

# Part XI: Reference Materials

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## Abbreviations and Acronyms

|      |   |
|------|---|
| AE   | Accountable Executive   |
| AHRQ | Agency for Healthcare Research and Quality  |
| CBO  | Allina Consolidated Business Office   |
| CDC  | Centers for Disease Control and Prevention  |
| CMS  | Center for Medicare and Medicaid Services—formerly called Health Care Financing Administration (HCFA) |
| DHHS | Department of Health and Human Services   |
| DD   | Department Director   |
| DOD  | Department of Defense   |
| DSIS | Department Service Information Sheet  |
| FDA  | Food and Drug Administration  |
| FTE  | Full Time Equivalent  |
| HDE  | Humanitarian Device Exemption   |
| HUD  | Humanitarian Use Device   |
| IDE  | Investigational Device Exemption  |
| IND  | Investigational New Drug  |
| IRB  | Institutional Review Board  |
| M+C  | Medicare+Choice   |
| NAP  | Non-Allina Protocol-Induced Cost  |
| NCD  | Medicare Coverage of Clinical Trials ~ National Coverage Decision                                     |
| NIH  | National Institutes of Health   |
| NOR  | Notice of Research  |
| PIC  | Protocol-Induced Cost   |
| RC   | Routine Care  |
| ROF  | Research Order Form   |
| RPC  | Research Plan Code  |
| RSF  | Research Service Form   |
| SOE  | Schedule of Events  |
| SPA  | Sponsored Projects Administration   |
| SPRP | Sponsored Projects Review Process   |
| VA   | Department of Veterans Affairs  |

## Glossary

**510(k)** — is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). See <http://www.fda.gov> for more information.

**Abstract** — a succinct and accurate description of the research project. It should include: a) the reasons why the study is being undertaken; b) what is to be done; and c) what might be found and why this matters.

**Accountable Executive** — a senior member of an Allina Business Unit or Allina, with a position title of Vice President or above and who is given authority to accept an agreement on behalf of the individual Allina facility or the overall organization.

**Accounting Unit** — an identifiable department within Allina that has been assigned a specific number in the Lawson General Ledger Accounting System. Prior to Allina's implementation of Lawson, it was known as a cost center.

**Address Change** — a change in principal investigator location or billing address. These types of changes need to be sent to Allina Sponsored Projects Administration within five business days so that the information can be promptly updated in the billing system.

**Allina Facility or Business Unit** — a subdivision of Allina that operates semi-independently (i.e., any hospital).

**Ambulatory Payment Classification (APC)** — an APC is a method of classifying outpatient services into groups that are comparable clinically and in terms of resource use in APC groups.

**Arm or Study Arm** — a group in a clinical trial. For example, study arms may be a treatment arm and a control arm.

**Award** — financial assistance provided to Allina to support the accomplishment of a public purpose or activities that carry out Allina's mission. Awards include grants and other agreements in the form of money or property in lieu of money, provided to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; or contracts required under procurement laws and regulations.

**Billable** — a generic term that refers to the proper and legal submission of a claim for reimbursement for the provision of an item or service to a third-party, including private and government payers, for payment in accordance with that payer's policies.

**Category A** — innovative devices for which absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved. The FDA is unsure whether these device types can be safe and effective. CMS will continue to exclude Medicare payment for Category A devices. (*The Medicare A Communicator, Special Supplement No. 20, Section A, subparagraph 3, August 1996.*)

**Category B** — the types of devices that are newer generations of proven technologies. Initial questions of safety and effectiveness of these devices have been resolved. Devices placed in this category are considered to represent evolutionary changes in proven technologies and will be viewed as potentially reasonable and necessary by Medicare and therefore eligible for coverage and payment. (*The Medicare A Communicator, Special Supplement No. 20, Section A, subparagraph 3, August 1996.*) This policy change does not mean that all devices classified in Category B will be covered under Medicare.

