```
┌─────────────────────────┐                ┌─────────────────────────┐              ╭───────╮
│   Is the activity a     │                │ This activity is NOT    │              │ QA/PE │
│ systematic investigation│───No──▶        │       research          │              ╰───────╯
│ designed to develop or  │                └─────────────────────────┘
│ contribute to           │
│ generalizable knowledge?│
└─────────────────────────┘
             │
            Yes
             │
             ▼
┌─────────────────────────┐                                                          ╭───────╮
│ Activity is RESEARCH.   │                                                          │ NHSR  │
│ Does the research       │──────────────────────No─────────────────────────────▶   ╰───────╯
│ involve obtaining       │
│ information about living │
│ individuals?            │
└─────────────────────────┘
             │
             │
        ╭─────────╮
        │Expedited│◀──Yes──────────────No──────────────────┐            No
        ╰─────────╯                                         │            │
             │                          ┌────────────────────────────┐   │
            Yes                         │ Do you have a Clinical     │   │
             │                          │ Relationship with the      │   │
             │                          │ participants OR access to  │   │
             │                          │ their identifiers through  │   │
             │                          │ a parent study?            │   │
             │                          └────────────────────────────┘   │
             │                                       │                    │
             │                                      No                    │
             ▼                                       │                    │
┌─────────────────────────┐      ┌──────────────────────────┐   ┌──────────────────────┐
│ Does the research       │      │ is the information       │   │ Is the information   │
│ involve intervention or │─No─▶ │ individually             │─Yes▶│ private (ie health   │
│ interaction with the    │      │ identifiable?            │   │ information)?        │
│ individuals             │      │ (See HIPAA 18 identifiers)│   │                      │
└─────────────────────────┘      └──────────────────────────┘   └──────────────────────┘
             │                                                              │
            Yes                                                            Yes
             │                                                              │
             ▼                                                              │
┌─────────────────────────┐                                                │
│ Activity is research    │◀─────────────────Yes───────────────────────────┘
│ involving HUMAN SUBJECTS│
└─────────────────────────┘
             │
             ▼
┌─────────────────────────┐      ┌──────────────────────────┐        ╭───────╮
│ Are the data/samples    │      │ Will it be provided in a │        │Exempt │
│ currently in existence? │─Yes─▶│ way where identifiers    │──Yes──▶│       │
│                         │      │ will never be linked to  │        ╰───────╯
└─────────────────────────┘      │ health information? (ie  │          ▲  ▲
             │                   │ "Cross Off Method" or    │          │  │
             No                  │ honest broker)           │          │ Yes
             │                   └──────────────────────────┘          │  │
             ▼                                                        No │
┌─────────────────────────┐      ┌──────────────────────────┐   ┌──────────────────────┐
│  Is this a Survey study │─Yes─▶│ Is the information       │─Yes▶│ Will the information │
│                         │      │ collected Sensitive?     │   │ be de-identified/    │
└─────────────────────────┘      └──────────────────────────┘   │ anonymous?           │
             │                                                   └──────────────────────┘
             No                                                             │
             │                                                             Yes
             ▼                                                              │
┌─────────────────────────┐                     ╭───────────╮              │
│ Does the study fit the  │                     │ Expedited │◀──No─────────┘
│ definition of           │──────Yes───────────▶│           │
│ "minimal risk"?         │                     ╰───────────╯
│ (some exceptions may    │
│ apply - please speak    │
│ with ARC Clinical       │
│ Research Specialist)    │
└─────────────────────────┘
             │
             No
             │
             ▼
        ╭───────────╮
        │ Full Board│
        ╰───────────╯
```

| | What to send to ARC first | Other documents needed from Study Team * | ARC will draft * | Reviewer | Expected IRB Turn Around (estimate, subject to change) | CRV Required? |
|---|---|---|---|---|---|---|
| QA/PE | QA Checklist | N/A | N/A | N/A | N/A | No |
| NHSR | NHSR Questionnaire | Data Collection Tool | Application | IRB Coordinator | 14 - 30 days | No |
| Exempt | Exempt Questionnaire | Data Collection Tool; Subject facing documents; List of personnel | Application; Consent | IRB Coordinator | 14 - 30 days | No |
| Expedited | Protocol | Data Collection Tool; Subject facing documents; Advertisements; List of personnel | Application; Consent; Portal Submission | Single Reviewer (IRB Chair) | 30 days | Yes |
| Full Board | Protocol | Data Collection Tool; Subject facing documents; Advertisements; List of personnel | Application; Consent; Portal Submission | Full Panel Meeting | 30 - 60 days | Yes |

*Please do not consider these comprehensive lists, but rather starter documents.  Further documents may be needed after discussions between ARC and PI