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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* |       |