**Certify** — to state officially, usually in writing, that something is true or correct (*Cambridge International Dictionary of English*).

**Clinical Trial** — a formal study carried out according to a prospectively defined protocol that is intended to discover or verify the safety and effectiveness in human beings of interventions to promote well-being, or to prevent, diagnose, or treat illness. The term refers to both controlled and uncontrolled trials. It includes not only trials carried out in a clinical setting and involving clinical disease, but also other types of trials, such as health promotion and disease prevention, and trials carried out in the community. In practice, other terms such as “research,” “trials,” “study” or “research protocol” may be used synonymously with this definition.

**Compassionate Use** — is a treatment use of experimental drugs for an individual patient rather than a group of patients and this can occur in one of several ways. FDA can grant a single patient exception to receive drug under an existing IND when a patient is ineligible for the specified protocol. Under a single patient exception, the existing commercial IND sponsor provides drug and is responsible for reporting to the FDA. (FDA website) The FDA refers to these as single patient use.

**Complication** — a pathological process or event occurring during a disease that is not an essential part of the disease; it may result from the disease or from independent causes (*Stedman’s Medical Dictionary*). Allina separates these into two categories: expected and unexpected.

**Contribution** — any cash, securities, or in-kind gifts or grants from private sources, whether solicited directly or not, for which the donor does not retain any reversionary interest and cannot expect to receive material, unique or preferential benefit of commensurate value as a result of making the donation.

**Cooperative Agreement** — a financial assistance mechanism used when the NIH Institute or Center anticipates substantial Federal programmatic involvement with the recipient during performance. (*NIH Grants Policy Statement, October 1998*).

**Current Procedural Terminology (CPT)** — is a set of codes, descriptions, and guidelines intended to describe procedures and services performed by physicians or other health care providers. (AMA CPT 2004 Professional Edition). These codes are also used as payment mechanism.

**Department Service Information Sheet (DSIS)** — a form used to assist in the communication between an Allina service department and a project site about a pending project. The form communicates price information, contact information, billing information, and approximate number of services involved. **The DSIS does not replace the need to contact the Allina service department directly about the initiation of a new project.**

**Deemed Trial** — a trial that meets all the qualifying criteria of the Medicare Clinical Trial National Coverage Decision (NCD).

**Department Director** — an employee who oversees a major department within an Allina facility and who reports to a Vice President at his or her business unit. For example, Radiology is considered a “major department” comprised of different service components (e.g., CT, X-ray, etc.).

**Diagnostic Related Group (DRG)** — provides a basis for payment based on the services required for treatment of the average person with that disease. It is grouped by using the ICD-9 codes or other billing codes.

**Double Dipping** — receiving payment for an item or service and subsequently billing a third party payer for the same item or service. It is illegal and considered fraud. See Part II, “Billing Guidance” of the Guide for additional information.

**Expected Complication** — a pathological process or event that is typical for the disease or described within the protocol. For example, it is typical that a patient receiving chemotherapy will have nausea.

**Fair Market Value** — (for the purposes of this Guide) is the reasonable value of the items or services provided by a research site in a clinical trial. For example, if a Principal Investigator is participating in a trial and is receiving \$5,000 per patient to collect a history and physical and complete three data collection worksheets, the \$5,000 would appear to exceed Fair Market Value.

**Federal Grant** — a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity

**Financial Conflict of Interest** —

Situations that may affect conflict of interest in research include:

1. Undertaking basic or clinical research when the investigator or the investigator’s immediate family has a financial, managerial or ownership interest in the sponsoring company or in the company producing the drug or device under evaluation.
2. Accepting sponsorship, gratuities or special favors from research sponsors.
3. Entering a consultantship arrangement with an organization or individual having an economic interest in the related research.

Definitions of levels of financial interest:

1. Basic financial interest: the company producing the product or drug sponsors the research project.
2. Significant financial interest: current or pending ownership interests such as equity interest (stock holdings), salary (consulting fees or honoraria) or property rights (patents or royalties).
3. Personal financial interest in the outcomes: the investigator owns the device or drug or has a managerial or ownership role with the company.

