## FORM: Regulatory Review

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### Protocol Information
- **Protocol Title:**
- **IRB ID:**

### Reviewer Information
- **Person completing form:**
- **Date:**

### The IRB needs to apply the following additional requirements:
- **Select:**

### The IRB needs to use the following additional worksheets and checklists:
- **Select:**

### The IRB needs to consider the following issues:
- **Select:**

### The IRB needs to take into account the following additional local, state, or international requirements:

### List all drugs and note the IND status of the protocol (leave blank if no drugs)
- **Select:**
- **IND Status:**

### List all devices and note the IDE status of the protocol (leave blank if no devices)
- **Select:**
- **IDE Status:**

### Contingencies for IRB approval
- **Select:**

### Tracking items
- **Select:**

### List any missing materials (leave blank if none)

### Risk Level

### Notes