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Description of Contents:
The U-M HRPP Metrics reports show the size of the U-M human research protections program (HRPP) and measures IRB activity over recent fiscal years. This compilation of metrics contains the Approved Projects report for the U-M IRBs, plus four (4) reports for each IRB office:

- Quarterly Volume reports:
  - Incoming Submissions by Submission Type
  - Approvals by Review Type
  - Approvals by Submission Type
- Quarterly Turnaround Times by Review Type report

FY 2019 Impacts:
The revised Common Rule was implemented in Q3 2019 with a pilot project for non-federally funded projects implemented in Q1 2019. Metrics for FY 2020 reflect these changes to the review of minimal risk and exempt research, including the elimination of continuing review, expansion of the exemptions, and implementation of a process for system-generated exemption determination for some projects.

Oversight for U-M Dearborn research transitioned to IRB-HSBS in Q3 2019.

FY 2020 Impacts:
Oversight for U-M Flint research transitioned to IRB-HSBS in Q1 2020.

Metrics for Q4 2020 reflect the impact of COVID-19, including an increase in exempt applications resulting from: 1) Increase in exempt survey/interview projects which could be conducted remotely 2) Deactivating the exempt system-generated determination function.
Number of Approved Projects Under the Oversight of the IRBs as of 8/11/2020 10:05:58 AM

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>IRBMED</td>
<td>5,177</td>
</tr>
<tr>
<td>Health Sciences</td>
<td>1,542</td>
</tr>
<tr>
<td>Grand Total</td>
<td>6,719</td>
</tr>
</tbody>
</table>

**Notes:**
- Unique Count of Initial/New Submissions processed by U-M IRBs, for each IRB.
- Color indicates the IRB - IRB HSBS and IRB MED.
- The data is filtered on Project Status of the Initial/New Submission, including:
  - Approved;
  - Contingencies Pending;
  - Core Committee Staff Contingency Review;
  - Designated Reviewer Contingency Review;
  - Validate Committee Decision
Notes:
Unique count of all Submissions for each Quarter of the IRB Receipt date. Submissions that are not received by IRB (such as self-determinations) are not included in this view.
Color shows the Submission Type.
The data is filtered on IRB Receipt Date - including only Projects received by IRB (and not self determinations)
The **Number of Projects** scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

* U-M Common Rule pilot for non-federally funded research only.

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**Full Committee**

**Expedited**

**Exempt**

**Not Regulated**

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**Color shows the Submission Type**

- **Submission Type**
  - AE/ORIO
  - SCR
  - Amendment
  - Initial Submission
The Number of Projects scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

* U-M Common Rule pilot for non-federally funded research only.
IRB HSBS: Turnaround Time by Review Type

The graphs and numbers below represent the **brodest range** used to calculate median turnaround time (TAT), which is from the study team’s initial submission to the IRB determination. This median TAT calculation encompasses:

- The initial IRB Office review of the application for completeness and accuracy,
- Required application changes to be made by the study team and submitted to the IRB,
- IRB assignment to the committee/reviewer once the application criteria are met, and
- IRB determination

**Full Committee**

The **Number of Submissions** scale changes per graph

The **Median Turnaround Time** scale is calendar days

Q1 = July – September
Q2 = October – December
Q3 = January – March
Q4 = April – June

**Average Full Committee Turnaround Times:**

- FY 2020 = 21.75 days
- FY 2019 = 90.00 days
- FY 2018 = 69.75 days
- FY 2017 = 75.75 days
- FY 2016 = 49.25 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)
**IRB HSBS: Turnaround Time by Review Type**

**Expedited**

Average Expedited Turnaround Times:

- **FY 2020** = 17.75 days
- **FY 2019** = 22.50 days
- **FY 2018** = 25.50 days
- **FY 2017** = 22.50 days
- **FY 2016** = 21.25 days

**Exempt**

Average Exempt Turnaround Times:

- **FY 2020** = 6.00 days
- **FY 2019** = 6.25 days
- **FY 2018** = 6.25 days
- **FY 2017** = 3.75 days
- **FY 2016** = 3.00 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)
IRB HSBS: Turnaround Time by Review Type

Not Regulated

Average Not Regulated Turnaround Times:

FY 2020 = 6.25 days
FY 2019 = 7.50 days
FY 2018 = 6.50 days
FY 2017 = 4.00 days
FY 2016 = 3.25 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)
IRB MED Incoming Submission Volume

**FY 2019**

- **Q1**: 3,718
  - AE/ORIO: 395
  - Amendment: 3,369
  - Initial Submission: 390
  - SCR: 1,618

- **Q2**: 3,578
  - AE/ORIO: 422
  - Amendment: 1,469
  - Initial Submission: 396
  - SCR: 1,339

- **Q3**: 3,507
  - AE/ORIO: 393
  - Amendment: 1,557
  - Initial Submission: 408
  - SCR: 1,469

- **Q4**: 3,475
  - AE/ORIO: 478
  - Amendment: 1,656
  - Initial Submission: 478
  - SCR: 1,557

**FY 2020**

- **Q1**: 3,774
  - AE/ORIO: 664
  - Amendment: 3,467
  - Initial Submission: 502
  - SCR: 1,656

- **Q2**: 3,774
  - AE/ORIO: 664
  - Amendment: 3,467
  - Initial Submission: 502
  - SCR: 1,656

- **Q3**: 3,883
  - AE/ORIO: 641
  - Amendment: 1,595
  - Initial Submission: 586
  - SCR: 1,487

- **Q4**: 3,704
  - AE/ORIO: 641
  - Amendment: 1,487
  - Initial Submission: 586
  - SCR: 1,487

**Notes:**
- Unique count of all Submissions for each Quarter of the IRB Receipt date. Submissions that are not received by IRB (such as self-determinations) are not included in this view.
- Color shows the Submission Type.
- The data is filtered on IRB Receipt Date - including only Projects received by IRB (and not self determinations).
IRBMED: FY 2020 Approvals by Review Type

**Full Committee**

- **Exempt**
- **Not Regulated**

The *Number of Projects* scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

* U-M Common Rule pilot for non-federally funded research only.
IRBMED: FY 2020 Approvals by Submission Type

The Number of Projects scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

The Revised Common Rule was implemented in FY20, Q4: COVID-19, and FY19, Q3: Revised Common Rule implemented.
The graphs and numbers below represent the **broadest range** used to calculate median turnaround time (TAT), which is from the study team’s initial submission to the IRB determination. This median TAT calculation encompasses:

- The initial IRB Office review of the application for completeness and accuracy,
- Required application changes to be made by the study team and submitted to the IRB,
- IRB assignment to the committee/reviewer once the application criteria are met, and
- IRB determination

### Full Committee

The graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)
IRBMED: Turnaround Time by Review Type

**Expedited**

![Expedited Graph]

**Average Expedited Turnaround Times:**

- **FY 2020** = 29.75 days
- **FY 2019** = 49.25 days
- **FY 2018** = 33.50 days
- **FY 2017** = 34.50 days
- **FY 2016** = 37.50 days

**Exempt**

![Exempt Graph]

**Average Exempt Turnaround Times:**

- **FY 2020** = 10.00 days
- **FY 2019** = 41.25 days
- **FY 2018** = 22.50 days
- **FY 2017** = 20.75 days
- **FY 2016** = 20.75 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
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IRBMED: Turnaround Time by Review Type

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)

**Average Not Regulated Turnaround Times:**

- FY 2020 = 17.25 days
- FY 2019 = 26.50 days
- FY 2018 = 14.25 days
- FY 2017 = 15.00 days
- FY 2016 = 12.00 days