Levels of recommendation by the IRB dependent on levels of financial interest:

1. Full disclosure of actual and potential financial interest by all investigators.
2. Peer review - have own department or a committee evaluate conflict of interest in the research on an ongoing basis.

**FTE** — an abbreviation for full time equivalent. An FTE for the purposes of Allina is 2080 hours per year.

**Fringe** — the costs associated with providing compensation to employees in addition to wages. They include such things as medical, dental, life, PTO, unemployment, etc.

**Guarantor** — (for the purposes of this Guide) is the party that is responsible for any balance remaining on an account after all third party payers have been exhausted and any discounts applied.

**Good Faith** — the absence of malice or any intention to deceive.

**Grant** — a generic term that refers to funding from outside sources and generally requires little input from the source of the funds. Allina usually receives either contributions or sponsored project funds. The term grant, while it is found within the Allina documentation, is avoided because it lacks the clarity needed to classify funds appropriately. (*See either Contribution or Sponsored Project.*)

**Health Care Procedural Coding System (HCPCS)** — are additional codes used to classify services in an outpatient setting. They are used in conjunction with CPT codes.

**Human Subject** — a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information. [Source: 45 CFR 46.102(f)(1,2); a subject may be either a healthy individual or a patient. Source: 21 CFR 56.102(e).]

**Humanitarian Device Exemption (HDE)** — a pre-market approval application submitted under 21 CFR 814 Subpart H seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the Act.

**Humanitarian Use Device (HUD)** — a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

**ICD-9** — refers to International Classification of Diseases, Ninth Revision – is a coding system used to assign diagnosis and procedure codes to inpatient stays.

**IDE Number** (Investigational Device Exemption) — a number assigned by the FDA that allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support its application to the FDA. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated. Refer to the FDA web site at [www.fda.gov](http://www.fda.gov)

**IND Number** (Investigational New Drug) — an application number assigned by the FDA to the drug. The IND is a request for an exemption from the Federal statute that prohibits an unapproved drug from being shipped via interstate commerce. Types of INDs are: Commercial, Investigator, Emergency Use and Treatment INDs.

**Indirect Costs** — costs that cannot be specifically identified to a particular project, department, etc., but are costs of operating the facility. Examples of such costs include depreciation on buildings and equipment; the costs of operating and maintaining facilities; and general administration and general expenses, such as accounting and personnel administration.

**Informed Consent** — legal concept that provides that a patient has the right to know the potential risks, benefits, and alternatives of a proposed procedure prior to undergoing a particular course of treatment.

**Item** — an article necessary for a particular service or procedure (e.g., a device).

**Major Change** — a material change that may impact Allina's participation in the project, such as, a change in the Principal Investigator, a change in protocol-induced items or services, change in the project sponsor, etc. The research site has five business days in which to notify SPA on the Project Change Form and to resubmit all affected documents. More information can be found in Research Compliance Policy RES 313.01, "Changes in an Approved Project Procedure."

**Medical Device** — (Abbreviated version from FDA website <http://www.fda.gov/cdrh/devadvice/312.html>)

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

**Medicare** — Medical assistance provided in Title XVII of the Social Security Act. Medicare is a health insurance program administered by the Centers for Medicare and Medicaid Services for persons aged 65 years and older and for disabled persons who are eligible for benefits. Medicare Part A benefits provide coverage for inpatient hospital care, skilled nursing facility care, home health care and hospice care. Medicare Part B benefits provide coverage for physician services, outpatient hospital services, diagnostic tests, various therapies, durable medical equipment, medical supplies and prosthetic devices.

**Medicare Outpatient Self-Administered Drug Trial** — a trial in which the purpose of the trial is to study an outpatient self-administered drug. Additional information can be found in Part II, Billing Guidance of this Guide.

