Guidelines for SBIR/STTR Applications at Duke University School of Medicine

SBIR (Small business innovation research) and STTR (Small business technology transfer research) grants are a means for a small business to obtain research funding from the Federal Government. In some cases these grants may involve a non-profit like Duke as a sub-contractor (the grants must primarily go to the small business). These two grant categories have important differences, and both can have complications regarding conflicts of interest (COI) if the faculty member has financial arrangements with the small business. The guidelines below should be considered prior to making any agreements with sponsors.

SBIR

SBIRs involve a three phase award to a small business in order to allow it to develop innovative concepts. SBIR grants can come from many federal sponsors, including the NIH, NSF, and DOD. Phase I awards are for a period up to six months and $100,000. Phase II awards are for further development of the ideas funded with Phase I grants and can be for up to two years and $750,000. The PI on an SBIR award must be a >50% employee of the small business, which means full-time regular rank Duke faculty are not eligible to be PIs on SBIRs. Duke does not allow the same person to be the PI on the primary grant and the Duke sub-contract. In addition, if a Duke faculty member has a significant ownership interest in, or >$25,000/year financial relationship with, the small business they cannot serve as PI on any subcontracts from the company to Duke. During Phase I more than 2/3s of the research and/or analytical effort must be done by the small business, and in Phase II more than 50%.

The reason Duke faculty are generally not allowed to be PIs on an SBIR subcontract are: 1) Lack of control of the Duke facility (is the PI using their Duke lab to support their own company); 2) Blurring of the non-profit/for-profit boundary (i.e. use of Duke’s tax-exempt facilities in a way that competitively advantages a for-profit entity); 3) Conflict of interest in the research since the investigator may want to produce certain results for financial reasons, to advance the company’s fortunes rather than to advance Science.

Institutional Conflict of Interest is another frequent problem involved in SBIRs granted to start-ups. In many cases a non-profit like Duke will have licensed its intellectual property to the small business in trade for equity. It could be perceived that Duke would be less assertive in its oversight of the research if the Institution stood to profit financially from the research. In addition, the non-
profit/for-profit boundary issues become particularly acute. For these reasons, institutional conflict of interest issues must be considered before any SBIRs involving a Duke subcontract and Duke licensed technologies can be submitted.

In general, SBIR subcontracts are discouraged if the Duke PI on the subcontract has a relationship, either ownership or payments, with the small business. If the institutional conflict of interest issues are not problematic, in some cases a Duke faculty member with no financial relationships with the small business could be the PI. The arrangements will need to be reviewed by the Conflict of Interest Committee.

The sponsoring agency will be notified if a personal or institutional conflict of interest is noted in the SBIR.

Sub-contracts are processed through the Office of Research Administration like any other application for external funding.

**STTR**

STTRs require collaboration between a for-profit and non-profit entity. The PI on the application may be a full-time Duke employee, but the grant is given to the small business (the primary applicant), and at least 40% of the research and analytical work must be done at the small business. The PI is required to have a formal relationship with the small business, and at least 30% of the research must be done at the non-profit (assumed to be Duke, in this case). Phase I in an STTR can last up to one year, but is still capped at $100,000. STTR Phase II work can be for up to two years and $500,000.

Conflict of interest questions again loom large in STTRs. In most cases, a faculty member who is an equity holder in the small business, or who has received more than $25,000 a year in extramural income, will not be eligible to be a principal investigator of a Duke sub-contract. However, they may be able to act as the PI through the company. This should be discussed with the COI Committee prior to applying for the STTR. In that case, there would need to be a Duke PI who does not have a financial relationship with the small business placed in charge of the Duke subcontract. This individual should not have a reporting or dominance relationship with the conflicted faculty member.

All STTR applications require review for institutional conflict of interest questions. Agreements should be in place between the small business and Duke
regarding intellectual property, contracting costs, and anticipated resource utilization.

Approved by the COI Advisory Board on July 17, 2008