

Conflict of Interest Statements for NIH Protocol Consent Forms March 2008

In a Section called **Conflict of Interest** suggested **standard statements**:

1. The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process <http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf> You may ask your research team for additional information or a copy of the Protocol Review Guide.
2. One or more investigators participating in this study may have less than \$15,000 of stock in the manufacturer of the product(s) used in this study. Under federal regulations, however, this is permissible and does not create a conflict of interest.
3. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

Optional statements:

Use this statement if developing a new drug or device:

1. The National Institutes of Health and the research team for this study have developed (a drug, imaging agent, device) being used in this study. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of _____.

Use this if the protocol is part of a CRADA:

2. The National Institutes of Health and the research team for this study are using (a drug, imaging agent, device) developed by (company name) through a joint study with your researchers and the company. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of _____.

Use this if an investigator has a waiver:

3. No conflicts of interest exist among NIH investigators based on federal regulations. One or more NIH employees have a personal financial holding in the manufacturer of the product(s) used in the study, but the conflict has been resolved by NIH ethics staff and Institute Leadership.