**Minor Change** — any change that is administrative in nature and does not directly affect the scope of the project, such as an e-mail address. More information can be found in Research Compliance Policy RES 313.01, “Changes in an Approved Project Procedure.”

**No Reimbursement Allowed Trial** — a trial in which the items, devices, services, or any related services are not billable to a third party payer. Additional information can be found in Part II, “Billing Guidance” of this Guide.

**Non-Allina Protocol-Induced Cost** — a protocol-induced item or service that will not be performed at any time during the project period at an Allina facility and where the research site or researcher is not part of Allina. For example, a heart research participant with a cardiologist researcher needs an EKG in four weeks, in all probability the researcher’s office has an EKG and would not need that service done in an Allina facility. However, if the researcher is an Allina employee, the service would be a protocol-induced cost.

**Non-billable** — the generic term for items or services that cannot be submitted for payment to a third party insurance payer. (However, the item or service may be billed to the researcher or research site for payment.)

**Off Label Use** — is using a drug for a treatment for which it is not approved of by the FDA. For Allina’s SPRP, this means collecting data as part of clinical trial and usually part of an IND.

**Phase 1** — includes the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. (FDA Website)

**Phase 2** — includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people. (FDA Website)

**Phase 3** — studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people. (FDA Website)

**Phase 4** — are post-marketing studies typically done after a drug is approved for use. See Post-Marketing Studies in this section.

**Protocol-Induced Cost** — items or services that may not be billed to a third party payer because they are not covered under the Medicare Coverage of Clinical Trials ~ Final National Coverage Decision, such things include:

- investigational item or service itself;
- items or services solely for data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT Scans for a condition usually requiring only a single scan);
- items or services which are specifically identified in the budget as being paid by the sponsor or another third party;
- items that are customarily provided for free from the sponsor;
- items or services that cannot be billed because of the lack of a specific charge, e.g., phlebotomy for a sample that is to be sent to the sponsor or no Medicare benefit category;
- items or services provided solely to determine trial eligibility;
- items or services that fall under a national non-coverage policy; and, items or services which are statutorily excluded.

**Non-Covered Benefit Trial** — a trial that does not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision, but follows the standard of medically reasonable and necessary. Self-administered outpatient drugs would be an example. Please see Part II of the Guide for further information.

**Non-Qualifying Trial** — a trial that does not meet the qualifying criteria for Medicare coverage under the National Coverage Decision (NCD).

**Participant** — a person enrolled, or may be enrolled, in a project. Other names may include eligible subject, research subject, or study participant. (The term patient may be used. However, it is not the preferable term.)

**Plan Code (PC)** — a set of alphanumeric characters that separates the various third party payers in medical billing systems. It may also be known as insurance type or insurance code.

**Post Marketing Studies** – are studies that are conducted usually after a drug is approved for wide distribution by the FDA. These PM Studies may be done to collect additional information at the request of the FDA or the sponsor to ensure the drug is effective.

**Pre-Market Approval** — is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

**Primary Payer** — (for the purposes of this Guide) is a third party payer that will be billed for services first.

**Principal Investigator/Project Director** — an individual designated by the grantee to direct the project or activity being supported by the project. He or she is responsible and accountable to the grantee for the proper conduct of the project or activity.

**Project** — a broad term meant to include the many different types of names for which it is appropriate to use these forms, although, it is most often referred to as research, clinical trial, sponsored project or study.

**Project Period** — the total time for which support of a project has been programmatically approved. The total project period is comprised of the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

**Project Site** — the location where the local Principal Investigator is directing the project. It may also be known as a research site.

**Project Sponsor** — the entity or individual that provides the funding or collects the data surrounding the project.

**Proposal** — the communication of a project to a sponsor that describes such things as the scope of work, budget, budget narrative, hypothesis to be tested, work to be completed, goals, etc. It may be either programmatic or clinical and may be considered a sponsored project under Research Compliance Policy RES 301.00, “What is a Sponsored Project.”

