**CTSA Bioethics Consultation Repository User Guide** *Version 1.3 July 30, 2015*

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| **Consult ID**: Enter an arbitrary number that is useful to you to identify your consults and to link to your internal records |
| **Institution:** The consult service institution, not the requestor’s location. Choose from the drop-down menu. |
| **Title:** should provide enough information about the project and/or the consultation question to allow you to recognize the consult distinctly and so others can decide whether to look at the details. *Do not use specific identifiers related to the requestor, investigator, institution, etc* |
| **Date of Consult (MM-DD-YYYY)**. Either the date the consult was initiated or completed, depending on your institutional convention. |

***In the fields below, use “Other” when there is no reasonable fit and you believe the current categories are not sufficient and the standard fields should be amended.***

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| **RESEARCH PROJECT INFORMATION- this section relates to the research that is the reason for the consult** | |
| **Research Activities-**  *Select one*  The purpose of this question is to understand the types of research activities in projects that are associated with consultation requests. When a study involves more than one activity, select the first one on this list that is applicable. | **Clinical interventions***-* includes the use of drugs, devices, invasive biopsies, invasive imaging (bronchoscopy, CT with contrast or sedation).  **Clinical observations**-includes medical history, physical exams, diagnostic tests (blood tests, EKG, pregnancy tests), non-invasive imaging, (Ultrasounds, MRIs, CT) and natural history studies.  **Behavioral/psychological/ interventions***-*includes engagements that are intended to change knowledge, attitudes or behaviors.  **Behavioral/psychological/ observations***-*includes surveys, focus groups, interviews, and other observations to asses knowledge, attitudes or behaviors.  **Analysis of existing samples/data** *-*samples or data previously collected; already ‘on the shelf’ or ‘in a database’.  **Other***: Fill in the text box.* |
| **Research stage-**  *Select one*  These are discrete for an individual research project. For question that are not specific to a study, select “planning” | **Planning** *-* includes all study planning and design except for grant-related activities.  **Grant application** *-* includes writing or revising a grant application.  **Regulatory review -**includes initial applications to IRBs, ESCROs, or federal agencies such as the NIH, FDA or RAC before the study is initiated.  **Data collection –**includes questions that arise once a study has begun. Also includes questions that arise during recruitment are about.  **Analysis -**includes questions that arise about the interpretation of data or other questions that arise after collection is completed  **Publication/dissemination** - includes presenting research in public, publications, and media communications.  **Post-publication translation -** includes issues specific to commercialization of research e.g., intellectual property or marketing. |

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| **Translational Research Phase**  *- select one*  These are the phases of a research trajectory from the discovery to impact on the population health outcomes.  These phases can be applied across a spectrum of research including drug development, genetic testing, or public health programs.  A particular research approach (observational research, randomized controlled trials, survey research, health system database) can be applied across phases and in different research contexts.  **USE THE TABLE BELOW TO ASSIST WITH APPROPRIATE CHOICE**  **Not applicable-** use this option if the translational phases do not apply to the research project |
| |  |  |  |  | | --- | --- | --- | --- | | **Translational Research Phase** | **Drug Development Research**  (inhaled steroids and asthma) | **Genetic testing research**  (Carrier Testing and Cystic fibrosis ) | **Public health research**  (second hand smoke and lung cancer) | | **T1**  **Discovery** | Do inhaled steroids reduce lung inflammation?  (Laboratory research for molecular mechanisms, biomakers, and safety; clinical research for safety and efficacy (Phase I and II) | What genes cause CF?  (family genetic studies) | Does second hand smoke cause lung cancer?  (questionnaires, health system database studies, population database studies) | | **T2**  **Development** | Do inhaled steroids improve asthma symptoms and lung function? (clinical research for effectiveness ) (Phase III) | Are women interested in carrier testing for CF?  (questionnaires, randomized intervention studies, health system database studies) | Are household contacts at increased risk of lung cancer?  (longitudinal studies, cross sectional studies) | | **T3**  **Delivery** | Will doctors offer inhaled steroids to patients and will patients use them?  (focus groups, questionnaires, randomized interventions comparative effectiveness studies, health system database studies) | How do physicians offer testing in practice?  (questionnaires, randomized intervention studies, health system database studies) | What educational interventions reduce risk of second hand smoke?  (questionnaires, intervention studies, observations) | | **T4**  **Outcomes** | Does the incidence of hospitalizations for asthma decrease?  ( health systems database studies) | Does carrier testing decrease the incidence of CF in newborns  (population database studies) | Does the incidence of lung cancer in non smokers decrease?  (health system database and population database studies) | |

