Budget Outline

* Budget due to Deanna 3 weeks prior to IRB submission

**Full Study Title:**

**Short Title:**

**Study Start and End Dates:** *Prepare budget for two years in 12 month increments.*

*(i.e. Oct 1, 2013 to Sept. 30, 2014 and Oct 1, 2014 to Sept. 30, 2015)*

**Funding Source/ Sponsor:** *(Usually Pharmacy Department, unless applying for a grant.)*

**All Personnel, Titles & Effort as in table below:**

*Example: Year 1 Year 2 “Note2” below*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Personnel**  | **Title** | **Months****(Year 1)** | **Effort** | **Months****(Year 2)** | **Effort** | **✓ = Benefits** | **✓= Bonus** |
| Mary Adams, PharmD  | Primary Investigator | 12 | 5%  | 12 | 3% |  |  |
| Jane Doe, PharmD | Co-Investigator (Resident) | 12 | 5% | 0 | 0% |  |  |
| Tim Data, PhD | Research scientist/Analyst | 12 | 2.5% | 12 | 2.5% |  |  |
| Deanna Kurz | Project Manager  | 12 | 1.5%  | 12 | 1.5% |  |  |
| Smart Laddie | Intern/Student | 12 | 1.5% | 0 | 0 |  |  |

***Note:*** *to calculate ‘% effort’ start by estimating how many hours you think you may spend on the entire study per year. Include meetings, calls, chart abstraction, etc. Then divide number of hours by 2080 to get % effort for the year.*

**Note2*:*** *ask PI or Deanna if you are not sure who gets Bonus and Benefits. (Usually: PI and Residents get Benefits. Resident does not get bonus. Students and Interns do not receive Benefits or Bonus.)*

**All Other Project Costs:** Equipment, supplies, travel, postage, etc. *Could include the following:*

**CONSULTANT COSTS:**

**EQUIPMENT: (**Larger priced items like laptops, scales, electronic thermometers etc.)

**SUPPLIES:**  (Mailing, copies, envelopes, paper, binders, software programs, etc.)

**PATIENT CARE COSTS: (**Patient stipends, patient supplies, BP cuffs etc.)

**TRAVEL: (**For presentations or classes, mileage)

*(Do not add ASHP Midyear Meeting, KP Interregional Meeting, or Western States Conference to this budget)*

**See following pages for guidance on how to complete:**

**Purpose:**

**Keywords:**

* ***Review FTE and budget with study team.***
* ***Send draft to Deanna Kurz for review along with protocol.***

**At least two weeks prior to IRB submission, Deanna will send a completed budget to:**

Sharisse E. Sanders, Sponsored Programs Administrator

Ph: 303-636-2923

Sharisse.E.Sanders@kp.org

**PURPOSE**

**Select one catagory**

**Career Development Awards** – Most often seen as K awards. Other agencies and entities have similar type awards. These awards are designed to promote the career development of specific individuals based on their past training and career stage. The objective of these is to bring candidates/recipients to the point where they are able to conduct their research independently and are competitive for major grant support. NIH, AHRQ, American Heart Association are all entities that have career development awards.

**Data Only Research** – Research that does not involve actual interaction with patients, rather the systematic review of data extracted from medical records or other systems, the statistical analysis, and related outcomes.

**Non-Research** – sponsored projects that are not considered research and/or don’t meet the definition of research. Typically, the IRB has provided a determination letter validating this decision.

**Operational Non-Research** – These are projects that typically relate to quality improvement activities, analysis or assessment of a new operational initiative.

**Clinical Research** - is defined as research conducted on human subjects (or material of human origin such as tissues and specimens) where the investigator (colleagues or study staff) directly interacts with human subjects.

**For OneLink we break Clinical Research into 3 categories**

**Clinical Research Other** – This would include all clinical research that does not fit into one of the other 2 categories.

**Clinical Research Phase IV Clinical Trial** – These are often referred to as postmarketing studies and the primary goal is for postmarketing / safety surveillance (watching the drug’s use and long term effects in public) and ongoing technical support of a drug after it receives FDA approval to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or for other reasons

**Clinical Research Clinical Trial** – Clinical trials are defined as scientific studies that test the effectiveness of a treatment , device or drug that contribute to finding new and better ways of treating disease. An example would be a trial that tests the effectiveness of blood pressure medication or whether a certain drug is effective in lowering cholesterol. Typically clinical trials are multi-site and often originate from a pharmaceutical sponsor (although this is not always the case).

**Other Research** – A research project that does not fit into any of the other research categories.

**Surveillance Non-Research** – Most of surveillance projects related to epidemiological or pharmacological surveillance. Epidemiological surveillance is generally related to the continued watchfulness over the distribution and trends of incidence through systematic collection, consolidation and evaluation of morbidity and mortality reports and other relevant data and the regular dissemination of data to all who need to know. Pharmacological surveillance is the surveillance drug adverse events, interactions, effectiveness and other trends as related to FDA approved drugs. Mini-Sentinel is an example of pharmacological surveillance.