**Protocol** — a formal written document that describes the rationale for the trial, interventions, and other medical services that participants will get, numbers of participants needed, outcomes that will be measured, plan for analysis, and other details of the trial organization.

**Protocol-Induced Cost** — are additional items or services that the typical participant will receive during his or her participation in a research protocol or study that are not routine care. Items or services that the participant would receive in the absence of a clinical trial are not considered protocol-induced costs, even if these items and services are also listed in the protocol. It is important for all parties involved with the project to be consistent in applying the criteria listed below for all projects. Protocol-induced costs include the following:

Items or services provided solely to determine trial eligibility.

- Investigational item or service itself.
- Items or services required solely for data collection and analysis needs that are not used in the direct clinical management of the patient.
- Items customarily provided for free by the sponsor. *Note: This also means items and services that the sponsor covers wherever the study is being done, not just at the local research site.*
- Items or services which cannot be billed because of the lack of a specific charge; e.g., a phlebotomy for a sample that is to be sent to the sponsor or has no Medicare benefit category.
- Items or services which fall under a national non-coverage policy.
- Items or services which are statutorily excluded.

**Protocol-Induced Cost Worksheet** — a financial analysis worksheet that provides details to Allina facilities about a proposed project that an entity is interested in participating. It also serves a guide to help evaluate how the services should be billed to all the parties involved in the project.

**Purchased Service Agreement** — an agreement between Allina and an individual or another appropriate party under contract with a project sponsor. This agreement will be used when Allina is not a party to the contract with the sponsor, but is providing services to such a party. Provisions of the Purchased Service Agreement will include, but are not limited to, the scope of the project (e.g., protocol), a description of services to be provided by Allina, payment terms, confirmation of Allina IRB approval, reporting obligations, compliance obligations and a certification that information, relevant to billing, is accurate when provided to Allina by the contracting party.

**Qualifying Status Change** — based on the original submission, it is a change in the project that may or may not meet the definition of “Clinical Trial Services that Qualify for Coverage” as described in the Medicare National Coverage Decision. More information can be found in Research Compliance Policy RES 313.00, “Changes in an Approved Project Policy.”

**Qualifying Trial** — a trial that meets all the qualifying criteria outlined in the NCD. A copy of the NCD is in Part II, “Billing Guidance” of this Guide or at <http://www.cms.hhs.gov/coverage.8d.asp>

**Research** — a systematic, intensive study directed toward better scientific knowledge or the science and art of diagnosing, treating, curing, and preventing mental or physical disease, injury or deformity; relieving pain; and improving or preserving health. Research may be conducted at a laboratory bench without the use of patients or it may involve patients. There may be research that involves both laboratory bench and patient care research.

**Research, Human Subjects** — performing an *intervention* or having an *interaction* (including observation) with a person or persons which would not normally occur or not occur in this manner, and/or obtaining, utilizing, and/or recording *non-public* information, data, or specimens, which you would not have otherwise, or utilizing these in a different manner, with the intent to test an idea or *hypothesis*, amass knowledge, and/or attempt to draw a conclusion which may contribute to *generalizable knowledge* about whether one way of doing something, for or with people, is better than another. [Definition derived from *The Belmont Report: Ethical Principles & Guidelines for the Protection of Human Subjects of Research*, DHEW, 1979 and *The Code of Federal Regulations 45CFR46.102(f)(1&2)*.]

**Research Plan Code** — a plan code assigned to research sites to enable the separation of routine care and billable protocol-induced costs from non-billable protocol-induced costs within the Allina billing systems.

**Research Site** — the location of individuals, physician groups, Allina departments, Allina employees or any other party directing medical intervention items or services related to clinical trials within Allina facilities.

