of the subject to participation in the research.

### Where can I find Children’s Research Institute ClinCard policies?

There are two ClinCard policies. Both are available through Children’s intranet. Key “ClinCard Policy” in the search field at the top right corner of Children’s Intranet Home page. Both policies will appear at the top of your search results. One is the Grants and Contracts Policy, Policy GCA:Post:05P, dated 5-14-18. The other is the Office of Human Research Protections (OHRP) Policy that supports the IRB, Policy RA:HRPP:10.13, originally dated 3/08/10 and revised 5-14-18.

### Who may I contact to ask questions about ClinCard?

Please contact Natasha Martien at amartien@childrensnational.org or 301-565-8462, or Sze Nguyen at snguyen@childrensnational.org or 301-565-8554. Both work in Children’s Office of Grants and Contracts.