**Training Activities** – typically not research. Sponsored projects that provide funds for training (this could be a variety of different training activities – bioterrorism training, research training, etc.

Select at least one Keyword from the following:

|  |  |  |
| --- | --- | --- |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| A: TBD | Epidemiology: Reproductive | Neurologic: Parkinsons Disease |
| Addiction/Chemical Dependency | Female: Womens Health Care All | Neurology: Alzheimer's Disease |
| Aging: Epidemiology | Female: Estrogen | Nutrition: Body Size / Comp |
| Aging: Gerontology | Female: Hormone Replacement | Nutrition: Children |
| Asthma: Adult | Female: Menopause | Nutrition: Dietary Methods |
| Asthma: All | Female: Obstetrics-Gynecology | Nutritional Epidemiology |
| Asthma: Child | Female: Premenstrual Symptoms | Nutrition: Food Allergies |
| Traumatic Brain Injury | Gastrointestinal Disorders | Nutrition: Maternal |
| Cancer: Breast | Genetics | Nutrition: Nutrient Intake |
| Cancer: Cervical | Gestational: Rx Exposure | Obesity |
| Cancer: Colorectal | Health: Behavior | Organization, Delivery of Care |
| Cancer: Liver | Health Care: Access to | Patient: Compliance |
| Cancer: Prostate | Health Care: Economics | Patient: Decision Making |
| Cancer: Screening | Health Care: Quality | Doctor/Patient Relationship |
| Cancers: Other | Health Care Reform | Patient: Outcomes |
| Clinical Decision-Making | Health: Community partnerships | Patient: Rx Adherence |
| Clinical Trials | Health Care: Delivery Err Qty | Pediatrics |
| Community & Outreach Programs | Health Care: Delivery Err Redn | Perinatal Med/Health Services |
| Communication/Dissemination | Health Care: Delivery Risk Adj | Pharma: Pharmacoeconomics |
| Complementary Alternate Med | Health Care:Delivery Risk Mgmt | Pharma: Pharmacoepidemiology |
| Cost-Effectiveness Analysis | Health Disparities | Pharma: Pharmacogenetics |
| CVD: Health Promotion Adult | Health: Education | Physical: Activity/Exercise |
| CVD: Arrhythmias | Health Inequities | Physical: Function |
| CVD: Cardiovascular Disease | Health: Policy | Physical: Performance |
| CVD: Health Promotion Children | Health: Promotion in Community | Pregnancy: Adverse Outcomes |
| CVD: Ischemic Heart Disease | Health: Promotion peers | Pregnancy: Teen |
| CVD: Congestive Heart Failure | Health: Promotion Schools | Prenatal: Care |
| CVD: Other | Health: Promotion Clinics | Prenatal:Exposures-Epidemiolog |
| CVD: Stroke | Health Care: Rehospitalization | Prevention: Pregnancy |
| Dermatology | Health: Social Determinants | Prevention: Preventive Service |
| Diabetes: Child/Pediatric | Hypertension | Primary Care Research |
| Diabetes: Gestational | Cost of Illness Studies | Program Evaluation |
| Diabetes Mellitus | Informatics: All | Psychosocial |
| Disease: AIDS/HIV | Informatics: Medical | Pulmonology |
| Disease: Hepatic | Maternal: Lactation | Racial Disparity in Healthcare |
| Disease: Infectious | Maternal: Stress | Research Infrastructure |
| Disease: Osteoporosis | Maternal: Substance Abuse | Rheumatology |
| Disease: Sexually Transmitted | Maternal: Tobacco Use | Substance Abuse: All |
| Immunologic Disorders | Member Experience | Substance Abuse: Tobacco |
| Disorders: Neonatal Disorders | Mental Health: Access | Surveillance |
| Division of Research | Mental Health: All | Urology |
| Emergency Health Services | Mental Health: Children | Vaccines |
| Emergency Preparedness | Mental Health: Depression | Variations in Practice Pattern |
| Endocrinology & Metabolism | Mental Health: Minorities | Violence: Domestic |
| Environmental: Air Pollution | Nephrology: All | Violence: Prevention Adults |
| Environmental: Chemicals | Nephrology: Kidney stones | Violence: Prevention Youth |
| Env: Determinants of Health | Neurologic: ALS | Violence: Youth |
| Env: Health/Epidemiology | Neurologic: Epilepsy |
| Early Determinants of Chronic | Neurologic: Migraine |
| Epidemiology: General | Neurologic: Other Disorders |
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