**Routine Care** — care that is medically reasonable, necessary, and ordinarily furnished (absent of any research programs) in the treatment of patients by providers under the supervision of physicians as indicated by the medical condition of the patients. This definition intends that the appropriate level of care criteria must be met for the costs of this care to be reimbursable. Such care may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, skilled nursing and other related professional health services. Terms synonymous with routine care are usual patient care or standard care.

**Schedule of Events (SOE)** — a plan of the care a typical participant will receive in the research protocol. It will include routine care and protocol-induced care. It can also be called a matrix, protocol table, schedule of study evaluation, schedule of activities, etc.

**Secondary Payer** — a third party payer that may be billed after any payment or denial by a primary payer.

**Service (or procedure)** — a specific medical test that a participant must have in order to be evaluated regarding their medical condition or eligibility for participation in a project.

**Service Department** — a department within an Allina facility that usually conducts specific types of procedures, e.g., radiology, lab, etc.

**Sponsor Provision for Payment** — the amount that may be available from a sponsor if a third party payer is unwilling to pay.

**Sponsored Project** — any program or project supported in full, or in part, by funding from outside sources. It also requires specific performance or specified commitment of effort by Allina. It also obligates any Allina business unit to any type of performance or resource commitment. It may also be referred to as a study or a grant, but the term “sponsored project” is preferable. While this definition is written specifically for Allina, in defining projects it applies to non-Allina entities as well. Please see Allina Research Compliance Policy 301.00 for more information.

**Sponsored Project Administration (SPA)** — a function of the Allina Research Administration. SPA is responsible for compliance with respect to sponsored projects. The focus is on financial matters and their relationship to Allina. The title SPA follows that found in the academic community.

**Sponsored Project/Research Information Form** — the form that will be used to communicate information to an Allina facility to evaluate any sponsored project or research activity that will be done within an Allina facility. It does not include space that is rented to a non-Allina owned entity.

**Sponsored Project Review Process** — a program developed by Allina SPA comprised of two compliance areas: research billing compliance and sponsored projects compliance. The program will collect information, written agreements and monitor activities to ensure that research-related charges are billed correctly by Allina, and that all sponsored projects occurring at Allina facilities are reviewed and approved by Allina management before they are initiated.

**Standard Treatment** — an accepted mode of treatment for a given condition.

**Third Party Payer** — a generic term used to refer to an insurance company, HMO managed care plan, ERISA plan, or a government program (e.g., Medicare, CMS, Medical Assistance, etc.) that provides payment or coverage for medical treatments furnished to their members, subscribers and/or enrollees.

**Unexpected Complication** — a pathological process or event that is not typical or described in the protocol. For example, a person taking a heart medication gets pneumonia.

**Upcoding** — billing service at a higher level than actually delivered to receive increased reimbursement. It is illegal and considered fraud.

**Vendor Account** — account(s) created to accept Clinical Trial related charges that are to be paid by the research site and not billed to a third party payer.

**Vendor Agreement** — an agreement between Allina and an individual or another appropriate party under contract with a project sponsor. In general, this agreement will be used when Allina is not a party to the contract with the sponsor, is providing services to such a party in a vendor capacity only, and is not billing any third party payers for services rendered. A Vendor Agreement will only be used when Allina is providing non-experimental, minimal risk services, such as venipuncture, labs and EKGs. Provisions of the Vendor Agreement will include, but are not limited to, a description of the services to be provided by Allina, payment terms, and confirmation of IRB (Allina or other) approval of the research project. It is within the discretion of Allina Research Administration to approve the use of a Vendor Agreement in circumstances where Allina is billing third party payers for services rendered, if such payer has approved the billing in advance and Allina is not being compensated for the services by the project sponsor or any other party.

**Vendor Project** — a project meeting the criteria established in Research Compliance Policy RES 315.00 and discussed in Part III, Vendor Sponsored Projects Review Process of this Guide.

**Vendor Sponsored Project Review Process** — an abbreviated version of the Sponsored Project Review Process that must meet the criteria established in the Research Compliance Policy RES 315.00.

# Example of Setup Worksheets