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| **Consult ID**: (arbitrary local code) | |
| **Title of consult:** (brief informative label about reason for consult) | |
| **Date consult** (MM-DD-YYYY): | |
| **Research project information** |
| **Research activities**  *select one*  The purpose of this question is to understand the types of activities that are associated with the research that generate consultation requests. Many projects involve more than one activity. Select the first activity present on the list. | Clinical intervention (drugs, devices, biopsies, imaging w/contrast)  Clinical observation (imaging, EKG, exams, natural history studies)  Behavioral/psychological intervention  Behavioral/psychological observations (surveys, Interviews,)  Analysis of existing samples/data  Other |
| **Research stage**  *Select one*  These are discrete for an individual research project. For questions that are not about a specific project, select “planning” | Planning  Grant application  Regulatory review  Data collection  Analysis  Publication/dissémination  Post-publication translation |
| **Translational Research Phase**  *select one*  These research trajectory phases arc from laboratory discovery to impact on community health. The same approach (e.g. randomized controlled trials, survey research, health system databases) can be used in different phases. These phases can be applied to drug development, genetic testing, or public health research. | T1- Discovery  T2- Development  T3- Delivery  T4- Outcomes  Not Applicable |
| **Consult Information** |  |
| **Special Research Categories**  *select all that apply*  These categories may have special regulatory or ethical considerations and will be used a “key words” for searches for relevant consultations regarding categories. | None  Indigenous population  Pediatric population  Innovative treatment  Randomized controlled trial  First-in-human trials  International research  Community-engaged research  Quality improvement research  Emergency research  Human biological samples  Human stem cells  Gene transfer  Vertebrate animals  Select agents  Other |
| **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 would be best “key word” to identify this consult. | Benefit/risk assessment  Study design (use of placebo, randomization, active controls)  Subject selection and recruitment  Research/clinical practice Relationships  Ancillary care  Community considerations  Socially or economically vulnerable subjects  Undue influence/exploitation  Informed consent (assent, competence, proxy)  Privacy/confidentiality  Disclosure of Incidental findings/research results  Study withdrawal/termination  Communication of findings  Broader social impact  Research integrity (misconduct, authorship, data analysis)  Conflict of interest  Legal (liability, ownership, patent issues)  Other |
| **Secondary ethical concerns**  *select as many as applicable; be inclusive to facilitate key word searches* | None  Benefit/risk assessment  Study design (use of placebo, randomization, active controls)  Subject selection and recruitment  Research/clinical practice relationships  Ancillary care  Community considerations  Socially or economically vulnerable subjects  Undue influence/exploitation  Informed consent (assent, competence, proxy)  Privacy/confidentiality  Disclosure of incidental findings/research results  Study withdrawal/termination  Communication of findings  Broader social impact  Research integrity (misconduct, authorship, data analysis)  Conflict of interest  Legal (liability, ownership, patent issues)  Other |
| **Consult Process Information** |
| **Amount of interaction (hours)** (select one) | < 1h  1-4h  5-10h  11-15h  >15 |
| **Additional service(s) provided**  *Select as many of the as appropriate for specific services provided.* | None  Assessment/capacity of decision maker  Assistance with study design  Clarification of regulations, laws, or policies  Assistance with regulatory review  Assistance with consent process  Conflict mediation  Other |
| **Narrative report** |
| **Reason for consult**  *1-4 sentences* |  |