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| **CONSULTATION INFORMATION** | |
| **Research categories**  *Select all that apply to the consult.*  These categories may have special regulatory or ethical considerations and will be used a “key words” for searches for relevant consultations regarding categories. | **None-** use this option if none of the following apply.  **Indigenous population -** Involves participants who are considered ‘first peoples’ or natives of the location where the research is conducted (e.g., aboriginal persons, Native Americans).  **Pediatric population -** involves children (0-18/21).  **Pregnant Women**  **Prisoners**  **Innovative treatment** *-* includes activities that may be in the boundary between research and clinical treatment.  **Randomized clinical trial (RCT)-**if randomization is used.  **First-in-human trials -** Not previously been studied in humans.  **International research -** location of the research activities will occur outside the United States.  **Community-engaged research** *-* involves communities in the design, implementation and interpretation of the study.  **Quality improvement research** *-* involves using established approaches to improve effectiveness.  **Emergency research** - involves an emergency situation and where consent to participate may be waived under FDA regulations.  **Human biological samples** - involves using human tissues, serum or DNA.  **Human stem cells -** involves using any type of human stem cells (embryonic or adult). This does not include hemopoietic stem cells (HSC) or HSC transplants.  **Gene transfer-** involves inserting new genes into humans, either directly or by modifying cells that are transferred.  **Vertebrate animals-** involves animals ranging from rodents to non-human primates .  **Select Agents**- involves microorganisms and toxins specifically identified in DHHS and USDA regulations as having the potential to pose a severe threat to human, animal, or plant health.  **Other***: Fill in the text box.* Use this category if none of the other categories apply AND the issue is one for which you’d like a separate check-box/option in the future. |

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| **Primary Ethical Concern**  *Select one*  This is the major ethical issue identified by the consultants (not by the requestor).  Consider which category is the most important or controversial, and consult would be best “key word” to identify this consult. | **Benefit/risk assessment -**Balancing or assessing benefits and harms of study activities. Include questions about data & safety monitoring (e.g., whether or not a plan is required, or what type of plan is required)  **Study Design** *-* Options to design a study, including use of placebo, randomization, active controls. This category is a specific sub-set of ‘benefit-harm’.  **Subject selection and recruitment -** Which populations to include, how to approach participants, whether to provide research incentives.  **Research/Clinical Practice relationships***-* When research and clinical roles overlap, such as when clinicians enroll patients in clinical trials, or concerns bout participant understanding about research vs clinical care.  **Ancillary Care***-* Obligations to provide care in the context of research study, such as responding to elevated blood pressure.  **Community Considerations** - Includes cultural concerns and religious concerns for participants and concerns about community attitudes or impact.  **Socially/economically vulnerable subjects -** Should be used when some or all of the research participants are socially or economically disadvantaged (homeless people, schizophrenia).  **Undue influence/exploitation -** Concern that the participants may be pressured (undue influence) to join or remain in research. Concern that study participation may take unfair advantage (exploitation) of participants.  **Incidental findings/reporting results** *–* Concerns about wether or how to disclose individual research findings about individual participants to themselves or family members.  **Communication of findings** - Concerns about how best to communicate the overall, aggregate findings to the research population or the community.  **Broader social impact –** Whether potential social impact of the research itself should influence decisions about study design and/or publication. In other words, should this research be done, at all, or should the results be published?  **Research Integrity -**Concerns about misconduct, publication authorship, or integrity of data analysis.  **Conflict of Interest -**Concerns researchers, institutions or sponsors may have competing financial commitments that are important to the design or conduct of research project.  **Legal -** strictly legal issues such as liability, patent, or ownership, issues that require a analysis from legal counsel.  **Other***: Fill in the text box.* Use this category if none of the other categories apply AND the issue is one for which you’d like a separate check-box/option in the future. |
| **Secondary Ethical Concerns** | *Select as many as applicable using the directions above. Be inclusive to facilitate key word searching Select none if no others apply* |
| **Consult Process Information** | |
| **Amount of interaction** | *Include time spent in conversation, research, and documentation by all consultants involved with the consult.* |
| **Additional service(s) provided**  Select as many of the listed services as appropriate for the consult. | **None-**use this option if the consult did not concern any of the options below; i.e., the consultant engaged in ethical consultation only.  **Assessment/capacity of decision maker** *-* specific assessments of individual participants; either about the appropriateness as a surrogate decision maker or the capacity of a potential participant to decide to join a study.  **Assistance with study design** - specific discussion about alternative design approaches to address ethical concerns.  **Clarification of regulations, laws, or policies -** includes specific discussions about these as they apply to the requestor’s research.  **Assistance with regulatory review***-* includes advice or assistance about regulatory decisions or processes.  **Assistance with consent process -** includes assistance improving disclosure and understanding of information to join a study.  **Conflict mediation**- Involves simultaneous discussion with multiple parties to a dispute to improve communication and resolution of conflict. Does not require an agreement to follow recommendations. Do not choose this option if all parties were not engaged with the consultation.  **Other***: Fill in the text box.* Use this category if none of the other categories apply AND the issue is one for which you’d like a separate check-box/option in the future. |
| **Consult Note** | |
| **Reason for consult** | Two or three sentences to describe the reason for the consult. This should provide enough information so others have a general idea about research question, the project, and the ethical concern. *Do not use specific identifiers related to the requestor, investigator, institution, etc.* |